

Production Equipment Maintenance in QSR

One of the important elements in QSR is maintenance of production equipment. The evidence of the importance comes from the many subsections and detailed requirements. This is part of Production and Process Control (P&PC) in 21 CFR §820.70. In terms of Warning Letters that cite any part of QSR, it accounts for about 30%. In this group, 21 CFR §820.70(g) Equipment accounts for about 18% of the P&PC citations.

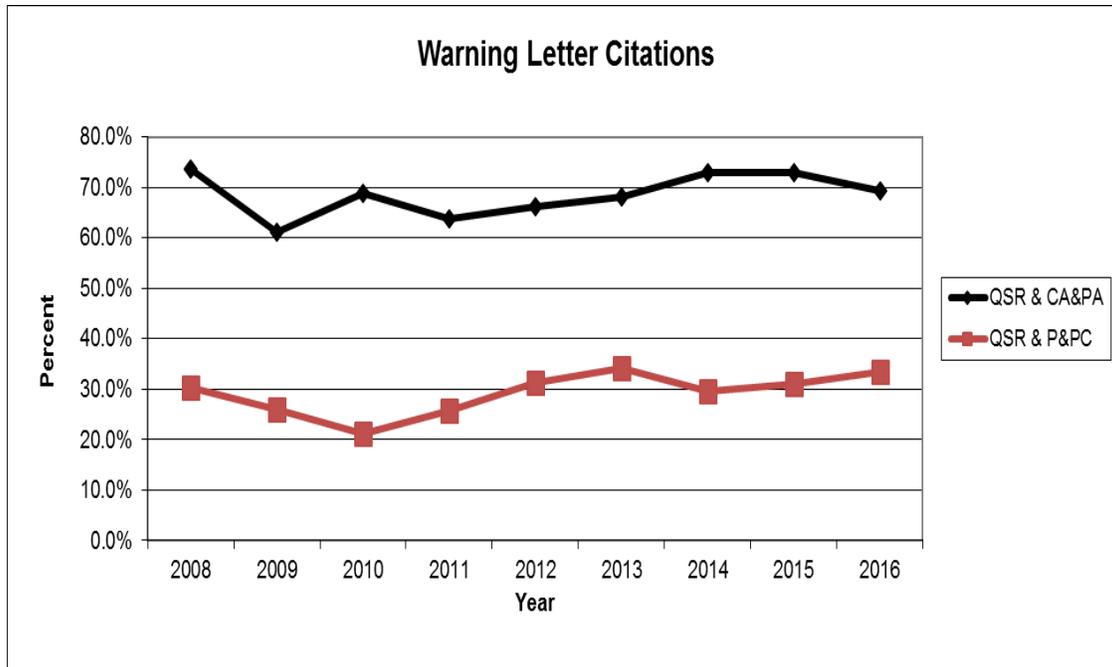


Figure 1 Warning Letter Citations for P&PC

820.70(g) Equipment

Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

Equipment Phases

One approach to understanding equipment issues identifies phases in the equipment life-cycle.

Purchasing

There are two ways to obtain production equipment, purchase it or make it in house. In either case, the equipment must be appropriately designed and constructed.

Selecting the supplier is an important element in the decisions making process. Standard production equipment may be purchased from a supplier. In some cases, a supplier may produce the equipment to the device manufacturers, in other cases, such as specialized test sets, the device manufacturer may produce the equipment in-house.

In all cases, the design and construction is important to the equipment’s life-cycle.

§820.50 Purchasing Controls relates to products or service from suppliers, contractors, or consultants. Typically, production equipment is not a product following the QSR definition, “*Product* means components, manufacturing materials, in-process devices, finished devices, and returned devices. [§820.3(r)]” However, the purchasing controls provide a good approach to supplier evaluation, supplier, and specifications (purchasing data).

Often, these equipment purchases are one-time events, so supplier monitoring and re-evaluation is not necessary. However, the supplier may also provide on-going support such as repair parts, corrective maintenance, and preventive maintenance.

