RPS: FDA Submission Guide for IMDRF Table of Contents (ToC) Submissions

Scope

For non-In Vitro Diagnostic Devices (nIVD) and In Vitro Diagnostic Devices, this pilot includes and excludes the following:

- Includes only original Traditional 510(k) submissions (supplements and amendments are excluded).
  - Special, 3rd Party, and Abbreviated submissions are **not** a part of the pilot program.
- Includes only original Pre-Market Application (PMA) submissions (reports, supplements and amendments are excluded).
- Bundled Submissions and Combination Products are **not** a part of the pilot program.
- The normal eCopy method should be used for all submissions after the original is submitted.

How it works

- Applicants should first read the TOC Pilot Plan document, found at the IMDRF webpage below, to learn about the pilot, as well as the Points to Consider document to learn what is involved in being in the pilot.
- Applicants use the nIVD or IVD Table of Contents (TOC) document, found at the IMDRF webpage link below, as well as the respective Classification Matrix, found at the FDA IMDRF Documents webpage below, to construct the submission.
- Applicants package the submission into a single .zip file with the name "MISC FILES.zip" and then load this .zip file onto media (e.g., CD, USB Drive). No paper copy of the submission is needed.
- Applicants then draft a physical cover letter (see below for contents), and send the Cover Letter and media via mail to the Document Control Center (DCC) at:

  Food and Drug Administration
  Center for Devices and Radiological Health
  Document Control Center - WO66-G609
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002

- Once received, FDA will login, load, and review your submission, and interact with you, via the normal methods.

Important Details for Industry

- All submissions are still expected to comply with the respective 510(k) or PMA RTA guidance document.
- All submissions are still expected to comply with the eCopy Guidance Document, except for:
  - Sections discussing paper copy requirements, including the statement usually required in the Cover Letter pertaining to the eCopy being an exact duplicate of the paper copy (you will still need to comply with those sections that discuss requirements for the Cover Letter)
  - Sections outside the scope of the pilot (e.g., sections pertaining to Bundled Submissions)
  - Attachment 1, Part B and D of the eCopy Guidance is superseded by the TOC document above.

- The Cover Letter needs to include the usual content, as well as the following statement in bold:

  "**This submission is part of the IMDRF TOC pilot, and is organized according to the IMDRF TOC. Accordingly, special eCopy processing applies. As per the agreement for this TOC pilot, no full paper copies are required, and the specially-formatted submission is zipped and placed within a MISC FILES folder in the eCopy.**"

- Due to the complexity of constructing the submission package, we request that only experienced applicants with a thorough understanding of the regulatory process participate in the pilot.

Resources

- The FDA IMDRF Documents webpage can be found here: http://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/ucm417027.htm
- The IMDRF webpage can be found here: http://www.imdrf.org/documents/documents.asp
- Questions can be sent to Kenneth Cavanuagh