



# Application Export

## Document Rendering Specification

Technical Specification — Client Reference

## Introduction

### 1. Purpose

This document defines the output format for the RegDesk Application Export module. It covers document rendering, file structure, naming conventions, path compliance, and FDA eCopy validator alignment. It is intended as a technical reference for clients integrating RegDesk exports into their submission workflows.

### 2. Scope

Applies to VOL (folder tree) and CON (merged document) export formats. XML and eSTAR follow separate submission-specific rules and are covered only where a rule applies universally across all formats.

### 3. Status Legend

Each requirement in this document carries a delivery status badge. The meaning of each badge is defined below.

| Status                       | Label             | Meaning                                                                                                              |
|------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------|
| <div>In Effect</div>         | In Effect         | Available in the current product release.                                                                            |
| <div>WIP Improvement</div>   | WIP Improvement   | Existing behaviour is partially implemented; the mechanism is present and will be revised to meet the specification. |
| <div>To be Implemented</div> | To be Implemented | No current implementation exists; this requirement will be built from scratch in an upcoming release.                |
| <div>Not Committed</div>     | Not Committed     | Outside the current delivery scope; subject to future roadmap decisions.                                             |

**Note:** Status reflects the state of the specification as of 17 September 2026. Implementation timelines are subject to change. For integration planning purposes, contact your RegDesk account representative.

## Section 1 — Core Rendering

### 1.1 Page Format

| Property           | Specification                                                                               | Status    |
|--------------------|---------------------------------------------------------------------------------------------|-----------|
| Paper size         | A4 (210 × 297 mm)                                                                           | In Effect |
| Orientation        | Portrait                                                                                    | In Effect |
| Content width      | 6.27 inches (A4 less 1-inch margins on both sides)                                          | In Effect |
| Page breaks        | Each section begins on a new page. Table rows are kept intact; headers repeat across pages. | In Effect |
| Backgrounds        | Background colours and images are preserved in the output.                                  | In Effect |
| Section-only pages | No page is generated that carries only a section name.                                      | In Effect |

### 1.2 Margins

| Edge   | Measurement      | Status    |
|--------|------------------|-----------|
| Top    | 1 inch (25.4 mm) | In Effect |
| Bottom | 1 inch (25.4 mm) | In Effect |
| Left   | 1 inch (25.4 mm) | In Effect |
| Right  | 1 inch (25.4 mm) | In Effect |

The running header occupies the top margin; the footer strip occupies the bottom margin. Neither intrudes into the content area.

### 1.3 Typography — Generated Pages

| Element                         | Typeface                | Size                     | Status    |
|---------------------------------|-------------------------|--------------------------|-----------|
| Title page — document title     | Montserrat              | 22 pt                    | In Effect |
| Title page — subtitle           | Montserrat              | 15 pt                    | In Effect |
| Title page — tertiary heading   | Montserrat              | 12 pt                    | In Effect |
| Title page — body text          | Montserrat              | 10.5 pt                  | In Effect |
| Table of contents — title       | Montserrat              | 19 pt                    | In Effect |
| Page header — section/question  | Montserrat              | 14 pt                    | In Effect |
| Content body — authored answers | Per font mapping (§1.4) | 18 px, 32 px line height | In Effect |

### 1.4 Font Mapping — Authored Content

| Editor Font              | Rendered Font | Status    |
|--------------------------|---------------|-----------|
| Arial, Helvetica, Tahoma | Roboto        | In Effect |
| Verdana                  | Open Sans     | In Effect |
| Trebuchet MS             | Lato          | In Effect |
| Times New Roman          | PT Serif      | In Effect |
| Georgia, Book Antiqua    | Merriweather  | In Effect |

## Section 2 — Page Structure

### 2.1 Running Header

Every generated page carries a running header. Its purpose is to allow an individual document to be identified when opened, forwarded or printed outside the folder tree that would otherwise provide context.

