Introduction

Overview

This document provides a checklist guideline for the management of installation processes for a new hematology instrument.

The following definitions are excerpted from the Clinical and Laboratory Standards Institute's *QMS18, Process MANAgement* guideline[1]:

INSTALLATION QUALIFICATION (IQ) - A SET OF FORMAL checks AND records THAT confirms the equipment or process AND its components, including ANY integrAl HARDWARe or softwARe, were supplied AS ORdered AND properly instALLED in the LABORAtory or other environment; NOTE: IQ CAn be performed by the MANUFACTURer's techNICAL service engineer.

OPERATIONAL qualIFICAtion (OQ) - process ANd records to confirm thAt the equipment or process is operAtionAl for its intended use ANd operAtion; NOTE: OQ CAN be performed by the MANUFACturer's techNICAL service engineer.

PERFORMAnce qualIFICAtion (PQ) - process And records to confirm THAt the equipment or process will perform to specified needs, producing ACCEPTABLE results under NORMAl operAting conditions; NOTE: PQ must be performed by LABORAtory staff.

IQ, OQ, and PQ are validation activities.[2]

Facility	Dr. Potdar's Laboratories (Shukravar peth)
Address/Location	Shashwat Heights, Office No.4, First Floor, Near old Fauzdar Chawadi, Shukrawar Peth, Solapur 413 002
Instance Number	9822323458
Instrument Serial Number	AZ090456
Laboratory Representative	Dr. Neelkanth Potdar

CHAPTER 1

Installation Qualification (IQ)

IQ Checklist

Instrument/SN: AZ090456

See next page for approval signatures.

Table 1.1 IQ Checklist

Action	Select One	
	N/A*	✓
An operator is trained or scheduled to be trained within the next two weeks.		✓
All the cartons on the shipping list have arrived.		✓
All of the cartons are intact and undamaged. If any cartons are damaged, a claim was filed with the carrier.		✓
The instrument area is easily accessible for maintaining and servicing the instrument.		✓
The ventilation fans are not obstructed.		✓
The female ac outlet is within 3 m (10 ft) of the area designated for the instrument.		✓
The main ac outlet is a three-wire outlet supplying 100 to 240 Vac; 50 to 60 Hz; single-phase with ground.		✓
The ground is a confirmed third-wire earth ground that can carry the full current of the circuit.		✓
The circuit is independent and protected.		✓
The power receptacle meets the local required configuration.		✓
If the waste from the instrument will drain into an open drain instead of a waste container, the drain is chemically resistant and is appropriate for biohazardous waste.		✓
The drain or waste container is located so that the waste drain tubing is always below the waste fitting at the base of the instrument.		✓
The typical ambient room temperature range is 18 to 32°C (64.4 to 89.6°F) and is in agreement with the ambient temperature in the Instructions for Use (IFU).		✓
The relative humidity (non-condensing) and ambient temperature does not exceed a maximum of 80% relative humidity (non-condensing) at 32°C (89.6°F).		✓
The instrument reagents, calibrators, and controls are available and within expiration dating.		✓
The paper supplies and blood collection tubes are available.		✓

* Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for IQ Checklist

Date:	12/29/2016
Beckman Coulter Representative and Title *(sign)*:	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*:	
Date:	12/29/2016
Laboratory Representative and Title *(sign)*:	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*:	
Comments:	

Software and Documentation Checklist

Instrument/SN: AZ090456

Table 1.2 Software and Documentation Checklist

Action	Select One	
	N/A*	✓
All appropriate software, manuals, letters, and installation instructions are available on the Beckman Coulter website. Replacements for missing components have been ordered.		✓
Required Safety Data Sheet (SDS) documents are available on the Beckman Coulter website.		✓

Approvals for Software and Documentation Checklist

Date:	12/29/2016
Beckman Coulter Representative and Title *(sign)*:	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*:	
Date:	12/29/2016
Laboratory Representative and Title *(sign)*:	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*:	
Comments:	

System Components

Instrument/SN: AZ090456

See next page for approval signatures.

Table 1.3 System Components

Instrument	
Model: DXH 500	
Serial Number: AZ090456	
Report Printer	
Model:	Epsone M100
Serial Number:	
Verify default printer:	
Print test page from printer:	
IP Address	
UPS (optional)	
Model:	
Serial Number:	
Handheld Bar-Code Scanner	
Model:	
Serial Number:	
Software	
Version:	

Approvals for System Components

Date:	12/29/2016
Beckman Coulter Representative and Title *(sign)*:	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*:	
Date:	12/29/2016
Laboratory Representative and Title *(sign)*:	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*:	
Comments:	

Interface Installation Checklist

Instrument/SN: AZ090456

Table 1.4 Interface Installation Checklist

Action	Select One	
	N/A*	✓
Ensure that the DB-9 connector for the Null Modem cable is securely connected.		✓
Power ON the instrument.		✓
From the DxH 500 LIS Setup screen, ensure that the Serial Communication parameters (baud rate, parity, data bits, and stop bits) match the host system.		✓

Approvals for Interface Installation Checklist

Date:	12/29/2016
Beckman Coulter Representative and Title *(sign)*:	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*:	
Date:	12/29/2016
Laboratory Representative and Title *(sign)*:	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*:	
Comments:	

CHAPTER 2

Operation Qualification (OQ)

OQ Checklist

Instrument/SN: AZ090456

See next page for approval signatures.

Table 2.1 OQ Checklist

Action	Select One	
	N/A*	✓
Ensure that all panels and covers are installed.		✓
Perform a daily checks cycle and verify that the results are acceptable.		✓
Perform a calibration of the instrument.		✓
Run the DxH 500 Control and verify that all the parameters are within acceptable limits.		✓
Retain printouts of the control results. NOTE If this is a new installation, retain printouts of the: • Carryover • Repeatability • Current calibration and calibration factors		
If this is a system upgrade, verify the instrument's whole-blood performance.		✓
Ensure that enrollment in IQAP is complete.		✓
Ensure access to all manuals and other support documents.		✓

* Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for OQ Checklist

Date	12/29/2016
Beckman Coulter Representative and Title *(sign)*	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*	
Date	12/29/2016
Laboratory Representative and Title *(sign)*	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*	
Comments	

CHAPTER 3

Performance Qualification (PQ)

PQ Checklist

Instrument/SN: AZ090456

See next page for approval signatures.

Table 3.1 PQ Checklist

Action	Select One	
	N/A*	✓
Hardware installation data verified		✓
Familiarization with software and software icons		✓
Daily Checks verified		✓
Carryover verified		✓
Repeatability verified		✓
Calibration verified		✓
System and reporting options set up		✓
QC files set up		✓
Quality Assurance set up and IQAP/eIQAP enrollment		✓
Set up and verify LIS interface		✓
Flagging limits and review criteria set up		✓
Method comparison data collated and submitted for data analysis		✓
Measuring range (linearity) verified		✓
Reference interval (normal ranges) verified or established		✓
QC lab limits (per lab protocol) established		✓
Data analysis reports reviewed with appropriate lab staff		✓
Proficiency testing plan established		✓
Pathology/Lab Director sign-off		✓

* Some items do not apply depending on instrument, test menu, laboratory protocol, and/or local regulatory agency.

Approvals for PQ Checklist

Date	12/29/2016
Beckman Coulter Representative and Title *(sign)*	Mr Akash Daingade
Beckman Coulter Representative and Title *(print)*	
Date	12/29/2016
Laboratory Representative and Title *(sign)*	Dr. Neelkanth Potdar
Laboratory Representative and Title *(print)*	
Comments	