BEST PRACTICE: CREATING IMDRF ASSEMBLY TEMPLATES FOR HEALTH CANADA

1 Contents

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2 Revision History

When Ennov releases a new version of Ennov InSight, they issue Release Notes which explain the new features and updates. The Ennov Business Consulting Team reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes-documented upgrade changes this Best Practice
- No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Ennov recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
v7.3.1	28-Jun-2024	Update Best Practice for Ennov rebranding & for v7.3.1 – No Impact
v7.2	20-Jun-2023	Update Best Practice for v7.2 – No Impact
v7.1	13-Jan-2022	Update Best Practice for v7.1 – No Impact
v7.0	25-May-2021	Update Best Practice for v7.0 – Impact

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3 Document Purpose

The purpose of this document is to provide best practice guidance for creating an International Medical Device Regulators Forum (IMDRF) Assembly Template to support submission publishing for Health Canada in vitro diagnostic (IVD) and non in vitro diagnostic (nIVD) medical devices.

The International Medical Device Regulators Forum (IMDRF) has identified the need to harmonize the documentation of evidence to support medical device market authorization requests. The Regulated Product Submission (RPS) working group of IMDRF has developed the Table of Contents (ToC) formats for both in vitro diagnostic (IVD) and non in vitro diagnostic (nIVD) devices, thereby promoting a globally harmonized structure for medical device applications. Use of the ToC formats will facilitate filing medical device applications for multiple jurisdictions and promote timely international access. It will also support the transition to a Health Level-7 (HL7) electronic environment. HL7 is a messaging standard that supports submission of information for regulated products. Each HL7 message includes the contents of a regulatory submission plus metadata that communicates the structure of the content and aids in electronic processing of submissions.

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4 General Considerations

This section describes basic rules and expectations.

4.1 Assembly Templates

1. An Assembly Template enables you to set up an Assembly structure that will generate a compliant output that meets submission requirements.
2. Templates can include elements and metadata that are common to the Assemblies you create.
3. You must have permissions to at least one of the following modules to perform Assembly Template activities:
    a. Electronic Lifecycle Publishing (ELP)
    b. Registered Document Analysis (RDA)
    c. Submission Planning and Tracking (SPT)
    d. Paper Review Publishing (PRP)
4. Creation of Assembly Templates should be limited to users with appropriate permissions to ensure compliance with the regulatory information management governance procedures.
5. A full understanding of the regional/regulatory agency guidance enables the Template administrator to choose the correct Assembly entities that will ensure the intended output.

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5 Design Overview

To meet the Health Canada requirements, two IMDRF Templates will be created. The Folder structure in the Templates should match the Table of Contents (ToC) formats for both in vitro diagnostic (IVD) and non in vitro diagnostic (nIVD) devices. The difference between the two templates is mainly the Folder headings for in vitro and non in vitro sections, all the Publishing Settings are identical. After creating the first Template, create the second Template using the the same Publishing Settings Library but use the correct Folder nomenclature as indicated in the Table of Contents (ToC) formats requirements document for both I diagnostic (IVD) and non I diagnostic (nIVD) devices.

When building the IMDRF Assembly, the structure will include Folders, Leaf elements, and Table of Contents for all the chapters. The guidance document can be found on the Health Canada website.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/toc-format-notice.html

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6 Creating a NEW (Empty) IMDRF Assembly Template

To create an empty Assembly Template:

Note: You must have the appropriate security privileges to create Assembly Templates in RIM.

1. On the home page, click **New > Assembly Template**.
2. On the Create Assembly page, select **New (Empty)** to create an empty Assembly.
3. Click the Publishing Settings Library to use with the Assembly.
    a. Users with appropriate permissions can create customized regional Publishing Settings Libraries based on the regulatory submission requirements. Select the appropriate Publishing Settings Library, if none exists select the default option.
    b. The Publishing Setting Library can be modified as necessary.
4. Click **Save.**
5. Enter attribute values for the assembly. See **Assembly Attributes**
    a. **Name**: Follow corporate naming conventions for clear naming of the Template
    b. **Assembly Type Values**: Standard
    c. **Auto Populate Output Folder**: Yes

Note: The Created From attribute is always blank

6. Click **Create.**

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7 IMDRF Publishing Settings

This procedure applies to both the Publishing Settings Library Template (PLT) and Assembly Specific Publishing Settings Library (APL).

