Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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DOCUMENT TITLE:

Configuration of Numbering Series Patterns in MasterControl

DOCUMENT NOTES:

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Configuration of Numbering Series Patterns in MasterControl

1   PURPOSE

1.1   This document describes the configuration of specific InfoCard numbering series patterns.

2   INTRODUCTION

2.1   MasterControl Portal allows for custom numbering sequences to be structured and created to automatically generate the next available number to be assigned to an InfoCard. Auto numbering supports prefixes, suffixes, incremental numbers, incremental characters, and dates as part of the numbering series.

3   SCOPE AND RESPONSIBILITIES

3.1   This procedure covers MC numbering configurations for all programs using the system.

3.2   This procedure applies to all new or revised SOPs, Change Control Requests, Deviations, Issue Reviews, CAPAs, OOSs, Material Specifications, and Organizers.

3.3   It is the responsibility of the MC System Administrator to configure numbering series for the different InfoCard Types used.

4   DEFINITIONS/ACRONYMS

4.1   MasterControl (MC) – A validated software product from MasterControl, Inc., which is used as the main document control agent, assisting in the automation and control of document approval, change control, and distribution processes. MC manages critical information throughout the entire document lifecycle.

4.2   MasterControl Portal – MasterControl Portal provides the functions needed to set up and maintain MC applications. These functions are typically used only by the System Administrator.

4.3   System Administrator – Person or position responsible for the administration, configuration, and control of the MC software.

4.4   SOP – Standard Operating Procedure.

4.5   Change Control – The process of approving and documenting changes to processes, operations, and documents to ensure compliance with regulatory requirements.

4.6   InfoCard – The InfoCard controls access to documents and the functions available to each user. InfoCards are the core of MC. MC collects header or metadata related to each document stored in the system. This header or metadata is then used by the system to organize, store, and retrieve files.

4.7   DCS – Document Control System

5   MATERIALS

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5.1   NA

6   EQUIPMENT

6.1   Hardware/Software

    6.1.1   Computer access to MasterControl

6.2   MasterControl is validated using Firefox and Chrome.

    6.2.1   Do not use Internet Explorer (IE) or Microsoft EDGE.

7   SAFETY

7.1   NA

8   PROCEDURE

NOTE: Use Numbering in MasterControl to set up standard numbering systems for InfoCards. MasterControl Portal automatically generates the next available InfoCard number with its auto-numbering feature, which supports numbering schemes that include the following:

- Prefixes
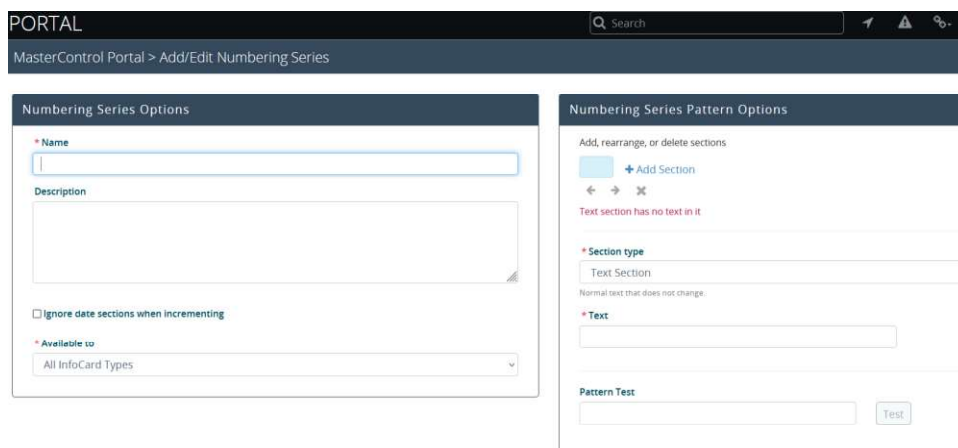- Suffixes
- Incremental characters
- Dates.

NOTE: A document number can be assigned automatically by MC for all work types; i.e., new SOPs, CCRs, Deviations, CAPAs, Material Specifications, etc.

8.1   Create a Numbering Series

    8.1.1   Portal > Configuration > Numbering

    8.1.2   Click the **New** icon ( ).

    8.1.3   Complete required fields.

    8.1.4   Click **Save**.

8.2   General Numbering Scheme

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8.2.1   Numbering schemes are generally created as follows, but recommend applying what works best for the type of document and/or the department for which a numbering scheme is created.

    8.2.1.1   alpha – indicates the program

    8.2.1.2   alpha – indicates specific category

    8.2.1.3   ### – indicates the document number, which is assigned sequentially for each document starting with 001

        Example: COMM-PAS-004 *Change Control*

        NOTE: Numbering schemes can be increased to #### (4-digits).

8.2.2   Change Control Numbering

    8.2.2.1   Change Control numbering will be assigned as X-CCR-###, where:

        8.2.2.1.1   X – indicates program

        8.2.2.1.2   CCR – indicates Change Control Request

        8.2.2.1.3   ### – indicates the document number, which is assigned sequentially starting at 001

            Example: PAS-CCR-042

8.2.3   Deviation Numbering

    8.2.3.1   Deviation numbering will be assigned as DEV-####, where:

        8.2.3.1.1   DEV – indicates Deviation

        8.2.3.1.2   #### – indicates the document number which is assigned sequentially for each document starting with 0001

            Example: DEV-0019

8.2.4   CAPA Report Numbering

    8.2.4.1   CAPA Report numbering will be assigned as CAPA REPORT-####, where:

        8.2.4.1.1   CAPA REPORT – indicates CAPA REPORT

        8.2.4.1.2   #### – indicates the document number, which is assigned sequentially for each document starting with 0001

            Example: CAPA REPORT-0036

8.2.5   Organizer Numbering

    8.2.5.1   Organizer numbering will be assigned as ORG-###, where:

        8.2.5.1.1   ### – indicates the document number, which is assigned sequentially for each Organizer starting with 001

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Example: ORG-013

8.2.6   Out of Specification Numbering

8.2.6.1   OOS numbering will be assigned as OOS-alpha-####, where:

8.2.6.1.1   OOS – indicates Out of Specification

8.2.6.1.2   alpha – indicates a specific category

8.2.6.1.3   #### – indicates the document number, which is assigned sequentially starting at 0001

Example: OOS-STCL-0008,

8.2.7   Material Specification Numbering

8.2.7.1   Material Specification numbering will be assigned as X-MSPEC-####, where:

8.2.7.1.1   X – indicates program (STCL)

8.2.7.1.2   #### – indicates the document number, which is assigned sequentially for each document starting with 0001

Example: STCL-MSPEC-0492

9   RELATED DOCUMENTS/FORMS

9.1   A paper file is maintained by the DCS staff, with the assistance of the APBMT Clinical Quality Program (CQP), specific to the numbering series configurations.

10   REFERENCES

10.1   MasterControl System Administration Online Help

11   REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	• New document

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Signature Manifest

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