**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

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| **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

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| **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

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| **System Name:** | nes.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:** | 10-23-2023 |

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| **URS tested: 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 succeeds. | Nymi Band Application disappears. | Pass |
| 2 | Log in to the NES Admin Console with an administrator account. | Log in succeeds. | NES Admin Console window appears. | Pass |
| 3 | Navigate to the Users tab and search the username that you used when you enrolled your band. | Username appears. | The results window displays the user. | Pass |
| 4 | On the Edit User screen, click disconnect. | Disconnection succeeds. | User is disconnected successfully. | Pass |
| 5 | Perform a delete user data operation on you Nymi Band. | Deletion succeeds. | Nymi Band vibrates and displays No User. | Pass |
| 6 | With the same username, log in again to the Nymi Band Application and enroll the same Nymi Band. | Enrollment succeeds. | Nymi Band Application closes. | Pass |
|  |  |  |  |  |
| 7 | Log in to the NES Admin Console with an administrator account. | Log in succeeds. | NES Admin Console window appears. | Pass |
| 8 | Navigate to the Users tab and search the username that you used when you enrolled your Nymi band. | Username appears. | Username appears. | Pass |
| 9 | On the Edit User screen, click disconnect. | Disconnect succeeds. | User is disconnected. | Pass |

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| **System Name:** | Nes.domain.com | | | |
| **Test Title** |  | | | |
| **Purpose** | Test the Nymi Band (8-day test) | | | |
| **Test Reference:** | | PQ-002 | **Test Run #:** | 02 |
| **Tester name:** | | Deb Claudio | **Execution Date:** | 10-23-2023 |

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| **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 is charged for 2 hours. | Pass |
| 2 | Wake Nymi Band while it is still attached to the charger. | Nymi Band display clearly displays the battery level. | Nymi Band displays a fully charged battery icon. | Pass |
| 3 | Log into the Nymi Band Application and follow the instructions to enroll your Nymi Band. | Enrollment succeeds. | Nymi Band Application disappears. | 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 9:15 AM. | 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 completed 300 taps with no false deauthentications. | Pass |
| 6 | Take off the Nymi Band and put it on a table. | Nymi Band deauthenticates within 2 seconds of removal. | Nymi Band vibrates. | Pass |
| 7 | Attempt to authenticate the Nymi Band while it is on the table. Leave for the day. | The Nymi Band does not authenticate. | Authentication does not succeed | Pass |
| 7 | **DAY 2:**  Record the time of your first authentication event/first tap. | Time is recorded. | First tap was at 9:23 AM | Pass |
|  |  |  |  |  |
| 8 | 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 completed 300 taps with no false deauthentications. | Pass |
| 9 | 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 vibrates. | Pass |
| 10 | **DAY 3:**  Record the time of your first authentication event/first tap. | Time is recorded. | First tap is at 9:10 AM | Pass |
| 11 | 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 completed 300 taps with no false deauthentications. | Pass |
| 12 | Take off the Nymi Band, leave it unauthenticated and untouched, and then leave for the day. | Nymi Band deauthenticates within 3 seconds of removal. | Nymi Band vibrates | Pass |
| 13 | Leave the Nymi Band off charge and observe the battery level. | Nymi Band screen displays the battery level. | Nymi Band displays one bar. | Pass |
|  | **Days 4-8:** |  |  |  |
| 14 | When the battery dies, wait until the 7th day after the battery was charged to put the Nymi Band no charge | Nymi Band displays the charging symbol. | Charging symbols is displayed on the screen. | Pass |
| 15 | When the Nymi Band is fully charged, put the Nymi Band on your wrist and authenticate with your fingerprint | Nymi Band authentication succeeds. | Nymi Band displays the success symbol | Pass |