1. On the **Publishing Settings Library** window, create **Publishing Settings**.
2. Complete and save the **Create Publishing Settings** page using standard corporate values. To meet IMDRF requirements the XML definition file should be set to ICH-3-2.
3. Complete and save the remaining **PRP/ELP Publishing Settings** library menus following standard corporate values.

Note: To meet IMDRF Publish Output requirements, the Output Channel should be set to Electronic wherever applicable.

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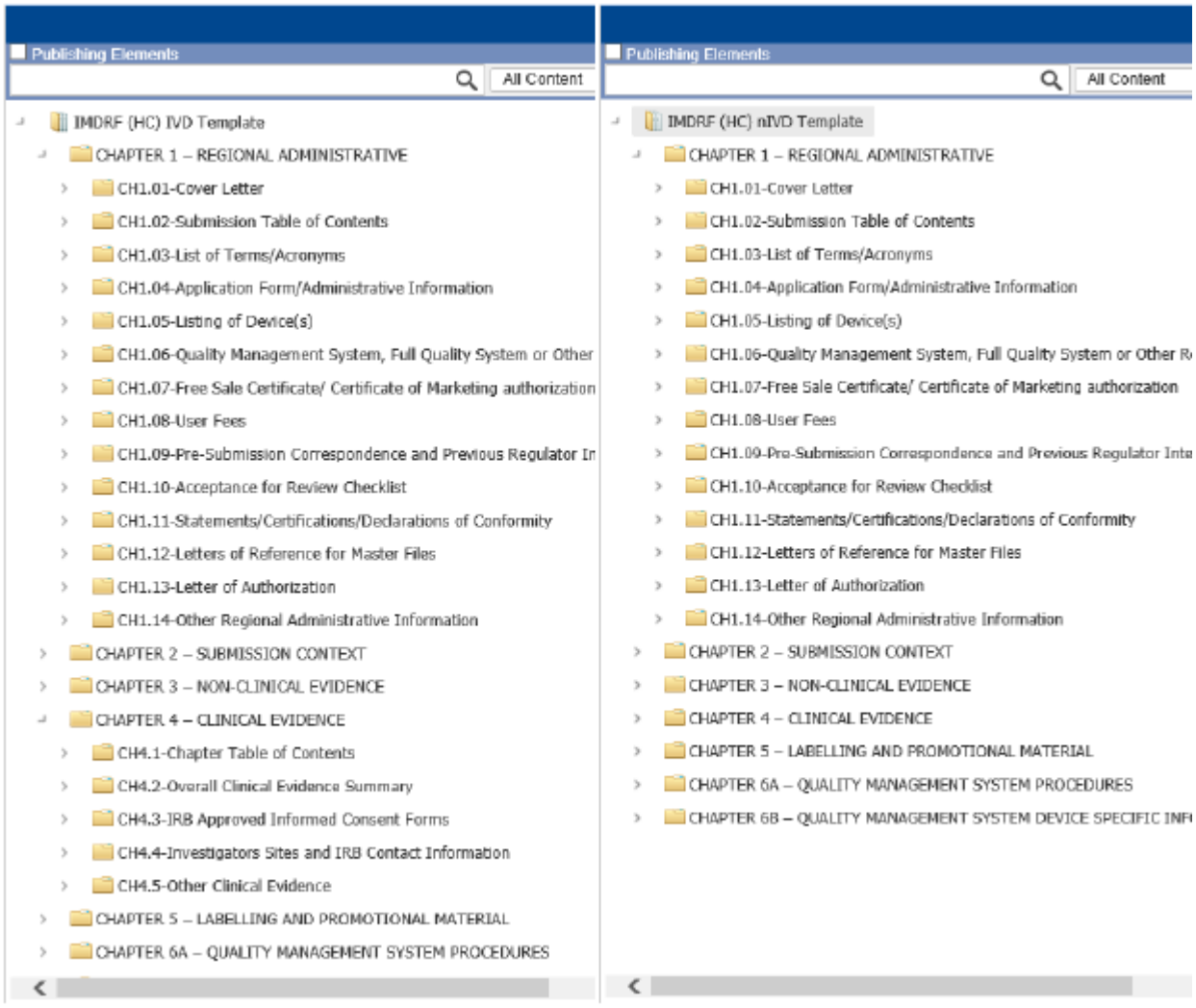
8 IMDRF Folder Structure

