Australian Government

Department of Health

Therapeutic Goods Administration

IMDRF Table of Contents pilot: TGA regional assembly and technical guide

International Medical Device Regulators Forum

Version 1.0, November 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

· The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.

· The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

· The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

· The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

· To report a problem with a medicine or medical device, please see the information on the TGA website <https://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Initial Release	Medical Devices Branch	November 2015

Contents

Background

The International Medical Device Regulators Forum (IMDRF) is trialling an internationally standardised structure for medical device regulatory submissions. More information on the IMDRF, various working groups, and this project can be found on the IMDRF website.

This document describes the Australian regional requirements for the IMDRF Medical Device Table of Contents pilot.

Any requests for clarification or other feedback should be sent to esubmissions@tga.gov.au.

Thank you for your support during the pilot.

Scope

This guidance:

· needs to be used in conjunction with

  – Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions

  – TGA Regional Classification Matrices: IVD and nIVD

  – TGA general dossier requirements.

· provides additional information in relation to TGA requirements during the pilot of the IMDRF Table of Contents.

· is intended for use in the assembly of submissions to the TGA for the IMDRF ToC-based medical device pilot.

Please note: there are three meanings for "Table of Contents" or "ToC" used in this document. Applicants should be aware of the different meanings:

· **IMDRF ToC:** the IMDRF structure of electronic folders for the evidence supporting a medical device submission for regulatory authorisation. There is a ToC for In Vitro Diagnostic medical devices (IVD) and one for non-IVD medical devices (nIVD).

· **ToCs within a submission:** the PDF table of contents files within each chapter of a submission that outlines and link to documents within the submission.

· **PDF ToCs:** the Adobe Acrobat Table of Contents function within a PDF file that links to content within the PDF file.

General process for building an IMDRF ToC-based submission

Please follow the guidance in the IMDRF Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions.

Preparing for your IMDRF ToC submission

In this section:

· [Obtain TGA agreement and apply through TBS](#)

· [Prepare the top level folders](#)

· [Prepare your Cover Letter](#)

· [Check the IMDRF ToC submission](#)

· [Select the electronic media](#)

· [Pack and send the submission](#)

Obtain TGA Agreement and apply through TBS

You will need to contact the TGA regarding suitability of your submission for the pilot of the IMDRF Table of Contents:

· send an email to esubmissions@tga.gov.au

· include the following information in your email:

– a request to be considered for the IMDRF ToC pilot

– the applicant's name as listed in the TGA client database

– a brief description of the device and its intended use

– the type of application (e.g. application for a new Part 1 conformity assessment).

Please note that IMDRF pilot submissions should cover multiple regions; however the TGA is willing to separately consider Australia only submissions using the same procedures.

The TGA will consider your application for the pilot and may request further information or discussion.

If the application is considered suitable for the pilot, the TGA's usual application processes should then be followed by logging on to the TGA Business Systems portal, submitting an application for conformity assessment and obtaining a submission identification number in the form DC 2015 XXXXX 1. The usual fees and timelines apply to pilot submissions.

Prepare the top level folders

Use a top level folder to contain the ToC folder structure. The name of the top level folder should be based on the TBS submission identification number by deleting the hyphens and the final tracking digit. For device applications the tracking digit are usually "-1".

> Example: if the TBS number is "DC-2015-12345-1" then the top level folder would be named \DC201512345\

The required folders should be placed below this.

> Example: \DC201512345\1-REG ADMIN

Prepare your Cover Letter

Prepare the letter in accordance with the requirements specified in the ToC and the Regional Matrix. Include the following information in the Cover Letter:

- The TGA Business Systems (TBS) submission identification number, e.g. DC-2015-xxxxxx-1

- A description of the submission:

    - type and number of electronic media

    - approximate submission size

    - any characteristics concerning the media that we might need to know

- The regulatory and information technology points of contact for the submission.

If sending the submission to the TGA using USB or DVD, please include a paper copy of the cover letter with the physical media.

If sending the submission to the TGA via email:

- the subject line should be the same as the subject line of the cover letter

- the body of the email should reflect the cover letter

- attach the submission as a ZIP file with the submission identification number as the name

- send the email to esubmissions@tga.gov.au

- note, the TGA email gateway is limited to approximately 40MB but other limitations may exist outside the TGA

- note, due to security requirements, the TGA email gateway may quarantine suspicious files. Please do not use encryption, executables or other scripts in relation to your submission and allow time for these security processes.

