1. Purpose

The purpose of this work instruction is to define and describe the file directory structure of the FDA's Cloud File Sharing system called Box, which is used for the sharing of documents and records by participant Regulatory Authorities of the Medical Device Single Audit Program (MDSAP).

2. Scope

This work instruction covers MDSAP assessment and audit related records that are uploaded for sharing amongst users of Box.

3. Work Instruction

Introduction

The FDA CFS a cloud-based file sharing and collaboration solution which allows for Regulatory Authorities (RA) to share files in a secure environment.

Assessment Records

The 📁 **MDSAP** folder contains the 📁 **Assessments** directory.

The 📁 **Assessments** directory is organized by a hierarchical structure according to each Auditing Organization (AO). Each AO has been assigned a unique AOID code as defined in the Naming convention of MDSAP Electronic Records procedure MDSAP QMS P0015.

Under the 📁 **Assessments** folder, the directory is organized by folders for each Auditing Organization following the folder naming convention 📁 **AO_AOID.**

Example of Assessments directory:

   📁 **MDSAP**

      📁 **Assessments**

         📁 **AO_BSIA**

         📁 **AO_GMED**

         📁 **AO_ITSN**

         📁 **AO_TUVS**

📁 **AO_TUVU**

Assessment Cycle and Assessment Stage Subfolders

The folders underneath each 📁 **AO_AOID** are first organized by the Assessment Cycle.

In the 📁 **Assessment_Cycle_#** folder are Assessment Stage subfolders organized sequentially and named by the assessment activity to help group the files by the stage in which the records were generated.
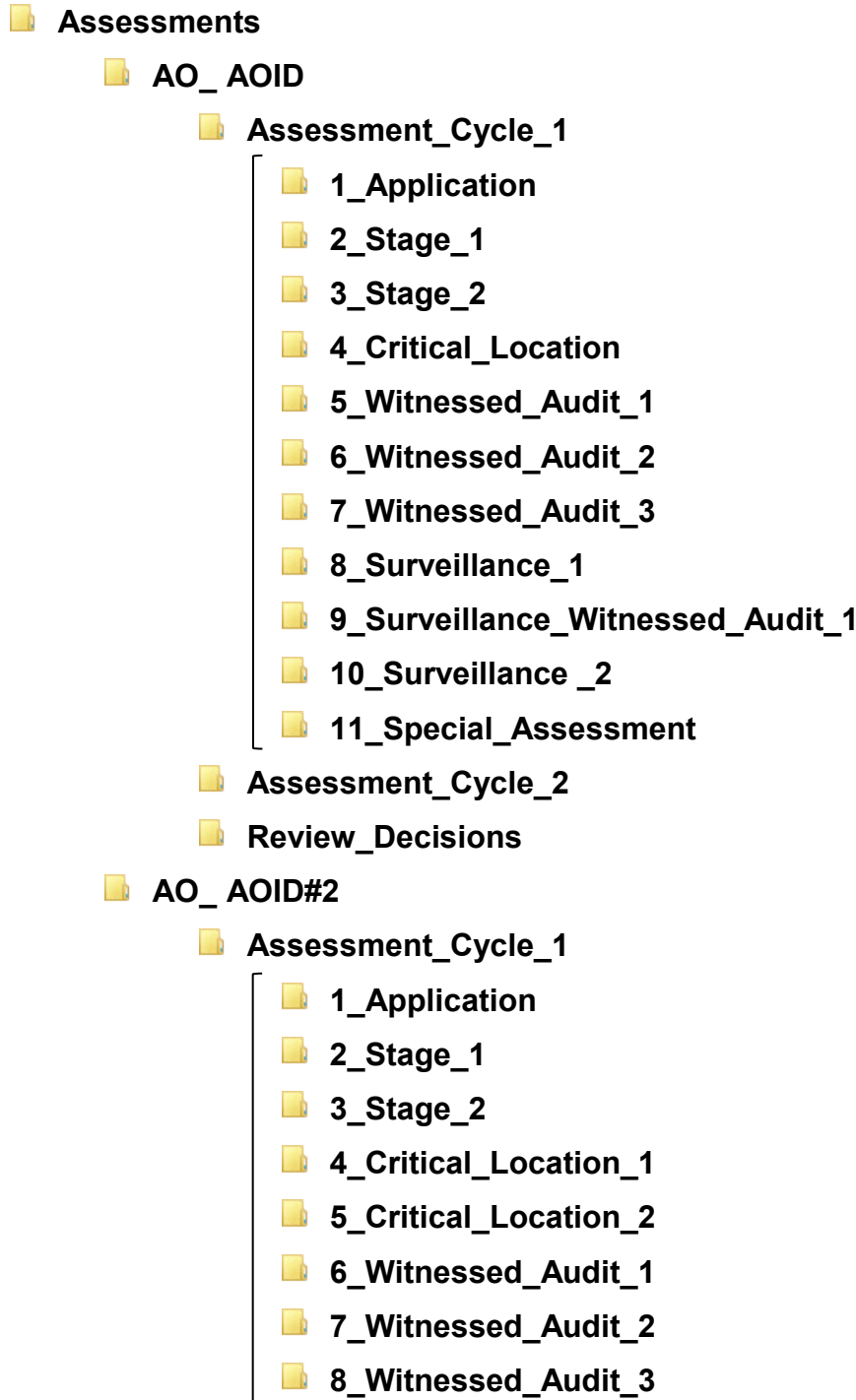
All relevant records generated from each assessment stage are organized into its corresponding folder. The subfolders are sequentially numbered to help identify and sort each Assessment stage chronologically.