For the IMDRF Template, follow the IMDRF folder granularity as specified in the in vitro diagnostic (IVD) and non in vitro diagnostic (nIVD) final requirements guidance document. The guidance document can be found on the Health Canada website.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/toc-format-notice.html

The IMDRF Folders should match the chapter titles in the guidance document. Refer to the following sample screenshots.



Example of IMDRF IVD and nIVD Assembly Template Folder structure.

Note: The Output Folder attribute captures the Folder Name to be created in the Published Output. In this case a System Variable e.g.($MNAME or $NNAME) may be used to display either the Major Folder Name or the Minor Folder Name.

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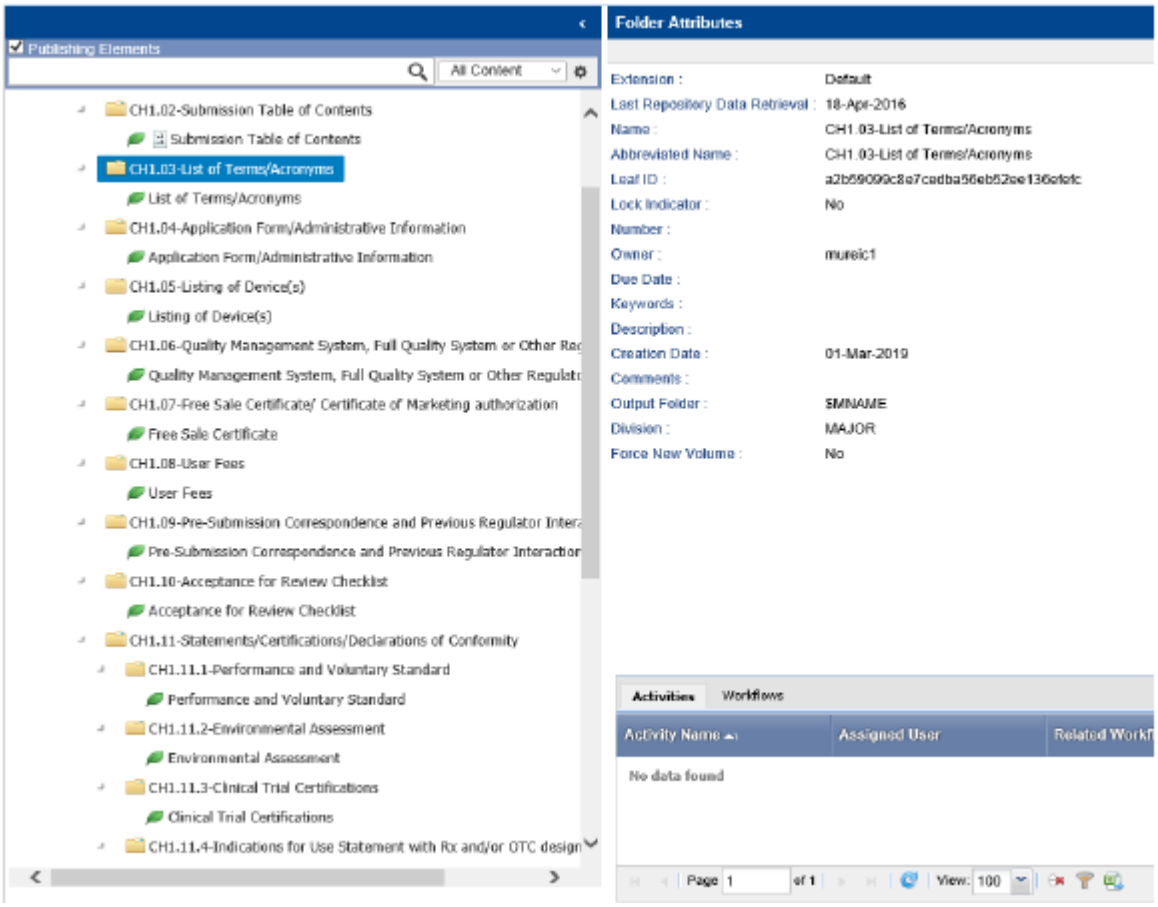

Example of Folder with Output Folder Variable.

