**Electronic Records and Electronic Signatures Assessment**

Signatures below indicate agreement and/or approval with the contents of this assessment.The author and approver names and functions are to be identified in the change documentation (change number) or project plan.

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| 1.0 | 29-May-2024 | Sazid Ahmed Nassir  Test Resource | Initial version |

#### 1.0 Overview

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#### 2.0 General System Questions

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| --- | --- |
| **System Owner** | Noa Rivlin |
| **System Owner Functional Area** | Technical and Development Lead, Digital Services & User Experience - OUS |
| **Site/entity geographic location** | Global |
| **Date of Assessment** | 28-May-2024 |

#### 2.1 Procedures and Controls for Closed Systems

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 2.1.1 | Is the system validated? | YES | The system is validated under BA0009700 | N/A |
| 2.1.2 | Is it possible to detect invalid or altered records? | NA | The application does not store or share any user information. | N/A |
| 2.1.3 | Is the system capable of producing accurate and complete copies of electronic records on paper? | NA | The system does not generate any records. | N/A |
| 2.1.4 | Is the system capable of producing accurate and complete copies of records in electronic form for inspection, review and copying by regulatory body? | NA | There are no records generated in the system. | N/A |
| 2.1.5 | Are the records readily retrievable throughout their retention period? | NA | The system does not generate any records. | N/A |
| 2.1.6 | Is archived data for this system checked for accessibility? | NA | There are no records stored in the system and therefore no records subject to archiving. | N/A |
| 2.1.7 | Are electronic records for this system backed up and is there evidence that the data can be restored? | NA | There are no electronic records stored in the system. | N/A |
| 2.1.8 | Is the system access limited to authorized individuals? | NA | There are no login requirements for the system as the user is not changing any informant | N/A |
| 2.1.9 | Is there a secure, computer generated time stamped audit trail that records the date and time of operator entries and actions that perform any of the following activities: |  | The system is not required to generate audit trail information as the users do not change any records in the system. | N/A |
| * Create | NA |
| * Modify | NA |
| * Delete electronic records | NA |
| 2.1.10 | Upon making a change to an electronic record, is previous recorded information still available (i.e. not obscured by the change)? | NA |  | N/A |
| 2.1.11 | Is an electronic record’s audit trail retrievable throughout the record’s retention period? | NA | The system does not contain electronic records and therefore is not subject to any record retention period. | N/A |
| 2.1.12 | Is the audit trail available for review and copying? | NA | The system is not required to generate audit trail information as the users do not change any records in the system. | N/A |
| 2.1.13 | Are there procedures in place requiring audit trail review for critical data? | NA | The system is not required to generate audit trail information as the users do not change any records in the system and therefore there are no critical records subject to review. | N/A |
| 2.1.14 | If the sequence of the systems steps or events is important, is this enforced by the system (e.g. as would be the case in a process control system)? | NA | The users do not perform any steps in the system. | N/A |
| 2.1.15 | Does the system ensure that only authorized individuals can perform the following actions: |  | There is no login information for the system, no electronic records and therefore no ability to sign or alter records. | N/A |
| 2.1.15.1 | * Use the system | NA | N/A |
| 2.1.15.2 | * Sign records electronically | NA | N/A |
| 2.1.15.3 | * Access the operation or computer system input or output device | NA | N/A |
| 2.1.15.4 | * Alter a record | NA | N/A |
| 2.1.15.5 | * Perform the operation at hand (intended operation) | NA | N/A |
| 2.1.16 | If it is a requirement of the system that input data or instructions can only come from certain input devices (terminals) does the system check the validity of the source of any data or instructions received? | NA | The system does not contain any functionality to interact with input devices. | N/A |
| 2.1.17 | Is there documented training, including on the job training for: |  | No training is required |  |
| * System users | NA | N/A |
| * Developers | NA | N/A |
| * IT supports staff | NA | N/A |
| 2.1.18 | Is there a written policy that makes individuals fully accountable and responsible for actions initiated under their electronic signature? | NA | System doesn't contain functionality to have electronic signatures. | N/A |
| 2.1.19 | Is the distribution of systems operation and maintenance documentation controlled? | NA | The system is vendor managed and the vendor is responsible for ensuring the operation. | N/A |
| 2.1.20 | Is access to the documentation controlled? | NA | N/A |
| 2.1.21 | Is the use of the documentation controlled? | NA | N/A |
| 2.1.22 | Is there a formal change control procedure for system documentation that maintains a time-sequenced audit trail of changes? | NA | System follows SLC Procedure. | N/A |

#### 2.2 Additional Procedures and Controls for Open Systems

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 2.2.1 | Are records or data transmitted by the system sent in a secure manner, such that their authenticity, integrity, and confidentiality are ensured? | NA | System does not contain functionality to transmit data to any other system | N/A |

