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Infrastructure

Purpose

This procedure establishes the requirements for development and maintenance of an infrastructure and work environment required to ensure an effective quality management system

Scope

This procedure applies to the facilities, equipment maintenance, and support required for the quality management system.

Definitions

No definitions are required for this procedure.

Responsibilities

EXEC MGMT Executive Management
DEPT MGR & SUP All Department Managers and Supervisors
IT Sys Admin Information Technology Systems Administrator
OPER Operator
PROD OPER Production Operator
BUYER Buyer or Purchasing Agent
MAINT MGR Maintenance Manager

Procedures

EXEC MGMT Infrastructure Development and Maintenance

Determines, provides, maintains and improves the facilities, equipment, work environment, and support services required to achieve conformity to the product requirements and enhance customer satisfaction (6.1[1]a[1], 6.1[1]b[1], 6.3[1], 6.3[1]a[1], 6.3[1]b[1], 6.3[1]c[1], 6.4[1]).

DEPT MGR & SUP Work Environment Maintenance

Establishes a system through which the cleanliness and organization of the work environment is maintained to ensure safe, efficient, and effective operations and to ensure conformity to product requirements (6.4[1]). Implements changes when required to ensure conformity.

IT Sys Admin Maintains Computer Equipement

Assures all major enterprise systems are operational, performs periodic maintenance (e.g. tape head cleaning, file resizing, etc.), performs backups on enterprise servers and stores most recent backup media (tapes, disk drives, etc) offsite and/or transfers to onsite fireproof safe.

DEPT MGR & SUP Develops Equipment Maintenance Requirements

Develops the preventive maintenance requirements for all equipment used to produce product (6.3[1]b[1]). Documents preventive maintenance requirements in checklists, tags or other appropriate means. These maintenance requirements are based upon manufacturer's recommendations, previous experience with equipment, and use of the equipment (6.3[1]b[1]).

DEPT MGR & SUP Performs Equipment Maintenance

Performs equipment maintenance as required by maintenance checklist or other suitable method during the setup process (6.3[1]b[1]). Documents maintenance completion on the maintenance checklist.

OPER Request Corrective Maintenance

Requests corrective maintenance as required

DEPT MGR & SUP Assign Maintenance Tasks

Assigns work to maintenance technicians (or appropriate designated employee) based on schedule. Monitors corrective maintenance workload and adjusts schedules if required.

PROD OPER Adjusts Machines

Performs routine machine checks and adjustments as required to meet product requirements.

BUYER Order Parts

Places orders for parts and materials as requested, subject to budget. Obtains approval for parts and materials that exceed budget level, when designated.

DEPT MGR & SUP Record Downtime and Cause

Reports equipment downtime and its suspected cause to COO or other executive management.

MAINT MGR Review and Modify Procedures

Reviews downtime results, repair history, product inspection results, and other information periodically. Modifies equipment maintenance procedures based on experience.

Related Procedures

Inspection Equipment Control, Maintenance and Calibration QSP-7.6.102

Process Setup QSP-7.5.103

Policy References

Provision of resources 6.1

Infrastructure 6.3

Work environment 6.4

Revision Notes

- Title was Infrastructur (5 Clause)
- Removed "References" section as they are already listed in QPM
- Removed "Records" section.