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1.0 Purpose

This procedure describes Preventive Maintenance (PM) activities required for the various types of process chromatography systems in the BDP. The procedure supplies a means for consistent documentation of maintenance of process chromatography systems.

2.0 Scope

This document pertains to individuals (to include equipment users as well as Facilities, Maintenance, and Engineering personnel) who perform PM on process chromatography systems. This procedure describes PM on the chromatography system (pumps, valves, flow paths, detectors, etc.) and excludes the chromatography column(s).

3.0 Authority and Responsibility

3.1 The Quality Engineering/Validation Manager, Biopharmaceutical Quality Assurance (BQA) has the authority to define this procedure.

3.2 BQA is responsible for quality oversight of this procedure.

3.3 BDP personnel who use process chromatography skids or Facilities, Maintenance, and Engineering (FME) Department Instrument Shop are responsible for performing routine PM that occurs on an annual or biennial schedule. These tasks are listed in Attachments I through III of this SOP.

3.4 The Quality Engineering and Validation Group is responsible for reviewing completed PM worksheets.

4.0 Procedure

4.1 Annual or Biennial PM to be completed.

4.1.1 Check with the Area Supervisor and the Master Equipment File (MEF) to see if the unit is under warranty.

4.1.2 If the unit is still under warranty or service contract, **STOP**. Notify the appropriate persons so that the warranty or service contract vendor can be called.

4.1.3 Locate the manufacturer's manual. If available, obtain the service manual.

4.1.4 Make sure that columns have been removed from the system and that there is a safety tag on the unit indicating that it is clean and safe to work on. If columns are still present, **STOP**, and contact the Area Supervisor. Do not proceed until column(s) are removed and the unit has been cleaned.

4.1.5 Review the PM worksheet and verify that the equipment owner has provided the necessary supplies and consumables.

4.1.6 Complete the PM and worksheets as described in Attachments 1 through 3.

4.1.7 Locate the equipment log and record activities in the log as described in ***SOP 21531, Equipment/Facility Logs***.

4.1.8 Ensure the unit under test is operational before leaving the area. If the unit is not operational, initiate the appropriate paperwork according to ***SOP 21526, Engineering Event Management and Status Placarding***.

4.1.9 Give the completed, original checklist to BQA Documentation (BQAD) to route for signature through the equipment owner and the Quality Engineering and Validation Group.

4.1.10 BQAD places the original paperwork in the Master Equipment File (MEF).

5.0 Documentation

5.1 The individual(s) performing this procedure records all pertinent data and comments on the appropriate attachment using Good Documentation Practices.

5.2 When the data contains calibration information, the format shall follow ***SOP 21508, Equipment Calibration Program***, and calibration data shall be stored according to that SOP.

5.3 A copy of all documentation generated during this preventive maintenance, except for calibration, is placed in the MEF.

6.0 References and Related Documents

6.1 **Form 21543-01** *6mm AKTA Process Non-User PM Work Sheet.*

6.2 **Form 21543-02** *ÄKTA™ Pilot User PM Work Sheet*.

6.3 **Form 21543-03** *ÄKTA™ Explorer and Purifier User PM Work Sheet.*

7.0 Change Summary