# Installation Qualification Template

1. Introduction
   1. Objectives

The objective of Installation Qualification (IQ) testing is to demonstrate that the solution is installable under normal expected conditions with acceptable and expected output results.

* 1. Scope

IQ testing involves deploying the solution in scenarios that are defined in the Nymi Design/Configuration Specifications document.

* 1. Assumptions
* A reliable network connection exists between each component in the environment.
* The tester has access to Connected Worker Platform documentation.
  1. Exclusions

1. Acronyms and References
   1. Acronyms and Definitions

|  |  |
| --- | --- |
| **Acronyms and Definitions** | |
| AC | Acceptance Criteria |
| CFR | Code of Federal (US) Regulations |
| cGxP | Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices |
| CS | Configuration Specification |
| CSV | Computer Systems Validation |
| DS | Design Specification |
| FS | Functional Specification |
| GUI | Graphical User Interface |
| IQ | Installation Qualification |
| LAN | Local Area Network |
| OQ | Operational Qualification |
| PQ | Performance Qualification |
| SOP | Standard Operating Procedure |
| URS | User Requirements Specification |

* 1. References

|  |  |
| --- | --- |
| **References** | |
| 21 CFR | Part 11, Part 210 |
| GAMP5 | Guide for Validation of Automated Systems |
| URS | URS for Biometric MES System |
| FS | NYMI FS-001 |
| DS/CS | NYMI CS-001 |

1. Responsibilities
   1. System Owner

To provide all required documentation, create the performance qualification testing document, and to provide a functional test environment.

* 1. System Validation Tester

To perform the qualification testing and record the results in this document. Documenting any issues that are encountered.

1. System Description

NES and AD servers reside in the same domain as do the user terminals. The configuration falls into GAMP5 Category 3.