Since the assessment plan of each individual AO will vary, the Assessment Program Manager (APM) will create assessment stage subfolders as necessary. A subfolder for each stage of the AO's assessment plan will be added as the assessment activity is planned and confirmed for.

For example, separate Critical Location subfolders can be added for each of the AO's identified Critical Locations.

Assessment File Directory

Example of the hierarchy of the Assessment directory and Assessment Stage subfolders:

- 📁 **Assessments**
  - 📁 **AO_ AOID**
    - 📁 **Assessment_Cycle_1**
      - 📁 **1_Application**
      - 📁 **2_Stage_1**
      - 📁 **3_Stage_2**
      - 📁 **4_Critical_Location**
      - 📁 **5_Witnessed_Audit_1**
      - 📁 **6_Witnessed_Audit_2**
      - 📁 **7_Witnessed_Audit_3**
      - 📁 **8_Surveillance_1**
      - 📁 **9_Surveillance_Witnessed_Audit_1**
      - 📁 **10_Surveillance _2**
      - 📁 **11_Special_Assessment**
    - 📁 **Assessment_Cycle_2**
    - 📁 **Review_Decisions**
  - 📁 **AO_ AOID#2**
    - 📁 **Assessment_Cycle_1**
      - 📁 **1_Application**
      - 📁 **2_Stage_1**
      - 📁 **3_Stage_2**
      - 📁 **4_Critical_Location_1**
      - 📁 **5_Critical_Location_2**
      - 📁 **6_Witnessed_Audit_1**
      - 📁 **7_Witnessed_Audit_2**
      - 📁 **8_Witnessed_Audit_3**

📁 **9_Surveillance_1**

📁 **10_Surveillance_Witnessed_Audit_1**

📁 **Assessment_Cycle_2**

📁 **Review_Decisions**

In addition to the records that are stored in the Assessment Stage subfolder, there are additional subfolders to help group records that may contain a large collection of files or files that are expected to have multiple revisions.

Example of the additional subfolders in each Assessment Stage:

📁 **Assessments**

   📁 **AO_ AOID**

      📁 **Assessment_Cycle_1**

         📁 **1_Application**

         📁 **2_Stage_1**

         └──▶ 📁 **AO_QS_Documentation**

         📁 **3_Stage_2**

         └──▶ 📁 **AO_Nonconformity**

            └──▶ 📁 **[YYYY-MM-DD-ANC-AOID-NN]**

               └──▶ 📁 **Follow-up_1**

               └──▶ 📁 **Follow-up_2**

         📁 **4_Critical_Location**

         └──▶ 📁 **AO_Nonconformity**

            └──▶ 📁 **[YYYY-MM-DD-ANC-AOID-NN]**

               └──▶ 📁 **Follow-up_1**

         📁 **5_Witnessed_Audit_1**

         └──▶ 📁 **AO_Nonconformity**

            └──▶ 📁 **[YYYY-MM-DD-ANC-AOID-NN]**

               └──▶ 📁 **Follow-up_1**

               └──▶ 📁 **Follow-up_2**

         📁 **Audit Report**

All relevant records for each particular stage in the Assessment program are to be included in each Assessment Stage subfolder.

Example files in Assessment Stage subfolders and subfolder content description.

📁 **Assessments**
  📁 **AO_ [AOID]**
    📁 **Assessment_Cycle_1**
      📁 **1_Application** *- Records from the Application stage*

        📄 YYYY-MM-DD-APP-AOID.VVV (AO Application Review Checklist)
        📄 AO Application for Recognition Form
        📄 Supplemental AO Application Matrix
        📄 AO Recognition Application Additional Information Sheet
        📄 AO Application Matrix
        📄 AO Critical Location Information Form
        📄 Auditor and Technical Expert Competency Summary
        📁 All other application attachments or additional submitted documents

      📁 **2_Stage_1** *- Records from Stage 1*

        📄 YYYY-MM-DD-AS1-AOID.VVV (Stage 1 Assessment Report)
        📁 **AO_QS_Documentation** *-The AO's QS documents submitted for review.*
          📁 AOID_QS_DOCUMENTS.zip

