



Table of Contents

| | | |
|-----|---------------------------------------|----|
| 1.0 | Purpose..... | 1 |
| 2.0 | Scope | 1 |
| 3.0 | Authority and Responsibility..... | 1 |
| 4.0 | Issuing Controlled Copies | 1 |
| 5.0 | Obsoleting Controlled Copies | 9 |
| 6.0 | References and Related Documents..... | 11 |
| 7.0 | Change Summary | 11 |

1.0 Purpose

This Standard Operating Procedure (SOP) defines the process of issuing official SOP Controlled Copies for SOP manuals. These manuals are available to appropriate personnel and located in key areas.

2.0 Scope

This SOP applies to BDP staff who issue controlled copies, own SOP manuals.

3.0 Authority and Responsibility

3.1 BQAD – issues controlled copies to SOP Manual owners with an updated Table of Contents and a **Controlled Copy Memo Form 21916-01**.

3.2 SOP Manual Owners

- Placing the Controlled Copies and Table of Contents into manuals.
- Acknowledging receipt of the Controlled Copy Memo by signing and returning to BQAD
- Returning obsolete SOPs.

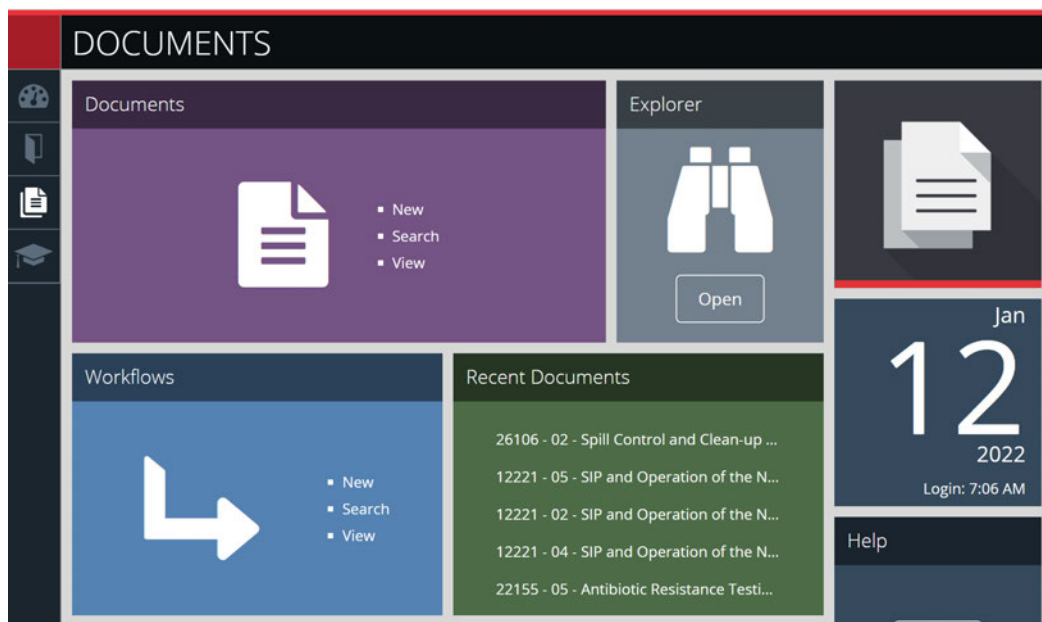
4.0 Issuing Controlled Copies

4.1 A scheduled report is sent to BQAD daily from MasterControl with newly effective SOPs. The report contains key information such as the Infocard Number (SOP number), revision number, title of SOP, Lifecycle Status (released) and SOP Manual controlled copies are assigned. Controlled Copies are issued on the effective date of a Standard Operating Procedure.

4.2 BQAD staff completes a **Controlled Copy Memo Form 21916-01**. This form accompanies the Controlled Copy and Table of Contents.

