 <b>MDSAP</b> MEDICAL DEVICE SINGLE AUDIT PROGRAM <b>Responsible Office/Division</b>	<b>Document No.:</b> MDSAP AU G0027.1.001	<b>Page:</b> 1 of 6
	<b>Version Date:</b> 2022-01-05	<b>Effective Date:</b> 2022-01-05
<b>Title:</b> Using Box for MDSAP Audit Report Submissions		<b>Project Manager:</b> Michael Chan

## GUIDELINES

### 1. Introduction

This document applies after the Regulatory Exchange Platform Secure (REPs) goes offline on 2021-12-31, and until it comes back online. It describes the interim process for Auditing Organizations to submit MDSAP audit report packages to the Regulatory Authorities.

### 2. Scope

This process applies to all RAs participating in the MDSAP and all formally recognized AOs, or AOs that have been authorized to conduct MDSAP audits.

### 3. Definitions/Acronyms

**AO** – Auditing Organization

**RA** – Regulatory Authority

**REPs** – Regulatory Exchange Platform – secure

### 4. Authorities/Responsibilities

#### **Auditing Organizations:**

Designate a person(s) to serve as the AO Submitter role in REPs.

#### **AO Submitter Role:**

- Creates audit report packages according the required folder structure
- Uploads and submits audit report packages in Box
- Notify RAs of changes required to submitted audit report packages









### 5. Instructions

#### 5.1. Box Folder Organization and Descriptions

MDSAP Auditing Organizations (AOs) will have their own separate folders in Box to upload and share MDSAP audit report packages to the Regulatory Authorities (RAs).

After logging into Box, each AO will have Four (4) main folders visible. The folder names and description of contents are as follows:

- **Audit Report Submissions** – The primary folder for AO’s to upload Audit Report packages
- **Audit Report Submissions [Processed]** – This folder is read-only for AOs and will contain Audit Report packages that have been moved from the Audit Report Submissions folder after RAs have processed the audit report package through its intake process.
- **Master List** – This folder is read-only for AOs and contains a report of the AO’s Master List. Master List updates submitted via the Master List Update PDF form will be processed periodically and a revised Master List report will be uploaded to this folder.
- **REPs Audit Report Data** – This folder will contain a historical report of the audit report packages that were submitted in REPs prior to the downtime.

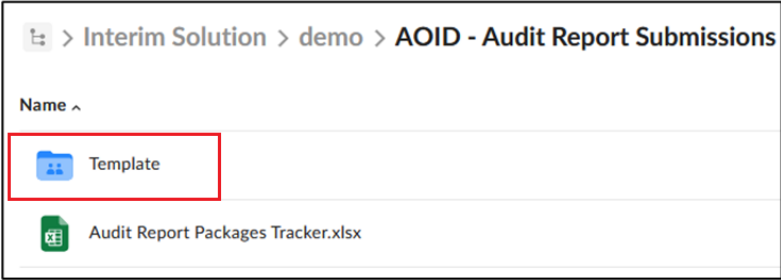
Name ^	Updated	Size	☰ >
 AOID - Audit Report Submissions	 Today by Michael Chan	1 File	
 AOID - Audit Report Submissions [Processed]	 Today by Michael Chan	1 File	
 AOID - Master List	 Today by Michael Chan	0 Files	
 AOID - REPs Audit Report Data	 Today by Michael Chan	0 Files	

**5.2. The Audit Report Submissions Folder Contents and Description**

The Audit Report Submissions folder is the primary folder that shall be used to upload complete MDSAP Audit Report packages.

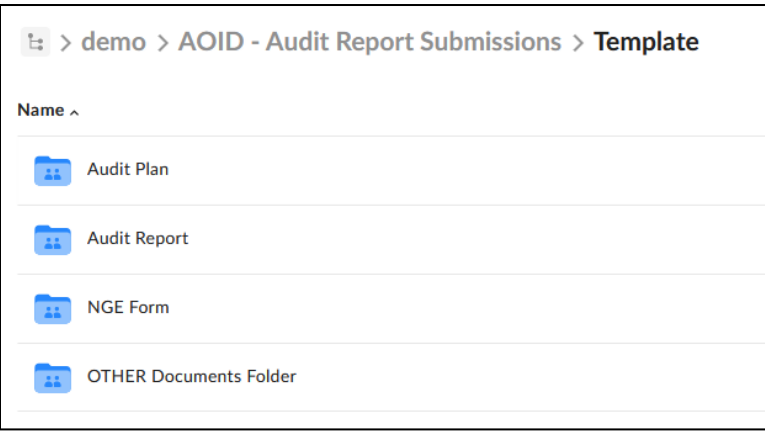


- **The “Template” Folder** - The Audit Report Submissions folder will contain a folder named “Template”. The Template folder is empty but contains the underlying folder structure to be used for each Audit Report package submission. Audit Report packages must be organized according to the folder structure of the Template folder.



