

METRC Policy & Procedure Manual

Title: Content Development and Document Standards

Document ID: PPM_CDDS

Version & Publication Date: V 1.0, 6/12/2019

Previous Version Date: N/A

General Description & Purpose: This document describes how the METRC Policy & Procedure Manual is developed and the organizational and formatting standards for its component documents.

I. Content Development for METRC's Policy & Procedure Manual

The contents of METRC's Policy & Procedure Manual are authored or developed by individuals or groups with relevant content expertise. When applicable, reference documents will be consulted and cited. Examples of reference documents include but are not limited to: Federal Regulations, FDA Guidance, institutional policies and procedures, institutional study document templates, etc.

Once drafted or once revised, a Policy & Procedure Manual document will be reviewed by appropriate stakeholders and decision-makers. Documents which pertain to METRC Coordinating Center policies and procedures will be reviewed by internal stakeholders. For example, a procedural document which describes procedures carried out primarily by Study Managers will be reviewed by individuals who at-that-time hold that position. The stakeholders' feedback will be incorporated into the PPM document and the stakeholders will then have an opportunity to conduct a final review of the document. Final feedback will be incorporated as necessary and the final document will be version dated and published to the appropriate document repositories.

Content which pertains to the Consortium as a whole, e.g., governance-related documents, will engage an appropriate group of stakeholders and decision-makers in both the development and review of the PPM document.

Revisions or updates to PPM content will adhere to the standards and procedures described above.

All Policy & Procedure Manual contents will include a document history which briefly but adequately describes the people who were involved in the development and approval of the document; this is described in greater detail in the section below.

II. Document Standards

All Policy & Procedure Manual contents, regardless of document type, will include standard header and footnote sections.

Header Section

- Title → The title should be brief but descriptive. The title of the document should be consistent across all content intended for PPM navigation, i.e., the Table of Contents and the Index.
- Document ID → The document ID is the short name for the document. The Table of Contents includes a key for how the Document IDs should be constructed in that each category and subcategory is assigned a standard “short name”. Therefore, to construct a Document ID one simply needs to piece together the relevant category short names separated by underscores.
- Version & Publication Date → The version and publication date should indicate the version and date of publication for the currently published document.
- Previous Version Date → The previous version date(s) should be the versions and corresponding publication dates of earlier versions of the document. All previous versions and dates should be included; there is no limit on the number of previous version dates which can be listed. Additional information about the previous version dates may be found in the Document History/Footer.
- General Description & Purpose → The general description and purpose should succinctly describe the piece of content and explain its purpose.

Footer Section: Document History

All Policy & Procedure Manual contents will have a footer section which minimally includes the following information pertaining to each version date of the document:

- Version Date (in reverse chronological order; current version first)
 - o Updates → briefly describe the updates which were made since the previous version date(s)
 - o Method of Disseminating Current Version → briefly describe how relevant consortium members were notified that the current version was published
 - o Primary Author(s) → the name and role for the primary author or authors
 - o Stakeholders Engaged in Development or Review → the names and roles or just roles for the stakeholders engaged in the development and/or review process
 - o Formal Review or Approval Process → if there was a formal review and approval process it should be described here including any corresponding dates, e.g., reviewed and approved by Executive Committee on MM/DD/YYYY

For Facilitated Training Sessions

- o Name & Role of Trainer → name and role of person facilitating the training
- o Date & Venue of Training → description of when and where training occurred
- o Who Attended → At least a general description of those individuals in attendance; specific names and roles should be noted if the information is available, but this level of detail is not required. For example, it would be sufficient to indicate that the training was given to MCC Staff. Ultimately, each individual will be responsible for indicating when and how s/he received training on his or her training log.

There are two documents which are maintained as “living documents” due to how frequently they are updated: 1) the Table of Contents and 2) the PPM Index. In the header section, instead of a version date,

these files will have a “Last Updated” date. These files will not contain the footer/ Document History section.

DOCUMENT HISTORY

- **V1, 6/12/2019**
 - Updates: N/A
 - Dissemination Method: MCC Staff Meeting; Publication to Dropbox
 - Primary Author(s): Lauren Allen, Operations Director
 - Stakeholders Engaged: Tony Carlini, Director of Informatics; Renan Castillo, MCC Deputy Director
 - Formal Review or Approval Process: N/A
 - Name & Role of Trainer: Lauren Allen, Operations Director
 - Date & Venue of Training: 6/12/2019, MCC Conference Room
 - Who Attended Training: MCC Staff, Dr. Bosse