

PQ

SPECIALTY SERVICES CHART

COMMISSIONING

QUALIFICATION AND VERIFICATION (VALIDATION)

Installation Checklist

Check of Utilities/ Installation

Run 1 Test Cycle



General Information

Security

System Settings

•Performance Testing

Traceable Calibration

Test Run Reports

Alarm Testing

(Test Cycles)

Installation Check (IC) Documentation Checks

Program Record

 Utility Verification Mechanical Checks Adjustments

·Electrical Checks 3 Consecutive days •I/O Tests

Operation Check (OC)



STEAM QUALITY

Steam Dryness

Superheat

Non-Condensible Gas

1 Day Tests 3 Tests per day

Uses HTM0101 EN285 Standards



IQ/OQ

DOCUMENT &

General Information

Installation Qualification

 Pre-Execution Checkout Document Verification

 Major Component Verification

 Control Hardware Verification

 Installation Piping Checks

Utility Verification

Operation Qualification (OQ)

Machine Configuration

Security Access

 Input/Output Testing Parameter Configuration

Cvcle Verification

Alarm Testing

Utility Shutdown

Traceable Calibration

Certificates

Unit Specification and Vessel Documentation

Reference Drawings

Components Parts List

Spare Parts List

Printouts and Display Verification Included



† DOCUMENT

General Information

Installation Qualification

 Pre-Execution Checkout Document Verification

Major Component

Verification Installation Piping Checks

Utility Verification

Operation Qualification (OQ)

Machine Configuration

Security Access

 Input/Output Testing Parameter Configuration

 Cvcle Verification Alarm Testing

Utility Shutdown

Printouts and Display Verification Included

HEAT DISTRIBUTION

Documents Chamber Temps and Spread

3 Consecutive Cycles

Traceable Calibration

Customer Approved Protocol Using Customer Specific Cycles

Comprehensive Final Report



±8 CYCLE

Loaded Chamber Defined and Documented

Cycle Parameters Defined and Documented

Cycle Development Summary Report

·Summary of CD Activities Discuss and Tabulate

Results ·Basis for Acceptance Criteria for PQ

Development

COMPLETE

Custom PQ Protocol

Empty Chamber Heat Distribution Study (3 Runs)

Loaded Chamber Studies (3 Runs of Each

Specified Loaded Cycle)

Final Summary Report ·Summary of PQ Activities

 Close any Open Items Discuss and Tabulate Results

•Release Unit for Use

REVALIDATION

Custom PQ Protocol

Empty Chamber Heat Distribution Study (1 Run)

Loaded Chamber Studies (1 Run of Each Specified Loaded Cycle)

Final Summary Report ·Summary of Revalidation Activities

 Close any Open Items Discuss and Tabulate Results



USES KAYE VALIDATOR

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- Performed by STERIS Validation Engineer
- Onsite execution performed by a STERIS factory trained technician
- † Electronic Word Document
- ‡ Prerequisite to PQ
- § Not applicable to VHP® products