The Template folder structure contains four (4) subfolders which are used to separate and identify three (3) key documents in each audit report package and are described below.

- **Audit Plan** – Contains the AO’s audit plan
- **Audit Report** – Contains the MDSAP AU F0019.1 Medical Device Regulatory Audit Report
- **NGE Form** – Contains the MDSAP AU F0019.2 Nonconformity Grading and Exchange Form (NGE), if issued.
- **OTHER Documents folder** – Contains all other documents related to the audit



- **The Audit Report Packages Tracker File** – The “Audit Report Packages Tracker.xlsx” excel spreadsheet is a record of audit report packages that have been submitted in Box by the AO.

The spreadsheet contains the same audit information that is required for Audit Report submissions in REPs but with the following two (2) additional items:

- Audit Report Reference Number
- Total # of Nonconformities Issued

### 5.3. Submitting Audit Report Packages to the Audit Report Submissions Folder



Flowchart diagram of the Audit Report submission process in Box

5.3.1. Navigate to the Audit Report Submissions folder in Box and download the Template folder from Box by right clicking the Template folder and selecting Download. Save the ZIP file containing the Template folder and unzip the file to access the Template folder.


5.3.2. Populating, organizing, and renaming the Audit Report package folders must be done prior to uploading into Box. Submitters will not be able to delete or rename files and/or folders in Box.

Populate the Template folder by copying and pasting the Audit Plan, Audit Report and NGE Form into their corresponding subfolder. Copy and paste all other related documents in the audit report package into the OTHER Documents Folder.

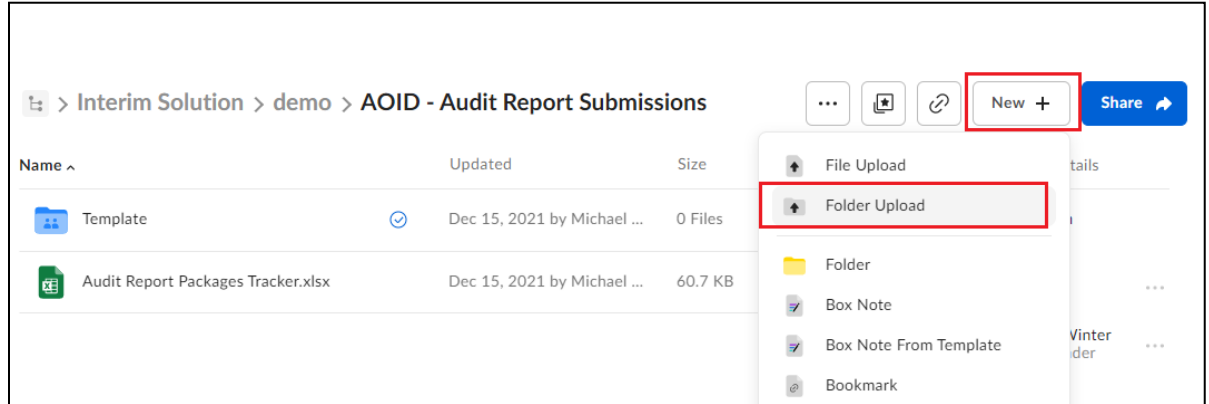
**Important:**

- Do not add any additional folders or subfolders to the folder structure
- Do not upload any ZIP or RAR files
- Do not upload incomplete or draft audit report packages