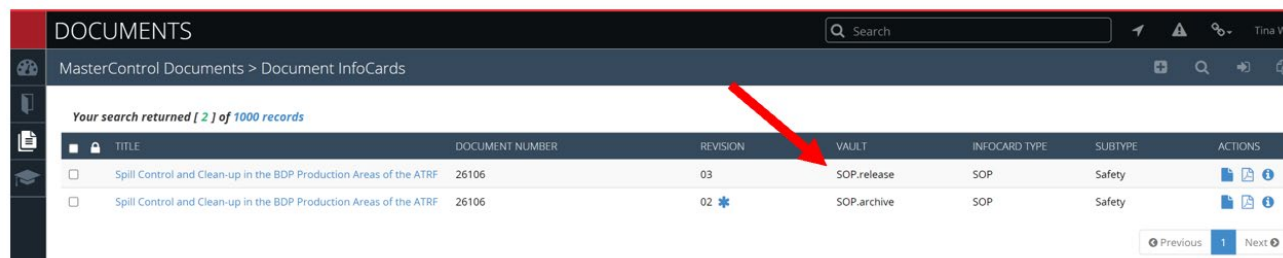
4.2.1 Using the report sent daily by MasterControl, BQAD prints the SOP for the designated Manuals from the report.

- 4.2.1.1 Using the Documents tab in MasterControl, enter the SOP infocard number and revision to be printed Select Documents and Search



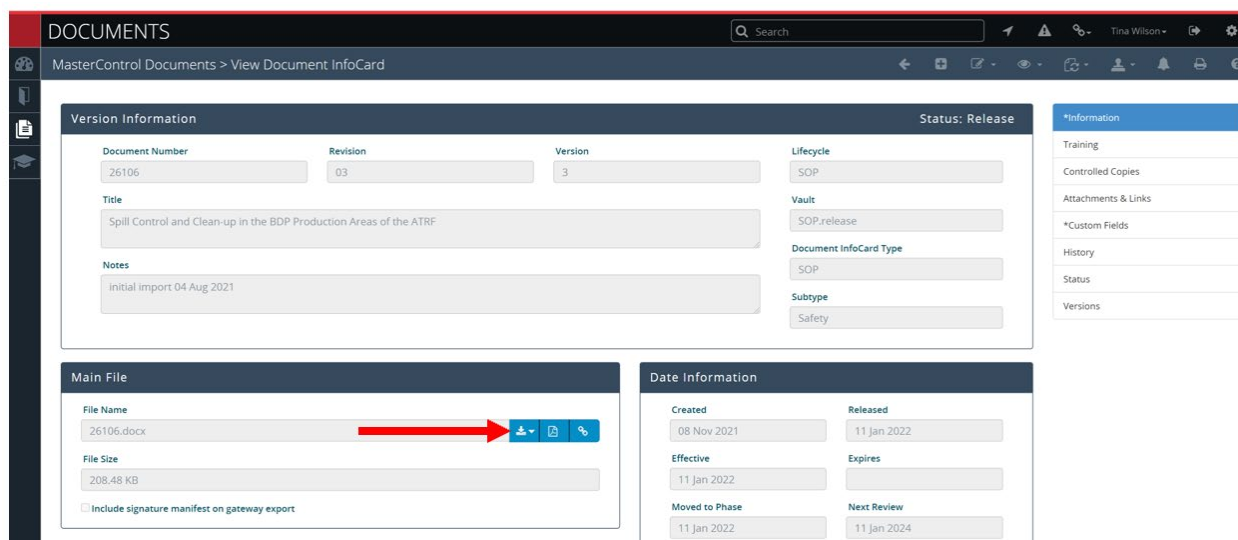
- 4.2.1.2 Enter the infocard number (SOP Number) and Submit Search.