| Component      | Specification                                               | Status    |
|----------------|-------------------------------------------------------------|-----------|
| Left element   | Organisation logo, 0.4 inch in height.                      | In Effect |
| Right — line 1 | The section or subsection that directly holds the document. | In Effect |
| Right — line 2 | The document's own number and name.                         | In Effect |
| Ancestry depth | Only the immediate parent is named, not the full ancestry.  | In Effect |
| CON behaviour  | Section context appears in the body rather than the header. | In Effect |
| Uploaded files | Delivered as supplied; carry no RegDesk header.             | In Effect |

### Logo Resolution Order

1. Logo selected in the export dialogue at time of export.
2. The organisation's configured export header logo.
3. The organisation's profile logo.
4. The RegDesk default logo.

### 2.2 Page Footer

| Component      | Specification                                                                                       | Status            |
|----------------|-----------------------------------------------------------------------------------------------------|-------------------|
| Branding strip | A single full-width image, 0.8 inch high, anchored to the bottom edge, bleeding to both side edges. | In Effect         |
| Page number    | Printed on every generated page, in the clear band of approximately 0.4 inch above the strip.       | To be Implemented |
| Footer image   | Resolved: (1) organisation's configured export footer image; (2) RegDesk default footer image.      | In Effect         |

### 2.3 Pagination

| Rule                | Specification                                                                                | Status            |
|---------------------|----------------------------------------------------------------------------------------------|-------------------|
| What is counted     | Content the system generates — the title page, the table of contents and authored answers.   | WIP Improvement   |
| What is not counted | Uploaded files. Delivered unmodified; need not be paginated documents.                       | WIP Improvement   |
| First page          | The title page is page 1. Front matter is counted and carries printed page numbers.          | To be Implemented |
| Number printed      | The page's position across the whole export, not its position within the file that holds it. | To be Implemented |
| Format agreement    | VOL and CON produce the same page numbers for the same content.                              | To be Implemented |
| TOC length feedback | The table of contents' own length is accounted for before content is paginated.              | WIP Improvement   |

**Implementation note:** Printed page numbers in VOL exports are in delivery. CON page numbers are rendered by the PDF service and are aligned to specification; server-side behaviour is verified. VOL–CON equality is an acceptance test to be built as part of the delivery work.

## Section 3 — Document Architecture

### Table of Contents

#### 3.1 Scope

A table of contents is produced for both VOL and CON exports; its structure is identical in both. XML and eSTAR exports produce no table of contents.

#### 3.2 Row Rules

| Row type               | Included                                     | Page column                           | Status          |
|------------------------|----------------------------------------------|---------------------------------------|-----------------|
| Section                | Yes — every section at every depth.          | First content page of the section.    | WIP Improvement |
| Subsection             | Yes — at every depth.                        | First content page of the subsection. | WIP Improvement |
| Question (answered)    | Yes.                                         | Page where content begins.            | WIP Improvement |
| Question (unanswered)  | Yes — row present, no page number.           | None.                                 | WIP Improvement |
| File row               | Yes — only where a file exists.              | None.                                 | In Effect       |
| Not Applicable items   | No row.                                      | —                                     | WIP Improvement |
| Condition-hidden items | No row.                                      | —                                     | WIP Improvement |
| Front matter           | No row — counted for pagination, not listed. | —                                     | In Effect       |

#### 3.3 Visual Design

| Row type               | Typeface   | Size  | Style                 | Status          |
|------------------------|------------|-------|-----------------------|-----------------|
| Section                | Montserrat | 14 pt | Bold, black           | WIP Improvement |
| Subsection (any depth) | Montserrat | 12 pt | Semibold, black       | WIP Improvement |
| Question               | Montserrat | 11 pt | Regular, black        | WIP Improvement |
| File                   | Montserrat | 11 pt | Regular, grey, italic | WIP Improvement |

Type distinguishes a question from a subsection when both sit at the same indent. Italic distinguishes a file row from a question row — colour alone is not relied upon, as it is lost in print. No icons are used on any row.

#### 3.4 Indentation

All measurements below are printed measurements.