      📁 **3_Stage_2** *- Records from Stage 2*

        📄 YYYY-MM-DD-ASP-AOID.VVV (On-Site Assessment Plan)
        📄 YYYY-MM-DD-ASR-AOID.VVV (On-site Assessment Report)
        📄 YYYY-MM-DD-ASA-AOID.VVV (On-site Assessment Attendance List)
        📁 **AO_Nonconformity**
          📁 **[YYYY-MM-DD-ANC-AOID-NN]**
            📄 YYYY-MM-DD-ANC-AOID-NN.VVV (AO Nonconformity Report)

📁 **4_Critical_Location** – *Records from the Critical Location(s)*

📄 YYYY-MM-DD-ASP-AOID.VVV (On-Site Assessment Plan)
📄 YYYY-MM-DD-ASR-AOID.VVV (On-site Assessment Report)
📄 YYYY-MM-DD-ASA-AOID.VVV (On-site Assessment Attendance List)
📁 **AO_Nonconformity**
  📁 **[YYYY-MM-DD-ANC-AOID-NN]**
    📄 YYYY-MM-DD-ANC-AOID-NN.VVV (AO Nonconformity Report)
📁 **Follow-up_1**
  📄 AO's Evidence of Correction
  📄 AO's Corrective Action

📁 **5_Witnessed_Audit_1** – *Records from Witnessed Audit 1*

📄 YYYY-MM-DD-MAN-AOID-DUNS.VVV (Manufacturer Profile Form)
📄 YYYY-MM-DD-WIT-AOID-DUNS.VVV (Witnessed Audit Report)
📄 YYYY-MM-DD-AUP-AOID-DUNS.VVV (Audit Plan)
📁 **AO_Nonconformity**
  📁 **[YYYY-MM-DD-ANC-AOID-NN]**
    📄 YYYY-MM-DD-ANC-AOID-NN.VVV (AO Nonconformity Report)
📁 **Audit_Report** – *Records related to the Audit Report issued by the AO*
📄 YYYY-MM-DD-AUR-AOID-DUNS.VVV (Medical Device Regulatory Audit Report)
📄 YYYY-MM-DD-NGE-AOID-DUNS.VVV (MDSAP Nonconformity Grading and Exchange Form)
📄 YYYY-MM-DD-MNC-AOID-DUNS.VVV (Manufacturer Nonconformity Report)

📁 **Review_Decisions** - *Records from Technical Review*

   📁 **YYYY-MM-DD-Technical_Review-AOID**

      📄 YYYY-MM-DD-RAD-AOID-DUNS.VVV (Decision File)

      📄 YYYY-MM-DD-REC-AOID-DUNS.VVV (Recognition Letter)

Audit Report Records

The 📁 **MDSAP** folder contains the 📁 **Audit_Reports** folder.

Records generated by Auditing Organizations from MDSAP audits are organized into the 📁 **Audit_Reports** folder by year. Each Audit Report package per manufacturing site (different DUNS number) submitted by an Auditing Organization is organized into its own individual folder.

The Audit Report folder name format has been defined by the following naming convention:

   📁 **YYYY-MFGNAME-AOID-DUNS-NN**

Where:

YYYY = Year the audit occurred

MFGNAME = Name of the manufacturer audited

AOID = Auditing Organization Identification Code (defined in MDSAP QMS P0015)

DUNS = DUNS# of the manufacturer (9-digit, not hyphenated)

NN = Audit number of the year for that manufacturing site

Note: Do not use spaces or punctuation in the manufacturer's name. Also, capitalize the first letter of every standalone word in the manufacturer's name.

The hierarchy of the Audit Report directory:

- 📁 **MDSAP**
    - 📁 **Audit_Reports**
        - 📁 **YYYY**
            - 📁 **2014-MFGNAME-AOID-DUNS-NN**

An example of the contents of an Audit Report folder:

- 📁 **MDSAP**
    - 📁 **Audit_Reports**
        - 📁 **2014**
            - 📁 **2014-DeviceMfgName-AOID-123456789-01**
                - 📄 YYYY-MM-DD-AUR-AOID-DUNS.VVV (Medical Device Regulatory Audit Report)
                - 📊 YYYY-MM-DD-NGE-AOID-DUNS.VVV (MDSAP Nonconformity Grading and Exchange Form)
                - 📄 YYYY-MM-DD-MNC-AOID-DUNS.VVV (Manufacturer Nonconformity Report)
                - 📄 YYYY-MM-DD-PLA-AOID-DUNS.VVV (Audit Plan)

4. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/ PROJECT MANAGER
001	2015-08-20	Initial release	Marc-Henri Winter, FDA
002	2015-09-29	Revision of procedure to incorporate use of SFTP.	Michael Chan, FDA
003	2018-06-18	Updated to change SFTP to Box Change designation from "F0015.1.002" to "G0015.1.003"	Michael Chan, FDA