4.2.1.3 Select the current SOP revision blue hyperlink in the **Release Vault**.



| TITLE | DOCUMENT NUMBER | REVISION | VAULT | INFOCARD TYPE | SUBTYPE | ACTIONS |
|--|-----------------|----------------------|-------------|---------------|---------|---------|
| Spill Control and Clean-up in the BDP Production Areas of the ATRF | 26106 | 03 | SOP.release | SOP | Safety | [Icons] |
| Spill Control and Clean-up in the BDP Production Areas of the ATRF | 26106 | 02 * | SOP.archive | SOP | Safety | [Icons] |

4.2.1.4 From the Main File Name select the PDF file from the drop down and print the Controlled Copy on blue poly paper.



Version Information

Document Number: 26106, Revision: 03, Version: 3

Title: Spill Control and Clean-up in the BDP Production Areas of the ATRF

Notes: Initial import 04 Aug 2021

Status: Release

Lifecycle: SOP

Vault: SOP.release

Document InfoCard Type: SOP

Subtype: Safety

Main File

File Name: 26106.docx

File Size: 208.48 KB

☐ Include signature manifest on gateway export

Date Information

Created: 08 Nov 2021, Released: 11 Jan 2022

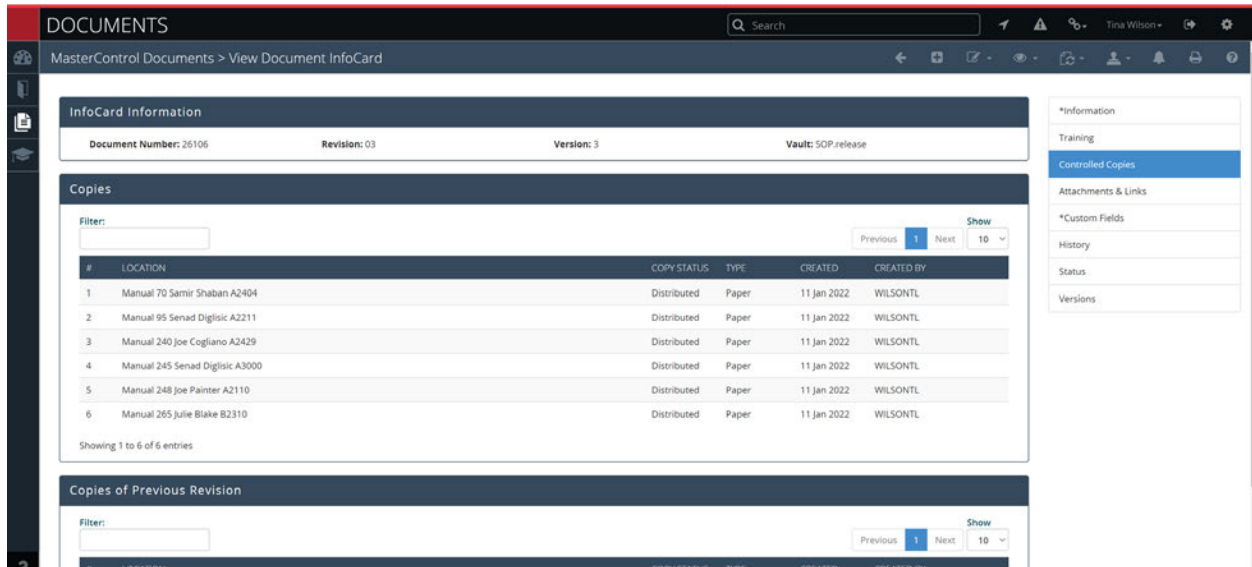
Effective: 11 Jan 2022, Expires:

Moved to Phase: 11 Jan 2022, Next Review: 11 Jan 2024

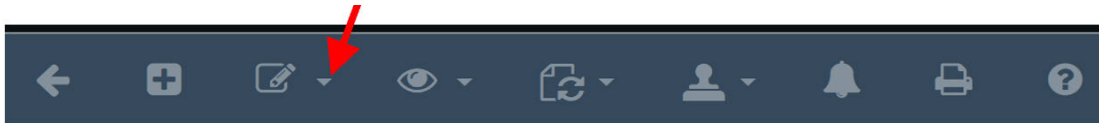
***Information**

- Training
- Controlled Copies
- Attachments & Links
- *Custom Fields
- History
- Status
- Versions