Check your IMDRF ToC submission

The TGA will undertake some preliminary checks to ensure the submission is fit for purpose. We may check for the correct form of PDFs, long path lengths and broken hyperlinks. We will assess whether the submission is of sufficient quality to enable us to process it.

To assist the TGA evaluators please ensure:

- PDFs are generated from an electronic source

- All hyperlinks and bookmarks are working

- PDFs are set to "Inherit Zoom"

- PDFs default to showing the internal PDF table of contents.

Select the electronic media

The size of the pilot submission to the TGA is only limited by the size of your media format. The IMDRF recommendation is to limit submissions to 4GB to maximise compatibility across regions.

Refer to TGA guidance for electronic dossiers in the general dossier requirements for the types of electronic media you can use for an IMDRF ToC pilot submission to submit it as one unit. In summary, you can use one CD, DVD, USB thumb drive or USB hard drive. Some small submissions may be able to be submitted via email as described previously.

Pack and send your dossier

Refer to How and where to send your dossier in the general dossier requirements for guidance on how to pack and send your dossier.

We will contact you if we have any issues during the checking and/or uploading of your submission.

AU regional content

In this section:

· Content

· Regional file formats

· Electronic signatures

· Empty or missing sections

· Table of contents, bookmarks and hyperlinks

Content

Use the TGA Regional Classification Matrices (IVD or nIVD) to determine the content that needs to be included in each folder of your submission.

Please delete all empty folders where content is not required.

Regional file formats

Where possible, generate PDFs from an electronic source.

Signatures may be embedded as a graphic file in the PDF.

Electronic signatures

While electronic signatures—for example, public key digital signatures—will be crucial in the future, particularly for authentication of electronic submissions and documents, we are currently accepting:

· Digital signatures as an adjunct to written signatures.

· Scanned signatures where the documents make up part of the IMDRF ToC submission.

Empty or missing sections where data is required

In applications for Conformity Assessment:

Do:

ü Include a statement in the Cover Letter on the absence of expected content (based on information in the TGA Regional Classification Matrices).

Do Not:

û Use documents with no substantive content – for example, documents that contain words like "not applicable". This causes delays for evaluators who must open and assess documents with no substantive content.

Table of contents, bookmarks and hyperlinks

Tables of contents

A pilot IMDRF dossier must contain tables of contents (ToCs) in PDF format as indicated in the [Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions](#).

To assist evaluators, the ToC in Chapter 1.02 should be linked to ToCs in each chapter which are linked to the documents in each chapter.

If the same document is used in more than one chapter, it should be provided with the correct file names in each chapter during the pilot.

û Do not include hyperlinks in the chapter ToCs to documents in other chapters except for the Chapter 1.02 ToC.

All documents lodged in your submission must be referenced from a hyperlinked table of contents.

Bookmarks and hyperlinks

We can increase the efficiency in evaluating your application if you prepare the documents so we can quickly locate content.

We recommend you:

· Use bookmarks and/or Tables of Content to assist us with navigating through PDF documents to quickly find information

· Include Table of Contents, and/or if appropriate, a Table of Tables, Table of Figures, etc. on the first page for documents with more than ten pages and with multiple sections

Structure and naming requirements

In this section:

· [Folder and file structure](#)

· [Folder and file naming conventions](#)

Folder and file structure

The structure of the IMDRF TOC submission must conform to the Assembly and Technical Guide for IMDRF Table of Contents (ToC) Submissions.

Name of the top level folder as per the section Prepare the top level folders which is based on the TBS application number.

Folder and file naming conventions

Folder naming

Folders are named in the zip file structure provided by IMDRF.

File naming

You can currently name the files with any meaningful name within the IMDRF 50 character limit and placed in the IMDRF folders except for [Custom] and [Trial details] folders which have specified file names. Please refer to the IMDRF guidance.

If you are submitting multiple files in one folder, ensure that you use names so that they display in the order that is most meaningful to the reviewer.

Dossiers constructed using the IMDRF guidance will result in the overall path length of less than 200 characters but Applicants do not need to include the top level directory (e.g. DC201512345) as this forms part of the TGA's file storage system.

Additional information

In this section:

· Responses to requests for information

· Application form

Responses to requests for information

Responses to requests for additional information should be sent via an email to the requesting TGA officer with:

· the reference number and the purpose of the email in the subject line

· explanatory text in the body

· documents as attachments

Application form

Always provide the TGA Business Systems (TBS) application form as a PDF file within the submission.

Therapeutic Goods Administration