- Content width: **6.27 inches**.
- Each structural level is indented a further **0.25 inch**.
- Structural indentation stops increasing after the **fourth level**; deeper items sit at the fourth level's indent and the number carries the depth.
- A question is indented one step beyond its section or subsection; a file one step beyond its question.
- Total indent never exceeds **1.25 inches**, leaving 5.02 inches for the text of the deepest row.

## Section 3 — Document Architecture (cont.)

### Numbering

A number is decided once and used everywhere — in the screen view, the folder tree and the table of contents. Only its written form changes between surfaces. No number carries leading zeros, with the single exception of top-level folders on disk.

#### 3.5 Numbering Rules

| Item                       | Rule                                                                                                      | Status          |
|----------------------------|-----------------------------------------------------------------------------------------------------------|-----------------|
| Sections                   | The first content section is 1, running consecutively.                                                    | WIP Improvement |
| Subsections                | Parent number, a dot, and the subsection's position among its siblings — 2.1, and 2.1.1 one level deeper. | In Effect       |
| Questions                  | Numbered from 1 within the section or subsection that directly holds them.                                | In Effect       |
| Subsections and questions  | Numbered independently; both sequences start at 1 within the same section.                                | In Effect       |
| Subsection among questions | Consumes no question number. The next question takes the next number.                                     | In Effect       |
| Not Applicable             | Consumes no number at any level. The next item takes the number it would have had.                        | WIP Improvement |
| Condition-hidden           | Removed before numbering runs; numbering never contains a gap.                                            | WIP Improvement |
| Unanswered question        | Keeps its number.                                                                                         | In Effect       |
| Screen ↔ export agreement  | Number shown on screen equals number in the delivered export, including MDA module.                       | WIP Improvement |

#### 3.6 Custom Prefixes

| Rule                   | Detail                                                                                                                    | Status          |
|------------------------|---------------------------------------------------------------------------------------------------------------------------|-----------------|
| Prefix replaces number | A custom prefix replaces the generated number at every level.                                                             | In Effect       |
| Descendant inheritance | Descendants without a custom prefix build on the replacement: a subsection under Annex I is Annex I.1.                    | In Effect       |
| Position consumed      | A custom prefix consumes its position in the sequence.                                                                    | In Effect       |
| Digit-only rejection   | A prefix made only of digits is rejected at entry — 000, 01, 7 and 0042 are rejected; Annex I, S.B.A and A1 are accepted. | WIP Improvement |
| Length limit           | Maximum 20 characters; rejected at entry, never shortened at export.                                                      | WIP Improvement |

#### 3.7 Separator Convention

Separators differ by surface, deliberately:

**On disk:** a number is followed by an underscore — 2\_Authorised Representative.pdf

**In the table of contents:** a dot and a space — 2. Authorised Representative

**In the screen view:** a dot and a space — same as the table of contents.

The dot in a filename means one thing only: hierarchy (e.g. Annex I.1\_Attachment.7\_... ). The underscore is the separator between a number and a name on disk.

## Section 4 — Archive Structure

### 4.1 VOL Folder Naming

| Level                      | Form                                                  | Example                             | Status          |
|----------------------------|-------------------------------------------------------|-------------------------------------|-----------------|
| Front matter               | VOL_000_Front Matter                                  | VOL_000_Front Matter/               | WIP Improvement |
| Section                    | VOL_ + 3-digit zero-padded number + name              | VOL_001_Application Type            | WIP Improvement |
| Section with custom prefix | Prefix replaces the number, not padded                | VOL_Annex I_Standards List          | In Effect       |
| Subsection (any depth)     | VOL_ + hierarchical number unpadded + name            | VOL_2.1_Applicant Details           | WIP Improvement |
| Empty section              | Folder delivered even when no questions are answered. | VOL_002_Administrative Information/ | In Effect       |