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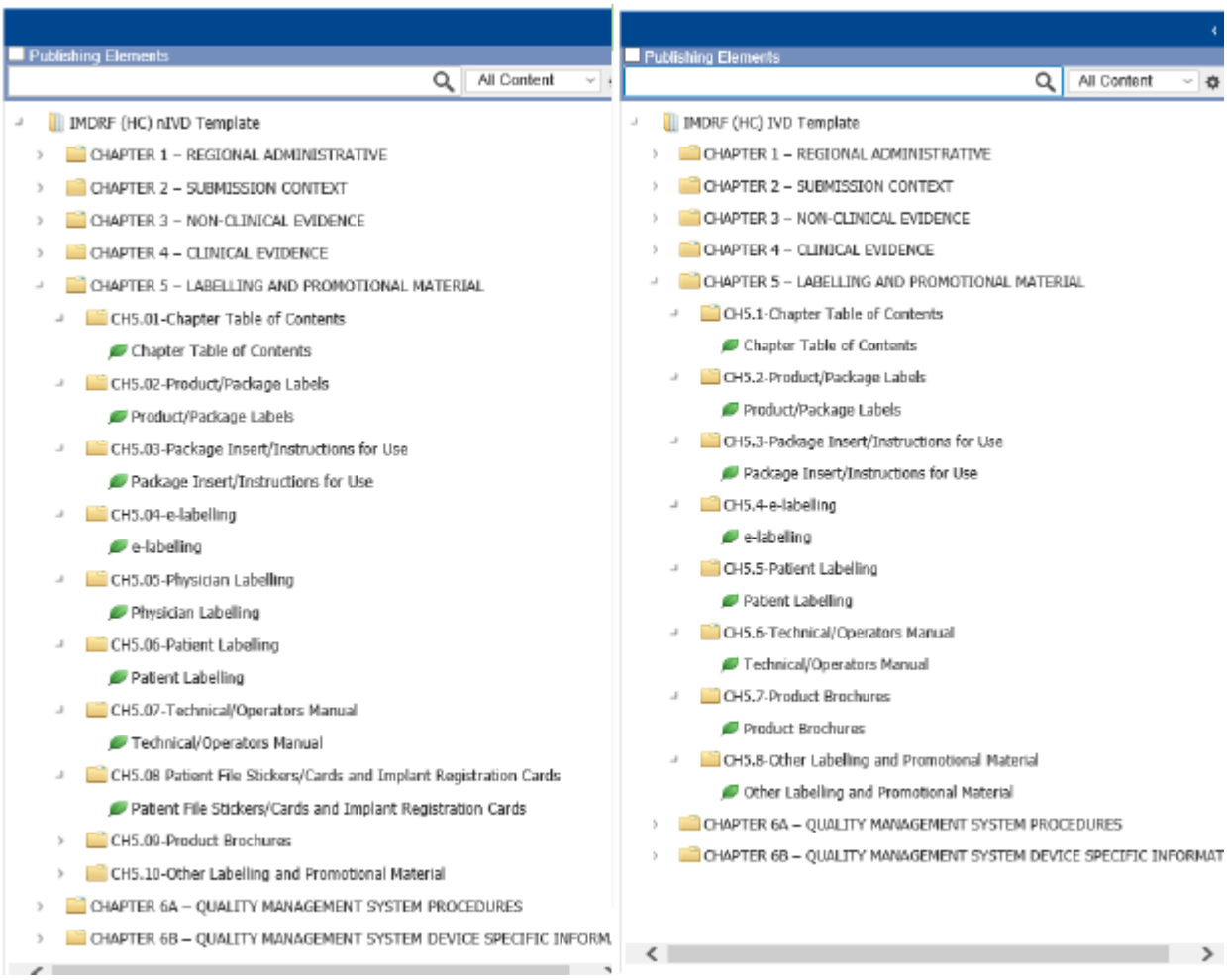
9 IMDRF Leafs

For the IMDRF template, each Leaf should follow the IMDRF granularity folder naming convention as specified in the in vitro diagnostic (IVD) and non in vitro diagnostic (nIVD) guidance document where applicable.