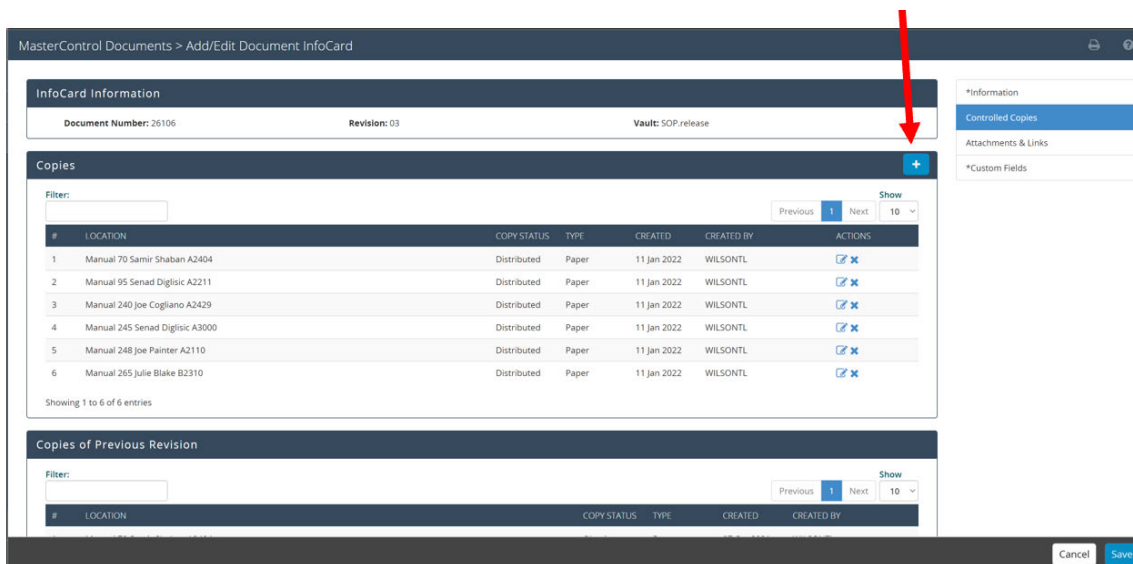
4.2.1.5 To add a new Controlled Copy to a SOP Manual, go to the information in MasterControl and select Controlled Copies on the right side of the screen. This is not needed for revisions.



4.2.1.6 Click the carrot on the edit button and select Edit.



The Actions and plus sign will appear.



Controlled Copies

SOP 21916

Rev. 02

4.2.1.7 Add Controlled Copy Screen will appear. The Location (specific to the manual is assigned as the format below), select type, record the create date to be the date the controlled copy is issued, and the Copy status remains "Distributed." Click the Save icon.

NOTE: If there is an existing Controlled Copy, this will already be populated under the Controlled Copy section for the designated manual. No need to update the current revision number.

Add Controlled Copy
✕

*** Location**

*** Type**

Paper
▼

☐ URL

*** Create Date**

📅
🕒

*** Copy Status**

Distributed
▼

Save

4.2.1.8 The item entered populates in this screen. The process is complete once this screen is saved.

MasterControl Documents > Add/Edit Document InfoCard

InfoCard Information

Document Number: 26106 Revision: 03 Vault: SOP.release

Copies

Filter:

| # | LOCATION | COPY STATUS | TYPE | CREATED | CREATED BY | ACTIONS |
|---|---------------------------------|-------------|-------|-------------|------------|---------|
| 1 | Manual 70 Samir Shaban A2404 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |
| 2 | Manual 95 Senad Diglisic A2211 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |
| 3 | Manual 240 Joe Cogliano A2429 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |
| 4 | Manual 245 Senad Diglisic A3000 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |
| 5 | Manual 248 Joe Painter A2110 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |
| 6 | Manual 265 Julie Blake B2310 | Distributed | Paper | 11 Jan 2022 | WILSONTL | 🔍 ✕ |

Showing 1 to 6 of 6 entries

Copies of Previous Revision

Filter:

| # | LOCATION | COPY STATUS | TYPE | CREATED | CREATED BY |
|---|----------|-------------|------|---------|------------|
|---|----------|-------------|------|---------|------------|