1. Test Procedure
   1. General

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **System Name:** | Nes-and-evidian.domain.com | | | |
| **Test Title:** | Installation Qualification of CWP | | | |
| **Purpose:** | Verify that the solution is installable in a virtual IT Infrastructure | | | |
| **Test Reference:** | | IQ-001 | **Test Run #:** | 01 |
| **Tester name:** | | Deb Claudio | **Execution Date:** | 04-17-2025 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **URS tested: URS-001, URS-002**  **Functional Specification: FS-CFG-01, CS-CFG-010**  **Environment details: NES and AD server reside in the same domain and are hosted on virtual Windows 2016 servers** | | | | |
| **Step#** | **Procedure** | **Expected Result** | **Actual Result** | **Pass/Fail** |
|  | **NEE component deployments:** | |  |  |
| 1 | Satisfy prerequisite requirements. | Supported configuration is in place and certificates have been obtained. | AD configured, Windows server in place, certificates obtained | Pass |
| 2 | Install IIS and ASP.NET, as documented. | IIS installation completes without error. | IIS installation completed successfully. | Pass |
| 3 | Import the TLS certificate, as documented. | TLS certificate import succeeds without error. | Certificate imported without error. | Pass |
| 4 | Add HTTPS bindings in IIS, as documented. | HTTP bindings are created by using the TLS certificate. | HTTP bindings created successfully. | Pass |
| 5 | In IIS, create an Application Pool for Authentication Service as documented. | Application Pool is created in IIS. | Application Pool is created in IIS | Pass |
| 6 | In IIS, Verify the Authentication Configuration as documented. | Authentication Configuration is verified. | Authentication Configuration is verified. | Pass |
| 7 | Secure IIS as documented | Default.htm is disabled and HTTP Response Headers is configured. | Default.htm is disabled and HTTP Response Headers is configured. | Pass |
| 8 | Import and configure the certificates, as documented. | Full chain certificate import and configuration completes without error. | Full chain imported and configured successfully. | Pass |
| 9 | Install the NES software using the wizard, as documented. | Installation process installs the prerequisite software and the NES software without error. | Prerequisite software installation completed without errors. | Pass |
| 10 | Configure NES with NTS as documented. | NES configuration completes without error. | NES configuration with NTS completed. | Pass |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Evidian component deployments (Follow the steps in the Nymi Evidian Deployment Guide):** | |  |  |
| 8 | Install and configure the Evidian EAM controller in the environment. | Installation completes successfully. | Installation succeeds. | Pass |
| 9 | Install the Evidian EAM client and Nymi Band Application for Evidian software on a terminal in the environment (enrollment terminal) | Installation completes successfully. | Installation succeeds. | Pass |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **System Name:** | Nes-and-evidian.domain.com | | | |
| **Test Title:** | Installation Qualification of CWP | | | |
| **Purpose:** | Verify that the NES is installable in a multidomain/multi-forest environment. | | | |
| **Test Reference:** | | IQ-002 | **Test Run #:** | 01 |
| **Tester name:** | | Deb Claudio | **Execution Date:** | 04-17-2025 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **URS tested: URS-003**  **Functional Specification: FS-CFG-03, FS-CFG-04** | | | | |
| **Step#** | **Procedure** | **Expected Result** | **Actual Result** | **Pass/Fail** |
|  | **CWP component deployments: (Follow CWP Deployment Guide):** | |  |  |
| 1 | Satisfy prerequisite requirements. | Supported configuration is in place and certificates have been obtained. | AD configured, Windows server in place, certificates obtained | Pass |
| 2 | Install IIS and ASP.NET, as documented. | IIS installation completes without error. | IIS installation completed successfully. | Pass |
| 3 | Import the TLS certificate, as documented. | TLS certificate import succeeds without error. | Certificate imported without error. | Pass |
| 4 | Add HTTPS bindings in IIS, as documented. | HTTP bindings are created by using the TLS certificate. | HTTP bindings created successfully. | Pass |
| 5 | Import and configure the certificates, as documented. | Full chain certificate import and configuration completes without error. | Full chain imported and configured successfully. | Pass |
| 6 | Install the NES software using the wizard, as documented. | Installation process installs the prerequisite software and the NES software without error. | Prerequisite software installation completed without errors. | Pass |
| 7 | Configure NES with multiple domains as documented. | NES configuration completes without error. | NES configuration with multiple domains completed. | Pass |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Evidian component deployments (Follow Nymi Evidian Deployment Guide):** | |  |  |
| 8 | Install and configure the Evidian EAM controller in the environment. | Installation completes successfully. | Installation succeeds. | Pass |
| 9 | Install and configure the Nymi Band Application on the enrollment terminal | Installation completes successfully. | Installation succeeds. | Pass |
| 10 | Install and configure the EAM client software on the enrollment terminal | Installation completes successfully. | Installation succeeds. | Pass |
| 11 | Install and configure the EAM client software on each user terminal. | Installation completes successfully. | Installation succeeds. | Pass |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **System Name:** | Nes-and-evidian.domain.com | | | |
| **Test Title:** | Installation Qualification of CWP HA | | | |
| **Purpose:** | Verify that the solution supports high availability | | | |
| **Test Reference:** | | IQ-003 | **Test Run #:** | 01 |
| **Tester name:** | | Deb Claudio | **Execution Date:** | 04-17-2025 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **URS tested: URS-029**  **Functional Specification: FS-CFG-02** | | | | |
| **Step#** | **Procedure** | **Expected Result** | **Actual Result** | **Pass/Fail** |
| 1 | Review the High Availability Architecture in the Nymi Connected Worker Platform Deployment Guide. | High Availability Architecture is specified in the guide. | Documentation is reviewed. | Pass |
| 2 | Configure load balancers for high availability deployment. | Load balance configuration is successful. | Load balance is successfully configured. | Pass |
| 3 | Perform SQL Database configuration for High Availability. | Configuration is successful. | SQL database is successfully configured. | Pass |