### 4.2 File Naming

| Kind                                  | Form                                                            | Example                                 | Status          |
|---------------------------------------|-----------------------------------------------------------------|-----------------------------------------|-----------------|
| Authored answer                       | Question number _ question name                                 | 1_Manufacturing Sites.pdf               | WIP Improvement |
| Authored answer (custom prefix)       | Prefix replaces the number                                      | Annex I_Intended Purpose.pdf            | WIP Improvement |
| Uploaded file                         | Attachment.N _ uploaded name (N continuous across whole export) | Attachment.7_device_photo_front.jpg     | WIP Improvement |
| Upload under custom-prefixed question | Prefix + file position + Attachment.N_                          | Annex I.1_Attachment.7_device_photo.jpg | WIP Improvement |
| Uploaded file (unconverted)           | Name and extension preserved exactly.                           | Attachment.2_ar_letter.pdf              | In Effect       |

### 4.3 CON Structure

| Component          | Contents                                                                                       | Status          |
|--------------------|------------------------------------------------------------------------------------------------|-----------------|
| Master File/       | Single merged document containing all authored content.                                        | WIP Improvement |
| Attachments/       | Uploaded files only — content that cannot be merged. No document appears twice in one package. | WIP Improvement |
| CON front matter   | In the merged document; none in Attachments.                                                   | WIP Improvement |
| Attachment folders | Folder created only where an upload lands; empty section folders are omitted.                  | WIP Improvement |

### 4.4 Filename Normalisation

Uploaded document filenames may be normalised at ingest according to a naming pattern configured for the organisation. The pattern supports tokens: {name} , {ext} , {date} , {timestamp} . Both the normalised filename and the originally submitted filename are retained on the document record for audit purposes. In Effect

### 4.5 Archive Naming

The archive is named as: YYYYMMDD-HHMMSS\_Country\_ApplicationName\_ExportType . Example: 20260916-143052\_USA\_Cardiac Monitor Mk II\_VOL . Where the user supplies a custom export name it replaces the application name. The export dialogue shows the resulting archive name as it is typed. In Effect

## Section 5 — FDA eCopy Validator Compliance

The RegDesk Application Export is a multi-jurisdictional dossier format. This section defines the current and future level of alignment with FDA eCopy validator requirements.

### 5.1 Background

The FDA eCopy program requires submission packages to pass the FDA eCopy Validator tool. The validator checks folder structure, file naming, path lengths, PDF compliance, and the presence of a loading index. RegDesk exports are not submitted exclusively to FDA; alignment is therefore partial by design.

### 5.2 Alignment by Requirement

| eCopy Requirement                             | RegDesk Behaviour                                                                       | Current | Future            |
|-----------------------------------------------|-----------------------------------------------------------------------------------------|---------|-------------------|
| Volume folder prefix VOL_ with numeric suffix | Current: Vol_NN_ (lowercase, 2-digit). Future: VOL_NNN_ (uppercase, 3-digit).           | Gap     | WIP Improvement   |
| Sequential file numbering within volumes      | Current: N.1_Name.pdf. Future: N_Name.pdf.                                              | Gap     | WIP Improvement   |
| Continuous attachment numbering               | Future: Attachment.N_ across whole export.                                              | Gap     | WIP Improvement   |
| Path length ≤ 260 characters                  | Not enforced today. Future: guaranteed with fair-division trimming.                     | Gap     | To be Implemented |
| Illegal/reserved filename characters removed  | Partial sanitisation at export only. Future: rejected at entry, reserved names handled. | Partial | Aligned           |
| Extraction guidance (README)                  | Not provided. Future: READ ME FIRST.txt with path info.                                 | Gap     | To be Implemented |
| Formal FDA eCopy loading index                | Not generated. RegDesk produces a Table of Contents PDF only.                           | Gap     | Not Committed     |
| PDF/A or specific PDF version                 | Standard PDFs generated; no PDF/A targeting.                                            | Gap     | Not Committed     |
| Pass FDA eCopy Validator tool                 | Not validated against the FDA eCopy Validator tool.                                     | Gap     | Not Committed     |

