**Performance Qualification Template**

1. Introduction
	1. Objectives

The objective of Performance Qualification (PQ) testing is to demonstrate that the solution operates under normal expected conditions with acceptable and expected output results.

* 1. Scope

PQ testing involves performing basic and interactive tasks that involve specifications that are defined in the Nymi Design/Configuration Specifications document.

* 1. Assumptions

The tests in this document assume that the following infrastructure is in place before testing begins:

* NES is deployed in the environment.
* The Nymi Band application has been installed on at least one machine that has network connectivity with NES.
* An MES is installed and configured on at least one machine that has network connectivity with NES.
* A reliable network connection exists between each component in the environment.
* The tester has access to Nymi 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** |  NES installation tests |
| **Purpose** | Validate that the NES is functional in the IT Infrastructure |
| **Test Reference:** | PQ-001  | **Test Run #:** | 01  |
| **Tester name:** | Deb Claudio | **Execution Date:** | 04-17-2025 |

|  |
| --- |
| **URS tested: URS-001****Functional specification: FS-CFG-01** |
| **Step#** | **Procedure** | **Expected Result** | **Actual Result** | **Pass/Fail** |
| 1 | Locate the Nymi Band Application and follow the steps on the interface to enroll your Nymi Band. | Enrollment is successful. | Enrollment succeeds.  |  Pass |
| 2 | Log in to the NES Admin Console with an administrator account.  | Log is successful. |  Log succeeds. |  Pass |
| 3 | Navigate to the About page, and review the system Diagnostics | System Diagnostics all Pass | All system diagnostics pass |  Pass |

|  |  |
| --- | --- |
| **System Name:** |  Nes-and-evidian.domain.com |
| **Test Title** |  Testing the Nymi Band battery |
| **Purpose** | Test the Nymi Band to confirm a 3-day battery life |
| **Test Reference:** | PQ-002 | **Test Run #:** | 02 |
| **Tester name:** |  Deb Claudio | **Execution Date:** | 04-17-2025 |

|  |
| --- |
| **URS tested: URS-007****Functional specifications: FS-BAT-001** |
| **Step#** | **Procedure** | **Expected Result** | **Actual Result** | **Pass/Fail** |
| 1 |  **DAY1:**Charge your Nymi Band for at least 2 hours. Record the amount of time that the Nymi Band was charging for in the actual results for this step. | Tester records the amount of time the Nymi Band is charged. |  Nymi Band left on charge for 2 hours. |  Pass |
| 2 | Wake Nymi Band while it is still attached to charger. | The Nymi Band display clearly displays that the band is fully charged. | A full battery icon appears on the Nymi Band screen. |  Pass |
| 3 | Log into the Nymi Band Application and follow the instructions to enroll your Nymi Band. | Enrollment is successful.  |  Enrollment succeeds. |  Pass |
| 4 | Record the date and time that you enrolled your Nymi Band for your first authentication event/first tap. | Time is recorded. | Nymi Band enrolled at 8:34 | Pass |
| 5 | Throughout the 10-hour shift, open the NFC tap application and perform 300 authentication events by tapping the Nymi Band against an NFC reader. | The battery lasts throughout the 10-hour shift. The Nymi Band does not falsely deauthenticate. | Nymi Band remained authenticated the entire 10 hours shift, Nymi Band was tapped 300 times over the course of the shift. | Pass |
| 6 | Take off the Nymi Band and put it on a table. | The Nymi Band deauthenticates within 3 seconds of removal. | Nymi Band deauthenticated in 1 second. | Pass |
| 7 | Attempt to authenticate the Nymi Band while it is on the table. Leave for the day. | The Nymi Band does not authenticate. | Nymi Band authentication failed | Pass |
|  | **DAY 2:** |  |  |  |
| 8 | Record the time of your first authentication event/first tap. | Time is recorded. | First tap occurred at 9 am. | Pass |
| 9 | Throughout the 10-hour shift, open the NFC tap application and perform 300 authentication events by tapping the Nymi Band against an NFC reader. | The battery lasts throughout the 10-hour shift. The Nymi Band does not falsely deauthenticate. | Nymi Band remained authenticated the entire 10 hours shift, Nymi Band was tapped 300 times over the course of the shift. | Pass |
| 10 | Take off the Nymi Band, leave it unauthenticated. and untouched, and then leave for the day. | The Nymi Band deauthenticates within 3 seconds of removal. | Nymi Band deauthenticated in 1.2 seconds. | Pass |
|  | **DAY 3:** |  |  |  |
| 11 |  Record the time of your first authentication event/first tap. | Time is recorded. | First authentication occurred at 8:56 am | Pass |
| 12 | Throughout the 10-hour shift, open the NFC tap application and perform 300 authentication events by tapping the Nymi Band against an NFC reader. | The battery lasts throughout the 10-hour shift. The Nymi Band does not falsely deauthenticate. | Nymi Band remained authenticated the entire 10 hours shift, Nymi Band was tapped 300 times over the course of the shift. | Pass |
| 13 | Take off the Nymi Band, leave it unauthenticated and untouched, and then leave for the day. | The Nymi Band deauthenticates within 3 seconds of removal. | Nymi Band deauthenticated in 2 seconds. | Pass |
| 14 | Leave the Nymi Band off charge and observe the battery level.  | The Nymi Band screen displays the battery level. | Nymi Band displays a one bar battery level. | Pass |
|  | **Days 4-8:** |  |  |  |
| 15 | When the battery dies, wait until the 7th day after the battery was charged to put the Nymi Band no charge. | The Nymi Band displays the charging symbol. | The charging symbol appeared on the Nymi Band when put on charge. | Pass |
| 16 | When the Nymi Band is fully charged, put the Nymi Band on your wrist. and authenticate with your fingerprint. | The Nymi Band indicates that the Nymi Band is fully charge and prompts the user to authenticate. | The Nymi Band displayed a full battery charge. Authentication succeeded on the first attempt and the Nymi Band displays 'READY'. | Pass |