*Information

Controlled Copies

Attachments & Links

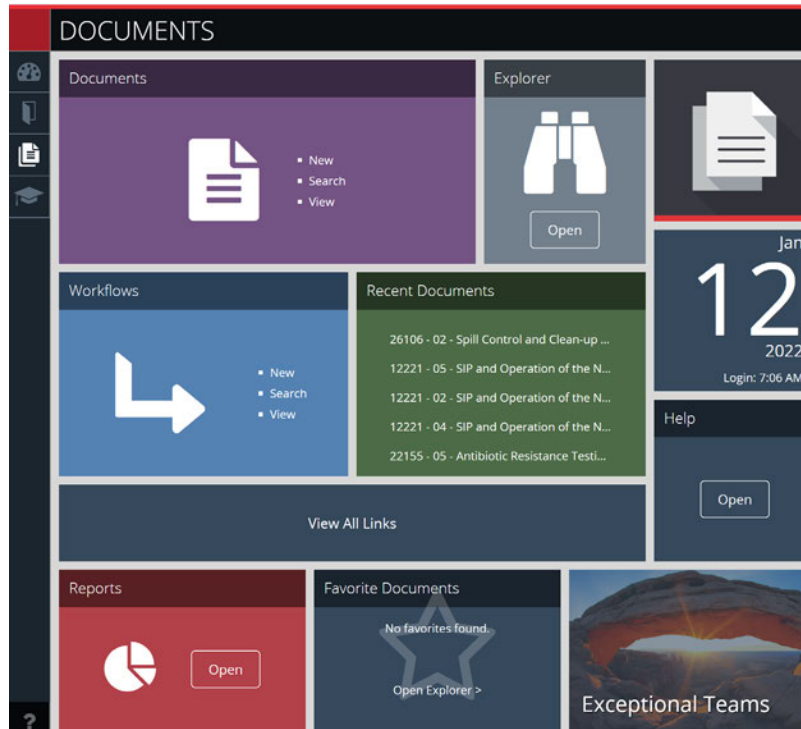
*Custom Fields

Cancel

Save

4.2.2 A new Table of Contents is compiled through a report in Master Control.

4.2.2.1 To print the Table of Contents, go to Documents and select Open Reports.



4.2.2.2 Select "Reports" in Documents and select "SOP Manual Table of Contents" report.



4.2.2.3 Select Full View and Live Interactive in the tool bar to generate a Table of Contents.

Table of Contents

| InfoCard Number | Title | Revision | Effective Date | Lifecycle Status | Location |
|-----------------|---|----------|----------------|------------------|---------------------------------|
| 11163 | Operation and Maintenance of the Sartorius Ultrapur Laboratory Water Systems | 02 | 5/13/2020 | Release | Manual 83 Feri Abedinpour B2200 |
| 15125 | Inspection of Labeled Vials of Finished Product | 05 | 6/10/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 16123 | Operation and Standardization of the FACSCalibur Flow Cytometer | 01 | 3/31/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 20003 | Materials Management and Inventory Control (MMIC) Program | 04 | 4/4/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 20309 | Ordering Inventoried Materials Using the pcMRP Inventory System | 04 | 12/6/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 20401 | Handling Rejected and Expired Materials | 05 | 11/10/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21001 | Policy for Visitors to the GMP Facilities | 06 | 11/17/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21409 | Good Documentation Practices | 04 | 6/30/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21500 | General Policies and Procedures for Balances | 05 | 8/21/2016 | Release | Manual 83 Feri Abedinpour B2200 |
| 21503 | Responding to Alarms | 04 | 5/31/2020 | Release | Manual 83 Feri Abedinpour B2200 |
| 21526 | Engineering Event Management | 04 | 6/29/2016 | Release | Manual 83 Feri Abedinpour B2200 |
| 21531 | Equipment Logs | 09 | 7/8/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 21533 | Policies for Operation, Cleaning, and Routine Maintenance of Controlled Temperature Equipment | 06 | 6/1/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21902 | Requirements for Establishing Part Numbers and Specifications for BDP Components and Materials | 07 | 5/17/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21903 | Using the Part Number/Master Specification Program to Establish Raw Material Part Numbers and Master Specifications | 06 | 6/18/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 22002 | Request for Quality Control Testing | 07 | 11/21/2017 | Release | Manual 83 Feri Abedinpour B2200 |
| 22004 | Managing Out-of-Specification Test Results or Unexpected Test Results | 03 | 2/15/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 22005 | Viral Inactivation Procedures with Guanidinium Buffers | 02 | 6/14/2021 | Release | Manual 83 Feri |