### 5.3 Compliance Summary

|                                                                                   |                                                                                 |                                                                                         |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <p><b>Current Alignment</b></p> <p><b>0</b></p> <p>/ 9 requirements fully met</p> | <p><b>Future Alignment</b></p> <p><b>5</b></p> <p>/ 9 fully met + 1 partial</p> | <p><b>Not Committed</b></p> <p><b>3</b></p> <p>Loading index, PDF/A, validator pass</p> |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|

### 5.4 Recommendation

⚠ **For submissions requiring formal FDA eCopy Validator compliance**, RegDesk provides a dedicated eCopy Export workflow. Contact your RegDesk representative for details.

## Section 6 — Delivery Status Summary

The table below summarises the delivery status of all areas covered by this specification. Requirements marked *In Effect* are available in the current product release. Requirements marked *In Delivery* are specified and actively in development.

| Area                                | Key Requirements                                                                                  | Status            |
|-------------------------------------|---------------------------------------------------------------------------------------------------|-------------------|
| Page format                         | A4 portrait, 1-inch margins, backgrounds preserved.                                               | In Effect         |
| Typography — generated pages        | Montserrat across all generated page elements.                                                    | In Effect         |
| Font mapping — authored content     | Editor fonts mapped to embedded print-quality equivalents.                                        | In Effect         |
| Running header                      | Organisation logo, section name, document number and name on every generated page.                | In Effect         |
| Footer branding strip               | Full-width footer image, per-organisation or RegDesk default.                                     | In Effect         |
| Per-organisation header logo        | Logo resolved from export dialogue, org settings or platform default.                             | In Effect         |
| Section context — VOL               | Immediate parent section named in the running header of each generated file.                      | WIP Improvement   |
| Section context — CON               | Section heading on first question; reference line on subsequent questions.                        | WIP Improvement   |
| Page numbers — VOL                  | Printed on every generated page, global position across the export.                               | To be Implemented |
| Page numbers — CON                  | Rendered by the PDF service; aligned to specification.                                            | WIP Improvement   |
| Table of contents — rows            | Sections, subsections, questions, file rows; NA and hidden items excluded.                        | WIP Improvement   |
| Table of contents — page column     | Page numbers aligned to global pagination; TOC length fed back.                                   | To be Implemented |
| Table of contents — typography      | 14 pt bold / 12 pt semibold / 11 pt regular / 11 pt grey italic.                                  | WIP Improvement   |
| Table of contents — indentation     | 0.25 in per level, capped at 1.25 in; printed measurements.                                       | WIP Improvement   |
| Numbering — sections from 1         | First content section is 1; front matter in VOL_000, not numbered.                                | WIP Improvement   |
| Numbering — NA and hidden exclusion | N/A and condition-hidden items consume no number.                                                 | WIP Improvement   |
| Custom prefix validation            | Digit-only prefixes rejected at entry; 20-character limit enforced.                               | WIP Improvement   |
| Folder naming                       | VOL_NNN_uppercase, 3-digit; subsections unpadded; VOL_000_Front Matter.                           | WIP Improvement   |
| File naming                         | Number_Name.pdf, no index suffix; Attachment.N_ continuous across whole export.                   | WIP Improvement   |
| CON structure                       | Attachments folder holds uploaded files only; no authored content duplicated.                     | WIP Improvement   |
| Path length guarantee               | Fair-division trimming ensures every path fits within 260 characters.                             | To be Implemented |
| Illegal and reserved names          | Nine illegal characters rejected at entry and stripped at export; Windows reserved names handled. | WIP Improvement   |
| Extraction guidance                 | READ ME FIRST.txt at archive root; same three lines on download screen.                           | To be Implemented |
| Uploaded filename normalisation     | Normalisation pattern with {{name}}, {{ext}}, {{date}}, {{timestamp}}; original name retained.    | In Effect         |
| Structure preview                   | Available at any time without running an export; flags shortened names.                           | WIP Improvement   |

For questions about delivery timelines or integration requirements, contact your RegDesk account representative.