Note: Output File attribute – Follow the guidance naming conventions and character limits to represent the relative path and/or the file name of the published output for the leaf. The guidance document can be found on the Health Canada website.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/toc-format-notice.html



Example of IMDRF IVD and nIVD Assembly Template with Leafs displaying IMDRF granularity and folder naming convention

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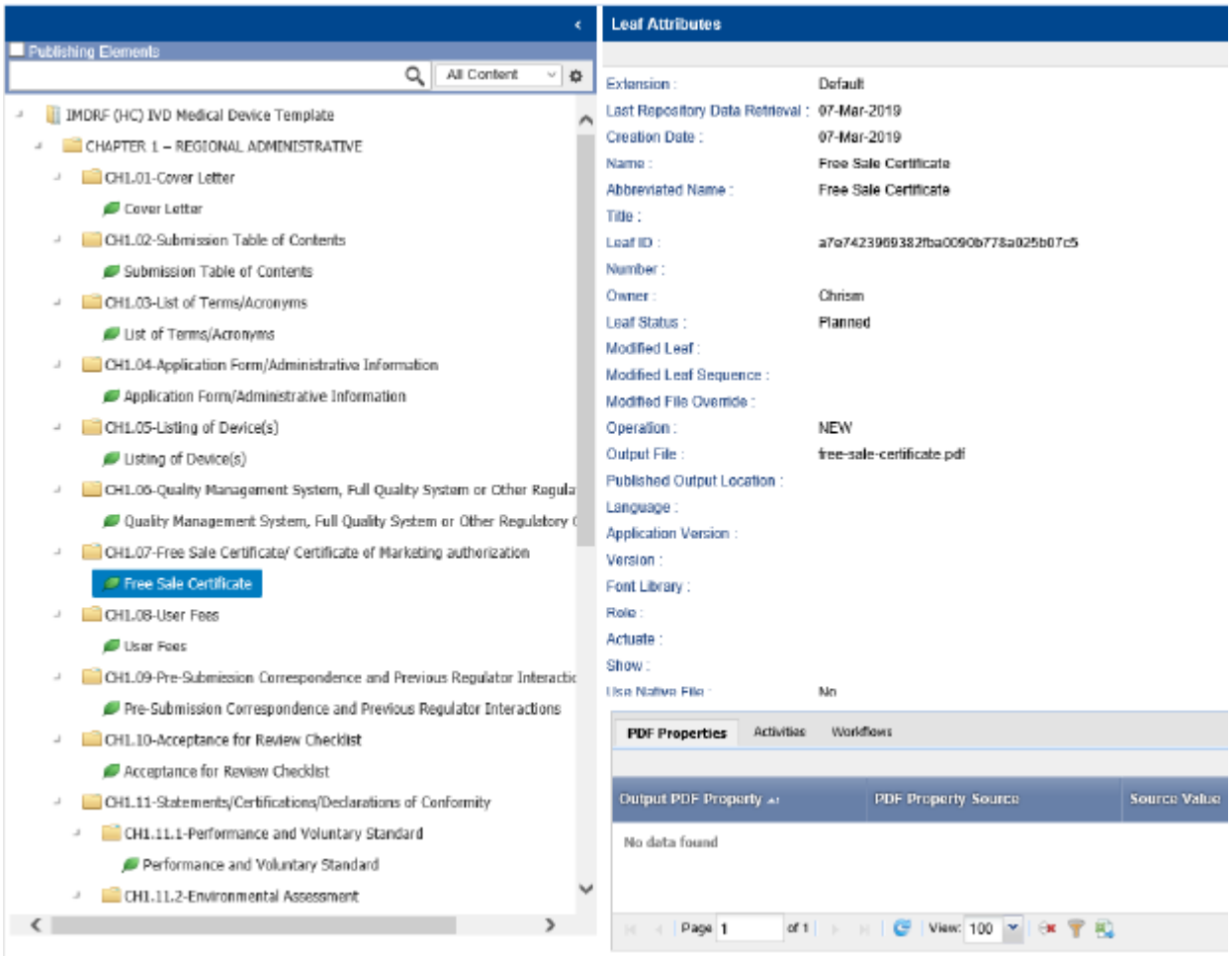