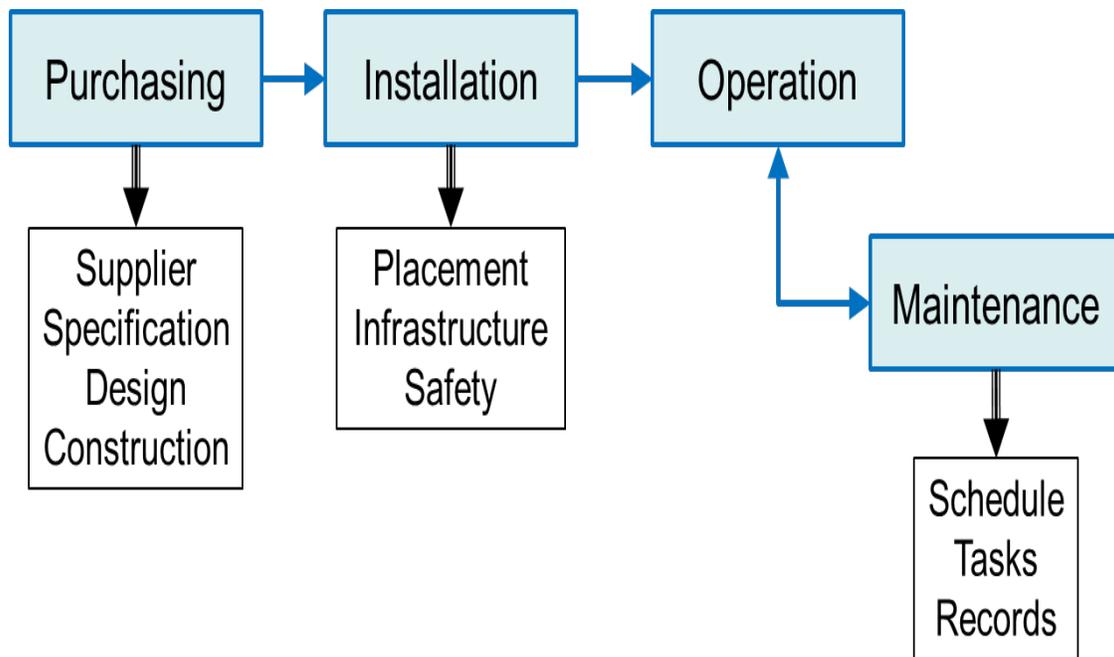


Figure 2 Equipment Life-Cycle Phases

Installation

Place and install the equipment to facilitate maintenance, adjustment, cleaning, and use.

One approach uses the concepts from Installation Qualification. *Installation Qualification (IQ)* means establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer’s approved specification and that the

recommendations of the supplier of the equipment are suitably considered. [GHTF/SG3/N99-10:2004¹, 2.1]

While IQ is commonly included as a phase in process validation, it also stands alone for production equipment. IQ is the initial qualification of the equipment used and provision of necessary services.

Equipment installation should also consider two OSHA standards.

Lock out – Tag out (LOTO) provides controls to prevent injury by a machine that is shut down. This means identifying and controlling all sources of input energy; a task easily accomplished during installation. It also identifies and controls stored energy in the equipment such as weights and springs.

Machine guarding provides controls to prevent injury by a machine that is operating. This means identifying and controlling hazards such as those created by point of operation, ingoing nip points, rotating parts, flying chips, and sparks. Also, machines designed for a fixed location need to be securely anchored to prevent walking or moving.

Operation

Equipment operation should be covered by SOPs, WIs, and training. This article doesn't discuss them further.

Maintenance

Maintenance ensures that the equipment, having installed the equipment correctly, operates correctly throughout its life cycle. This usually involves both assuring the equipment doesn't contribute to making non-conforming product and that its availability, a reliability measure, meets requirements.

QSR Requirements

QSR has two general equipment requirements for maintenance. One develops maintenance schedules while the other inspects maintenance records.

Maintenance Schedules

§820.70(g)(1) Maintenance schedule
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.

There are some key points to implement this requirement

- Identify each piece of production equipment including IM&TE
- Create a maintenance schedule for each piece of equipment

¹ Quality Management Systems – Process Validation Guidance

- Keep the maintenance schedule current, based on information learned from the maintenance activities
 - Analysis could change the frequency of the maintenance schedule
- Ensure the maintenance schedule includes any lubrication, cleaning, or adjustments required
- Ensure the maintenance activities consider the supplier's recommendations
- Develop forms (controlled documents) to record the maintenance activities
- Document each maintenance activity (quality records)
- Include enough information to allow analysis of the results
- Include the names of people who performed the maintenance
- Include the dates of the maintenance

To help prevent an FDA 483 or a Warning Letter, develop a solid internal audit program.

