



IMDRF International Medical
Device Regulators Forum

Final Document

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Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world.

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1.0 Introduction

The purpose of this document is to act as guidance to all those involved in developing and issuing International Medical Device Regulators Forum (IMDRF) documents and it is designed to be used with the accompanying Microsoft Word IMDRF Document Template. By using the IMDRF Document Template, members involved in developing new documents will be using a prescribed format, resulting in each new IMDRF document having a common and consistent appearance. This in turn, will contribute to their important use in achieving harmonized regulatory practices for medical devices around the world.

Comments or questions about the use of the Document Template or this guidance document should be directed to the IMDRF Secretariat.

2.0 Scope

All persons involved in or responsible for the creation or issuance of IMDRF documents are encouraged to read this document and to use the accompanying IMDRF Document Template.

The IMDRF document template was created, and should be used, in the application Microsoft Word.

3.0 References

Throughout this document, references are made to the IMDRF document entitled “Operating Procedures”.

4.0 Definitions

Template: the file ‘IMDRF document template.dot’

Field: a pre-formatted area of the template where specific text can be entered.

Click: one mouse click, using the primary button on the mouse

Right-click: one mouse click, using the secondary button on the mouse

Double-click: two mouse clicks, using the primary button on the mouse

5.0 Document Format

The following document format requirements have been incorporated into the IMDRF Document Template.

5.1 Word Processing Software

Microsoft Word was chosen as the word-processing software for the IMDRF Document Template since it is the most commonly used software amongst IMDRF members. Documents not created using the template will be converted by the IMDRF Secretariat prior to posting.

5.2 Paper Size

While it is preferable that a common paper size be used when creating IMDRF documents, it is recognized that different standard paper sizes are used around the world, i.e., A4 Letter size in Europe and Letter size (8 1/2" x 11") in North America. Document authors should therefore be advised that the arrangement of text from page to page in a document may be altered by the IMDRF Secretariat in preparation for posting on the IMDRF website.

5.3 Margins

All margins of IMDRF documents except the top margin, i.e., bottom, right and left, should be 2.54 centimeters (cm) unless a smaller margin is warranted, i.e., a page containing a schematic or flow chart that will not fit without the use of smaller margins. The top margin for all IMDRF documents will be 2.0 cm.

5.4 Font

All IMDRF documents will be generated in Times New Roman font, pitch 12. Document headings and subheadings will be numbered, i.e., 1.0, 1.1, 1.2, 2.0, etc. and headings will appear in bold text, pitch 14. Sub-headings will appear in bold text, pitch 12. Each word of a heading or sub-heading should be capitalized.

Examples: **2.0 Requirements**

2.1 Role of the Auditor

5.5 Line Spacing

IMDRF documents will be single-spaced with a double space appearing between text and each heading or sub-heading and a double space appearing between each separate section and sub-section. Paragraphs will be separated by a double space.

Example: **2.0 Method of Estimating Audit Duration**

This document provides guidelines for auditing organizations responsible for planning, carrying out and documenting quality system audits....

2.1 Factors Which May Increase the Initial Audit Duration

5.6 Page Numbering

All pages of a IMDRF document, with the exception of the cover page, will be numbered in the bottom right hand corner of each page, using the format “Page 1 of X”, with the page number appearing within the footer on each page (see section 8.4).

6.0 Document Elements

IMDRF members involved in IMDRF document development should consider the inclusion of each of the following sections. It is to be noted however, that in some cases, depending on intent or scope, a IMDRF document may not include a particular section because it does not apply.

For convenience, each of these sections with the exception of Section 6.1 Table of Contents has been included in the IMDRF Document Template.

6.1 Table of Contents

All IMDRF documents over four (4) pages in length will have a Table of Contents specific to heading and sub-heading level.

Example:

1.0	Introduction.....	2
2.0	Types of Audits.....	2
2.1	Initial Audit.....	3
2.2	Surveillance Audit.....	3
2.3	Special Audit.....	4

6.2 Preface

All IMDRF documents, regardless of their authoring group or intent, will bear a preface designed to summarize the composition of the IMDRF and its goals as an organization. The preface of any given document should not bear any document-specific information as this may be found in the Introduction section (see Section 6.4).