4.2.2.4 The filter tool must be selected to obtain the correct SOP Manual and populate the released SOPs designated for that manual.

Table of Contents

| InfoCard Number | Title | Revision | Effective Date | Lifecycle Status | Location |
|-----------------|--|----------|----------------|------------------|---------------------------------|
| 11163 | Operation and Maintenance of the Sartorius Ultrapur Laboratory Water Systems | 02 | 5/13/2020 | Release | Manual 83 Feri Abedinpour B2200 |
| 15125 | Inspection of Labeled Vials of Finished Product | 05 | 6/10/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 16123 | Operation and Standardization of the FACSCalibur Flow Cytometer | 01 | 3/31/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 20003 | Materials Management and Inventory Control (MMIC) Program | 04 | 4/4/2019 | Release | Manual 83 Feri Abedinpour B2200 |
| 20309 | Ordering Inventoried Materials Using the pcMRP Inventory System | 04 | 12/6/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 20401 | Handling Rejected and Expired Materials | 05 | 11/10/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21001 | Policy for Visitors to the GMP Facilities | 06 | 11/17/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21409 | Good Documentation Practices | 04 | 6/30/2021 | Release | Manual 83 Feri Abedinpour B2200 |
| 21500 | General Policies and Procedures for Balances | 05 | 8/21/2016 | Release | Manual 83 Feri Abedinpour B2200 |
| 21503 | Responding to Alarms | 04 | 5/31/2020 | Release | Manual 83 Feri |

- 4.2.2.5 Filter properties of the TOC desired will be similar to this. Select the correct SOP Manual Location. The Lifecycle must always be "Release" status. Select "Apply" to populate the correct Manual TOC.

The screenshot shows a 'Filter' dialog box with a title bar and a close button. Inside, there is a section 'Apply to:' with a dropdown menu set to 'Table Comp'. Below this, there are two filter criteria rows. The first row has a dropdown for 'Location' followed by an equals sign and a dropdown for 'Manual 83 Feri Abec'. The second row has a dropdown for 'Lifecycle Status' followed by an equals sign and a dropdown for 'Release'. To the right of these rows are 'AND' and 'END' dropdown menus. At the bottom of the dialog, there are six buttons: 'Advanced', 'Help', 'Reset', 'Apply', 'Cancel', and 'OK'. A red arrow points to the 'Apply' button.