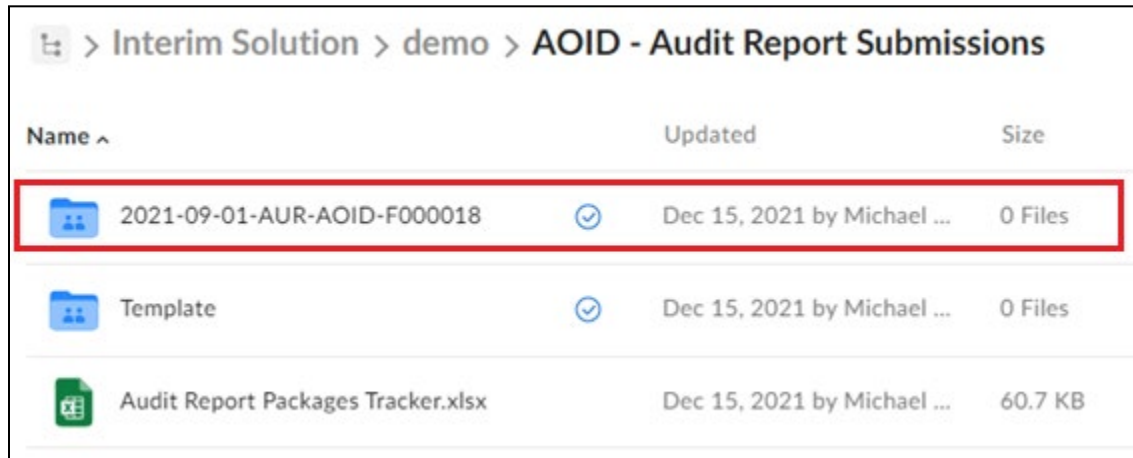
5.3.3. Rename the “Template” folder/Audit Report package folder according to the Audit Report Reference Number. The Audit Report Reference Number can be found on right side of the Audit Report header. The format of the Audit Report Reference Number is YYYY-MM-DD-AUR-AOID-F#####.

	<b>Medical Device Regulatory Audit Report</b>	<b>Medical Device Company XYZ</b> 2021-12-01-AUR-BSIA-F00001 / XXXXXX																	
<table border="1"> <tr> <td>1-2</td><td>3</td><td>4-5</td><td>6</td><td>7-10</td><td>11.1</td><td>11.2</td><td>11.3</td><td>11.4</td><td>11.5</td><td>11.6</td><td>11.7</td><td>11.8</td><td>12</td><td>13-15</td><td>16</td><td>17-18</td> </tr> </table>		1-2	3	4-5	6	7-10	11.1	11.2	11.3	11.4	11.5	11.6	11.7	11.8	12	13-15	16	17-18	From 2021-12-01 To 2021-12-03
1-2	3	4-5	6	7-10	11.1	11.2	11.3	11.4	11.5	11.6	11.7	11.8	12	13-15	16	17-18			
<b>Section 1. Audit Information</b>																			

5.3.4. Upload the renamed and Audit Report package folder to the Audit Report Submissions folder in Box by click on the New>Folder Upload buttons or by dragging and dropping directly into Box.



5.3.5. After the upload as completed, the Audit Report package folder should now appear under in the Audit Report Submissions folder.



5.3.6. Navigate to the Audit Report Submissions folder and open the “Audit Report Packages Tracker.xlsx” file. Enter a new record in the spreadsheet with the audit information of the uploaded Audit Report package. The tracker spreadsheet must be completed for each audit report package was uploaded into the Audit Report Submissions folder.

#	Audit Report Reference Number (Copy from Audit Report)	AO Audit Report Reference #	5-Day Notice Situation	Facility ID	Facility Name	Audit Type	Audit Start Date	Audit End Date	Submission Date
1	2021-09-01-AUR-AOID-F000018	A-100003	N/A	F000018	Medtronic, Inc.	Surveillance #2	2021-09-01	2021-09-04	2022-01-03
2	2021-09-07-AUR-AOID-F000200	A-100004	N/A	F000200	XYZ Medical Device	Initial	2021-09-07	2021-09-11	2022-01-03
3	2021-09-15-AUR-AOID-F007852	A-100010	N/A	F007852	Johnson and Johnson	Recertification	2021-09-15	2021-09-19	2022-01-03

5.3.7. The Audit Report package submission is now complete.

5.4. The RAs will periodically process Audit Report package folders that were uploaded in the Audit Report Submissions folder. After the Audit Report package has been processed, each package folder will be moved into the Audit Report Submissions [Processed] folder for archive.

5.5. If updates are needed for any Audit Report package AOs must email the FDA MDSAP team [MDSAPReps@fda.hhs.gov](mailto:MDSAPReps@fda.hhs.gov) and describe the changes that are necessary.

5.6. Audit Report package submission timelines remain unchanged during the REPs downtime. Audit Report package submissions should adhere to the due dates defined in Section 5.1 of the MDSAP AU P0027 Post Audit Activities and Timeline Policy.

## 6. Forms

Audit Report Packages Tracker.xlsx - Audit Report Packages Tracker File

## 7. Reference Documents

MDSAP AU P0027 Post Audit Activities and Timeline Policy

## 8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/ PROJECT MANAGER
001	2022-01-05	Initial release	Michael Chan