- For each piece of equipment in the audit:
 - Verify the existence of the maintenance schedule
 - Verify the maintenance activities appropriate lubrication, cleaning, or adjustments
 - Verify that the maintenance activities follow the manufacturer's recommendation for both tasks and their frequency
- For each maintenance activity:
 - Select records that cover at least three maintenance activities that should have been completed by the date of the audit
 - Verify that the records document the maintenance activity and that it agrees with the schedule, *i.e.*, each activity had been performed
 - The record includes the names of the people who performed the maintenance
 - The record includes the dates of the maintenance activity

Periodic Inspections

§820.70(g)(2) Inspection

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.

There are some key points to implement this requirement

- Develop procedures to verify adherence to the maintenance schedule
 - The procedure ensures the company implements and follows the maintenance schedule
 - The procedure should include a check of maintenance record completeness.
- Develop quality records
 - A quality records demonstrates adherence to the maintenance schedule
 - The quality record includes the name of the people who performed the inspection
 - The quality record includes the date of the inspection

To help prevent an FDA 483 or a Warning Letter, develop a solid internal audit program.

- For each piece of equipment in the audit, identify the procedure that covers maintenance inspection
- For each maintenance activity:
 - Select records that cover at least three maintenance activities that should have been completed by the date of the audit
 - Verify that the maintenance records have been inspected following the procedure
 - Verify that the inspection record includes the names of the people who performed the inspection
 - Verify that the inspection record includes the dates of the inspection

Overall View

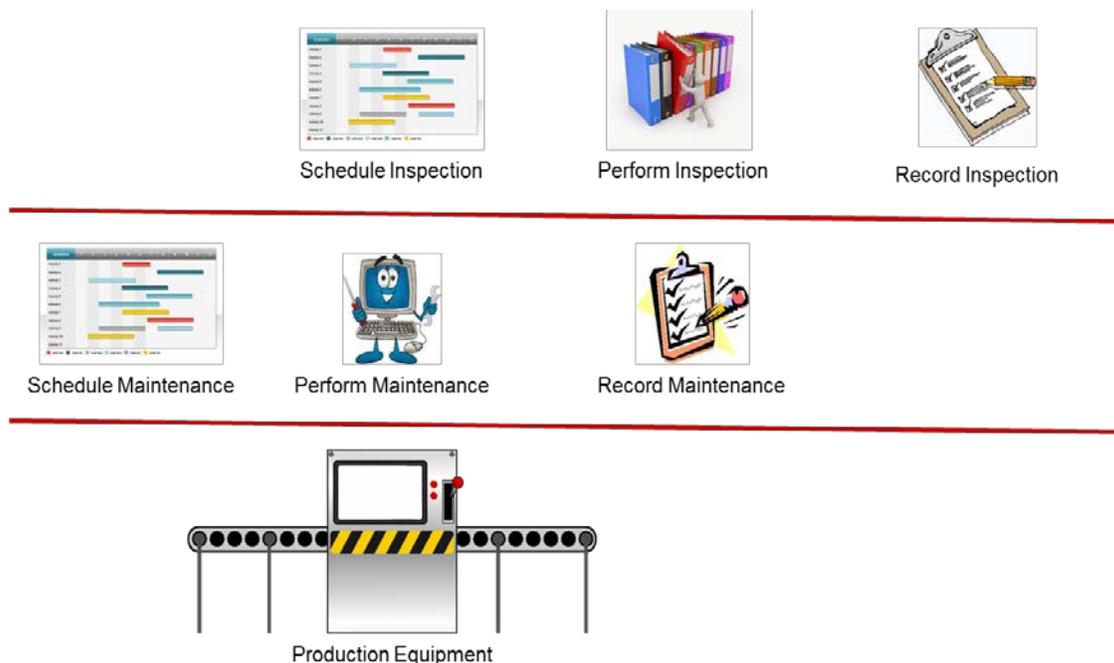


Figure 3 Overall View of the Equipment, Maintenance, and Inspection

Summary

QSR has requirements for production equipment including design, installation, operation, and maintenance. Properly designed, installed, and maintained equipment pays dividends in lower cost and increased availability.

In addition, there are regulatory requirements to support equipment maintenance. These include:

- Maintenance schedules for each piece of equipment
- Trained maintenance people with documentation to support their competence
- Maintenance records to demonstrate adherence to the maintenance schedule
- Maintain record inspection to ensure effective implementation