4.2.2.6 The report will appear as a pdf. Examine for accuracy and print in Portrait Orientation

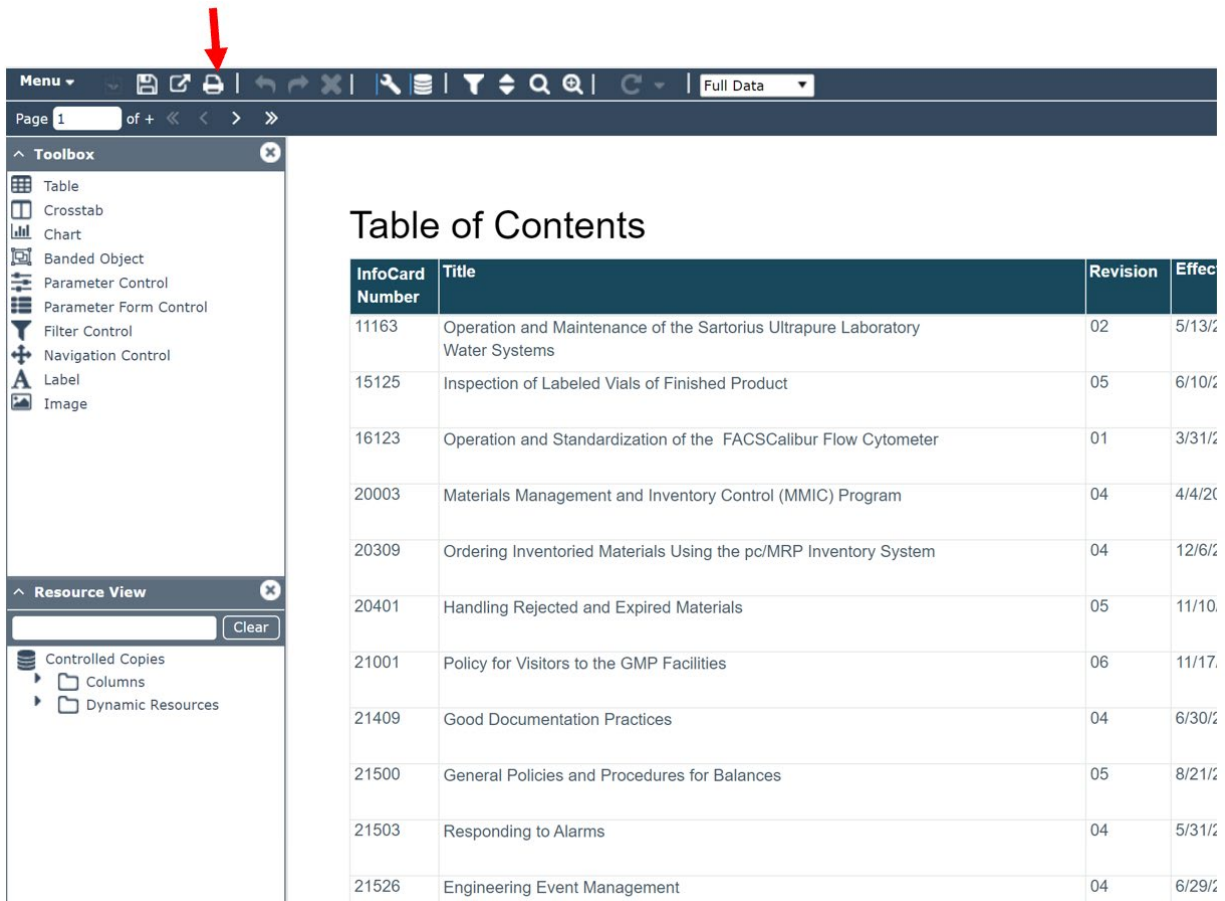


Table of Contents

| InfoCard Number | Title | Revision | Effective Date |
|-----------------|---|----------|----------------|
| 11163 | Operation and Maintenance of the Sartorius Ultrapure Laboratory Water Systems | 02 | 5/13/2011 |
| 15125 | Inspection of Labeled Vials of Finished Product | 05 | 6/10/2011 |
| 16123 | Operation and Standardization of the FACSCalibur Flow Cytometer | 01 | 3/31/2011 |
| 20003 | Materials Management and Inventory Control (MMIC) Program | 04 | 4/4/2011 |
| 20309 | Ordering Inventoried Materials Using the pc/MRP Inventory System | 04 | 12/6/2010 |
| 20401 | Handling Rejected and Expired Materials | 05 | 11/10/2010 |
| 21001 | Policy for Visitors to the GMP Facilities | 06 | 11/17/2010 |
| 21409 | Good Documentation Practices | 04 | 6/30/2010 |
| 21500 | General Policies and Procedures for Balances | 05 | 8/21/2010 |
| 21503 | Responding to Alarms | 04 | 5/31/2010 |
| 21526 | Engineering Event Management | 04 | 6/29/2010 |

4.2.3 The Controlled Copy and Table of Contents accompanies Form 21916-01 Controlled Copy Memo.

4.2.3.1 The memo contains the Manual Number, Owner Name, Location, current SOP being issued and requesting return of the obsolete SOP Controlled Copy.