For convenience, the IMDRF Document Template has been formatted to include the “generic” preface statement shown in Appendix A.

6.3 Cover Page

Documents at either the Working Draft or Proposed Document stage will bear a cover page containing the following information:

- (A) the title of the document;
- (B) the authoring group, e.g., Study Group 1;
- (C) the date of issue, i.e., the date that the document was created on or was last worked on
Note that the acceptable date format is Day Month Year, e.g., 25 June 2000
- (D) the words “Global Harmonization Task Force”, and
- (E) the document identification code, as described in Section 3.0 of the Operating Procedures document.

For convenience, each of the pieces of information listed above has been included as fields in the cover page of the IMDRF Document Template.

Final Documents endorsed by the Steering Committee will use the formal cover page attached as Appendix B to the Operating Procedures document, with the cover sheet being signed by the Chair of the organization at the time of endorsement.

6.4 Introduction

This section of the document should lay out the background leading to the document’s development and should include identification of the authors or authoring group involved in its creation, the document’s current stage of development, a brief summary of the process used to obtain comment on the document throughout its development (if applicable), a description of the document’s intended audience and a statement of the document’s purpose.

The introduction may also include reference to a contact person, to whom comments or questions about the document should be directed.

6.5 Scope

The scope of a IMDRF document should outline its applicability to a particular aspect or aspects of medical device regulation and/or the usefulness of the document to different sectors of industry or government.

The scope of the document should also clearly state any exclusions that may apply.

6.6 References

This section should list any references that may have used in developing the document and/or any international standards that are referred to in the document, i.e., ISO 9001:1992.

If no references were used, enter “Not Applicable” in the template.

6.7 Definitions

This section should contain a lexicon of all terms found within the document for which there may be different interpretations, the purpose being to provide the interpretation used by the document creators and therefore to facilitate implementation or use of the document by eliminating any uncertainties about the meaning of a certain term or requirement.

Each term in the lexicon should appear in bold text followed by a colon and the definition in an indented paragraph. See Section 4.0 for examples.

Enter ‘Not Applicable’ in the template, if appropriate.

6.8 Document Body

Since each IMDRF document will differ in subject matter, it is expected that the body of each document will differ in the sections that it contains also. For example, a document on auditing of quality systems may include sections on the audit team, types of audits and the audit process while another document on essential principles of device design may include sections on chemical properties and reduction of microbial contamination.

The organization of the text body of each document is therefore at the discretion of each authoring group, provided it is broken into logical and numbered sections. For convenience, the header and text for the first document section have been created as fields in the IMDRF Document Template. Additional sections should then be added as required.

The numbering of headings and sub-headings is controlled using Styles, which can be accessed from the pull-down menu on the control bar. Using the styles included in the template ensures that the table of contents can be generated correctly.

The default style setting is “Normal” and this style should be used for all text in a IMDRF document, with the exception of headings and sub-headings, etc.

Style “1.0 Heading 1” should be used for the titles of major sections within a document because it will automatically apply top-level numbering, i.e. 1.0, 2.0 ..., to the text. There is no limit to the number of sections you can create in a document.

Style “1.1 Heading 2” should be used for sub-headings within major sections of your document because it will automatically apply second-level numbering, i.e. 1.1, 1.2 ..., to the text.

Style “1.1.1 Heading 3” should be used for sub-sub-headings if required because it will automatically apply third-level numbering, i.e. 1.1.1, 1.1.2 ..., to the text.

6.9 Examples

The use of examples is encouraged as a way of promoting understanding of the document text. Examples should be preceded by the word “Example:” followed by the actual example in an indented paragraph (see the examples in this document).

6.10 Appendices

All diagrams, forms or flow charts, etc., not included in the body of the document should be included as appendices at the end of the document.

The IMDRF Document Template has been formatted to include a blank page with the word “Appendices” on it and this should be used to separate the body of the document and its appendices.

The template also comes formatted with one appendix (labeled Appendix A) and a field in which the title of the first appendix can be entered. If necessary, additional appendices should be added, following the same format. Alternatively, if there are no appendices, these sections of the document template can be deleted.

7.0 Installing the IMDRF Document Template

Before installing the document template, ensure that you close any Microsoft Word windows that are currently open on your computer.