Example of IMDRF IVD Assembly Template Leaf granularity and Leaf Attributes

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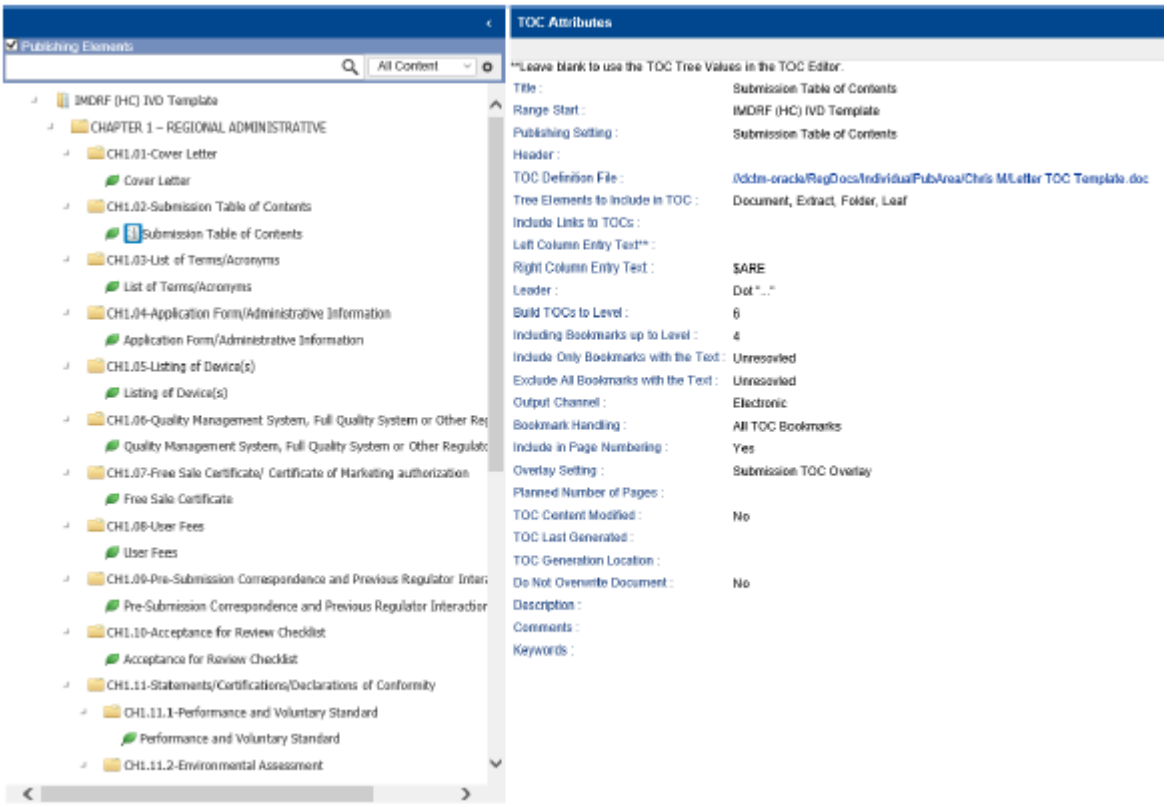
10 Inserting a TOC

The IMDRF Templates will require seven tables of contents. One overall submission table of contents in chapter one. One chapter table of contents for the each of the chapters. Insert a TOC in the corresponding Leaf element. When adding a TOC to a Tree Element, the TOC name inherits the name of the assigned Element. This name is used to create the Output File Name of the generated TOC.



Example of IMDRF IVD Assembly Template Table of Contents Attributes

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