**2.3 Controls for Identification Codes and Passwords**

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 2.3.1 | Are controls in place to maintain the uniqueness of each combined identification code and password, such that no individual can have the same combination of identification code and password? | NA | The system does not contain login information. | N/A |
| 2.3.2 | Are procedures in place to ensure that the validity of identification codes is periodically checked? (lock after a certain number of attempts; log file) | NA | The system does not contain login information. | N/A |
| 2.3.3 | Do passwords periodically expire and need to be revised? | NA | The system does not contain login information so no need to check password functionality. | N/A |
| 2.3.4 | Is there a procedure for recalling identification codes and passwords if a person leaves or is transferred? | NA | The system does not contain login information. | N/A |
| 2.3.5 | Is there a procedure for electronically disabling an identification code or password if it is potentially compromised or lost? | NA | The system does not contain login information. | N/A |
| 2.3.6 | Is there a procedure for detecting attempts at unauthorized use and for informing security? | NA | The system does not contain login information. | N/A |
| 2.3.7 | Is there a procedure for reporting repeated or serious attempts at unauthorized use to management? | NA | The system does not contain login information. | N/A |

**2.4 For tokens, cards, and other devices bearing or generating identification code or password information**

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 2.4.1 | Is there a loss management procedure to be followed if a device is lost or stolen? | NA | System does not contain any functionality for tokens, cards and other devices for generating identification codes or password information. | N/A |
| 2.4.2 | Is there a procedure for electronically disabling a device if it is lost, stolen, or potentially compromised? | NA | System does not contain any functionality for tokens, cards and other devices for generating identification codes or password information. | N/A |
| 2.4.3 | Are there controls over the issuance of temporary and permanent replacements? | NA | System does not contain any functionality for tokens, cards and other devices for generating identification codes or password information. | N/A |
| 2.4.4 | Is there initial and periodic testing of tokens and cards? | NA | System does not contain any functionality for tokens, cards and other devices for generating identification codes or password information. | N/A |
| 2.4.5 | Does this testing check that there have been no unauthorized alterations? | NA | System does not contain any functionality for tokens, cards and other devices for generating identification codes or password information. | N/A |

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#### 3.0 Electronic Signatures

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Justification** |
| --- | --- | --- | --- |
| 3.0.1 | Does the system employ electronic signature capabilities, subject to (but not limited to) 21 CFR Part 11 or Annex 11? | NO  Yes – Complete sections 3.1 – 3.4.  No – Provide detailed justification here and skip sections 3.1 – 3.4. | There is no login information for the system, no electronic records and therefore no ability to sign or alter records. |

#### 3.1 Signed Electronic Records

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 3.1.1 | Do signed electronic records contain the following related information? |  | The system does not contain functionality for Electronic signatures | N/A |
| 3.1.1.1 | * The printed name of the signer | NA |
| 3.1.1.2 | * The date and time of signing | NA |
| 3.1.1.3 | * The meaning of the signing (such as approval, review) | NA |
| 3.1.2 | Is the above information shown on displayed and printed copies of the record? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.1.3 | Are signatures linked to their respective electronic records ensuring that they cannot be cut, copied, or otherwise transferred by ordinary means for the purpose of falsification? | NA | The system does not contain functionality for Electronic signatures | N/A |

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#### 3.2 Electronic Signatures (General)

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 3.2.1 | Are electronic signatures unique to an individual? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.2.2 | Does the system restrict the reuse and reassignment of electronic signatures to another individual? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.2.3 | Is the identity of an individual verified before an electronic signature is allocated? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.2.4 | Is there a policy on the certification to the FDA that the electronic signatures used in the computerized system on or after August 20, 1997 are intended to be the legally binding equivalent of traditional hand-written signatures? | NA | The system does not contain functionality for Electronic signatures | N/A |

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#### 3.3 Electronic Signatures (Non-biometric)

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 3.3.1 | Is the signature made up of at least two components, such as an identification code and password, or an id card and password? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.3.2 | When several signings are made during a continuous session, is the password executed at each signing? (Note: both components must be executed at first signing of the session) | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.3.3 | If signings are not done in a continuous session, are both components of the electronic signature executed with each signing? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.3.4 | Are non-biometrics signatures only used by their genuine owners? | NA | The system does not contain functionality for Electronic signatures | N/A |
| 3.3.5 | Would an attempt to falsify an electronic signature require the collaboration of at least two individuals? | NA | The system does not contain functionality for Electronic signatures | N/A |

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#### 3.4 Electronic Signatures (biometric)

| **ID #** | **Question** | **Assessment Results**  *(select from drop down)* | **Objective Evidence**  *(provide evidence / rationale)* | **Proposed Remediation** |
| --- | --- | --- | --- | --- |
| 3.4.1 | Has it been shown that biometric electronic signatures can only be used by their genuine owner? | NA | The system does not contain functionality for Electronic signatures | N/A |

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