The IMDRF document template is a Microsoft Word file, called “IMDRF document template.dot”. This file can be found on the IMDRF web site (www.IMDRF.org) on the General Information page under the “IMDRF Documents” heading.

This file should be saved to your computer, using the instructions on the web site. It should then be copied to the “Templates” folder in your Microsoft Word or Microsoft Office folder. If you are not sure where this is, contact your technical support provider. A typical location would be C: \ Program Files \ Microsoft Office \ Templates.

8.0 Using the IMDRF Document Template

8.1 Opening the Document Template

The following instructions will allow you to open the template and start to create a new document:

- (A) Start Microsoft Word;
- (B) Select “New” from the “File” menu;
- (C) In the ‘New’ window that appears, select “General”;
- (D) Double-click on the icon marked “IMDRF Document Template.dot” (if the icon is not there, go back and make sure that you followed the installation instructions in Section 7.0), and
- (E) A new, untitled Word document, with the template fields in place, will appear.

At this point, it is recommended that the new document be saved with an appropriate name. Completed work should also be saved regularly to avoid loss in case of system failure.

8.2 Filling in the Template

The template comes with a number of pre-defined fields allowing pertinent information to be entered in the correct place. These fields are identified by square brackets enclosing instructions about what information should be included.

Example: [Click here to enter document title].

Clicking on the field will highlight it,.

Example: **[Click here to enter document title]**

When the field is highlighted, text can be typed into it. Note that the appropriate formatting for that section of the document will be automatically applied.

8.3 Using the Template Header

The IMDRF Document Template has been formatted to include a document header which appears on every page except the cover page. The header provides the following information:

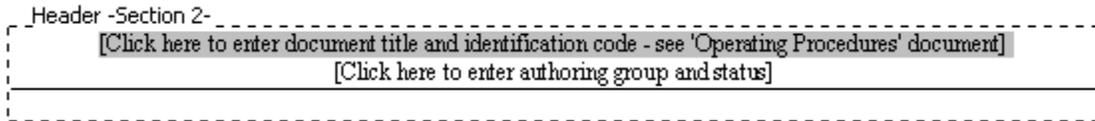
- (A) the document title and document identification code;
- (B) the authoring group, and
- (C) the document status, i.e., Final Document, Proposed Document, Draft#4, etc.

To edit the document header, follow these instructions:

- (A) Go to any page other than the cover page, and
- (B) Select “Header and Footer” from the View menu to display the header/footer control bar:



and the header region in a hatched box at the top of the page:



Text can then be entered by clicking on the different fields.

8.4 Using the Template Footer

The IMDRF Document Template also includes a document footer which appears on every page except the cover page. The footer provides the following information:

- (A) the date of issue, and
- (B) the page number

After completing the document header fields, switch to the document footer by clicking on the  button on the header/footer control bar. The footer region will be displayed in a hatched box at the bottom of the page:



Enter the date as entered on the cover page of the document but do not edit the page count as this is updated automatically by Microsoft Word. If you see what appears to be an incorrect page count, e.g., Page 9 of 7, save the document and then click on Print Preview from the File menu. The correct page numbers should appear.

To close the header & footer view and return to normal document editing, press the Close button on the header/footer control bar.

8.5 Creating a Table of Contents

Once all the information fields have been created and the sections numbered appropriately, a Table of Contents should be added to the document:

- (A) Delete the text “*The Table of Contents should be created on this page. See IMDRF Document Format and Style Guide for instructions*” from page 2 of the document;
- (B) Click on “Index and Tables” from the Insert menu on the control bar;
- (C) Select the “Table of Contents” tab;
- (D) Click on “From Template” in the “Format” window;
- (E) Ensure that the “Show page numbers” and “Right align page numbers” check boxes are selected and that the “Show levels” box is set to 3, and
- (F) Click on the “OK” button.

The table of contents should be generated, using the numbered headings and sub-headings that you have added to the document.

Note that the Table of Contents will require updating if changes (even small ones) are made to the document. To update the Table of Contents, repeat steps (B) through (F). When the prompt “Do you want to replace the selected Table of Contents?” appears, click “OK”.

APPENDICES

Appendix A: “Generic” Preface Statement for Use in All Documents

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