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| **CAPA Report** |

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| **CAPA Number** | CAPA-002 |
| **Source** | Audit A-002 |
| **Assignee** | Valerie Bookwalter |
| **Initiator** | Jacob Harris |
| **Initiated Date** | 03 Sep 2021 |

# Description

The SRF-06-PR-001 Records Management Procedure section 5.4 states, “Record correction must be annotated with the correction made, the person making correction and the date of correction.”.

Contrary to the above requirement, the Pansophy System does not indicate that a closed traveler (i.e. final record) is reopened for correction, what data was corrected, or which travelers have been corrected then reclosed.

# Extent of Condition

This condition exists for every corrected traveler in the Pansophy system.

# Cause

Original design of Pansophy did not account for tracking the reopening/reclosing of travelers to permit updating of data record. At the requests of users, the Pansophy team accommodated the production staff by administratively re-opening a traveler, but without noting the change of record content nor by whom.

# Corrective Action

Due to the design of Pansophy Travelers, there is no way to identify the “corrected travelers”. Therefore, no corrective is possible.

# Preventative Action

1. Each request for a traveler to be re-opened will be annotated in the database by:
   1. Obsolete the current record
   2. Duplicate the current record into a new record
   3. Re-Open the new Record
   4. Annotate the new record with requester’s name and date.
   5. Requestor changes the new record and closes it.
2. Create a new Administrative Panel to handle the reopening of travelers, automating the above steps.
3. Instruct Pansophy Database administrators on the appropriate way to re-open and annotate a traveler record and the use of the Administrative Panel.

# Verification Plan

1. An example of a corrected traveler that shows the annotation with the requestor’s name date.
2. Screenshot of the new Administrative Panel that handles re-opening of Traveler Records.
3. Verification that all Pansophy Database Administrators have been trained in the only approved method for re-opening Traveler Records.

# Action Plan Approval

Plan Acceptance Date: 02 May 2022

Target Completion Date: 31 May 2022

# Closure

<Initiator lists verification results.>

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| **Approved by:** | **Name:** | **Signature:** | **Date:** |
| Assignee |  |  |  |
| Initiator |  |  |  |
| SRF Department Head |  |  |  |