5.0 Obsoleting Controlled Copies

5.1 A scheduled report is generated daily through MasterControl upon the obsolete (expiration) date of an SOP, provided in an email to BQAD staff. The report contains information such as the Infocard Number (SOP number), revision number, title of SOP, Lifecycle Status (obsolete) and SOP Manual controlled copies to be returned.

NOTE: This process is the same procedure upon notifications for Obsolete SOPs that are not being revised. When a weekly report is generated, BQAD verifies the infocard status of SOPs in MasterControl. If the SOP is Archived, a Controlled Copy Memo and new Table of Contents is sent to SOP Manual owners, requesting the return of the obsolete SOP and obsolete Table of Contents.

- 5.2 All controlled copies that have been obsoleted are to be returned to BQAD to destroy with the Table of Contents and signed Form 21916-01 (if applicable). An updated Table of Contents will be provided by BQAD.
- 5.3 BQAD updates the copies as returned in MasterControl.
 - 5.3.1 All obsolete controlled copies must be updated as “Destroyed” with the destroyed date for the obsolete revision number.
 - 5.3.2 Under the Controlled Copies tab for the SOP for an obsolete revision, select the “edit” tool in the tool bar to update the obsolete revision.

The screenshot shows the MasterControl Documents interface. The top navigation bar includes a search bar and a toolbar with various icons. A red arrow points to the 'edit' icon (a pencil) in the toolbar. The main content area is divided into two sections: 'InfoCard Information' and 'Copies'.

InfoCard Information:

| | | | |
|------------------------|--------------|------------|--------------------|
| Document Number: 26106 | Revision: 03 | Version: 3 | Vault: SOP.release |
|------------------------|--------------|------------|--------------------|

Copies:

Filter:

| # | LOCATION | COPY STATUS | TYPE | CREATED | CREATED BY |
|---|---------------------------------|-------------|-------|-------------|------------|
| 1 | Manual 70 Samir Shaban A2404 | Distributed | Paper | 11 Jan 2022 | WILSONTL |
| 2 | Manual 95 Senad Diglicic A2211 | Distributed | Paper | 11 Jan 2022 | WILSONTL |
| 3 | Manual 240 Joe Coglianò A2429 | Distributed | Paper | 11 Jan 2022 | WILSONTL |
| 4 | Manual 245 Senad Diglicic A3000 | Distributed | Paper | 11 Jan 2022 | WILSONTL |
| 5 | Manual 248 Joe Painter A2110 | Distributed | Paper | 11 Jan 2022 | WILSONTL |
| 6 | Manual 265 Julie Blake B2310 | Distributed | Paper | 11 Jan 2022 | WILSONTL |

Showing 1 to 6 of 6 entries

Copies of Previous Revision:

Filter:

Previous 1 Next 10

5.3.3 Select “destroyed”, update the calendar to reflect the date it is destroyed and “Save.” Controlled Copy is then shredded.

MasterControl Documents > Add/Edit Document InfoCard

InfoCard Information

Document Number: 22919 Revision: 04 Vault: SOP_archive

Copies

Filter:

| # | LOCATION | COPY STATUS | TYPE | CREATED | CREATOR | ACTIONS |
|---|---------------------------------|-------------|-------|-------------|----------|---------|
| 1 | Manual 81 Senad Diglisic B2100 | Destroyed | Paper | 31 Jan 2022 | WILSONTL | |
| 2 | Manual 227 Senad Diglisic B2120 | Obsolete | Paper | 06 Oct 2021 | WILSONTL | |

*Information

Controlled Copies

Attachments & Links

*Custom Fields

Edit Controlled Copy

* Location

* Type

☐ URL

* Create Date

* Copy Status

Save

6.0 References and Related Documents

SOP 21418 *Control and Request of Documents/Records*

SOP 21419 *Origination, Modification, and Approval of Documents*

Form 21916-01 *Controlled Copy Memo*