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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

The Pansophy System was never designed to allow a closed traveler (record) to be re-opened for correction of and or addition of data to be entered. However, due to the nature of humans, this practice has been modified to allow database administrators to reopen a closed traveler to allow for updates and re-closure. This has been in existence for the life of 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

Each request for a traveler to be re-opened will be annotated in the database by:

1. Obsoleting the current record
2. Duplicate the record
3. Re-Open the new Record

At that point the change of the record is annotated with a name and data.

Traveler date can then be corrected or completed and the traveler will be closed by normal means. This will allow for all changed, names of users and dates to be collected.

# Preventative Action

A new Administrative Panel will be created to handle the reopening of travelers, automating the above corrective actions. All Pansophy Database administrators will be instructed on the appropriate way to re-open and annotate a traveler record.

# Verification Plan

1. Verify the new Administrative Panel is created and handles re-opening of Traveler Records.
2. Verify all Pansophy Database Administrators have been trained in the only approved method for re-opening Traveler Records.
3. Validate the Database no longer contains "re-opened" travelers without annotations of whom and date.

# Action Plan Approval

<Initiator lists date the corrective and preventative actions are approved and the target completion date.>

# Closure

<Initiator lists verification results.>

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