
WORKSHOP
Requirements-driven Intelligent Content
Scott DeLoach
ClickStart
Thomas Bro-Rasmussen
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Overview

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What we will cover

- How to identify regulatory requirements
- Issues with traditional development processes
- How to develop a requirements-driven process
- How to manage requirements

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Identifying requirements

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What's regulated?

- Manufacturer name and address requirements
- Intended use and audience
- Directions for use
- Alert formatting and use (Danger, Warning, and Caution)
- Installation information
- Handling instructions
- Storage information
- When statements must be provided in multiple languages
- Risk/benefit information
- Cleaning instructions
- Maintenance information

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Common standards, directives, and regulations

IEC/IEEE 82079-1

- International standard
- General principles and detailed design requirements

ISO 3864-2 and ANSI Z535

- International standard
- Alert formatting and use (Danger, Warning, and Caution)

RoHS ("Restriction of Hazardous Substances") Regulations and WEEE ("Waste Electrical and Electronic Equipment") Directive

- Required in Europe, UK, and some states in USA
- How to handle and dispose of potentially environmentally harmful components (e.g. batteries)

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Example

WEEE Article 14.4

"With a view to minimising the disposal of WEEE as unsorted municipal waste and to facilitating its separate collection, Member States shall ensure that producers appropriately mark — preferably in accordance with the European standard EN 50419 (1) — EEE placed on the market with the symbol shown in Annex IX. In exceptional cases, where this is necessary because of the size or the function of the product, the symbol shall be printed on the packaging, on the instructions for use and on the warranty of the EEE."

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Example

WEEE Article 14.4

The symbol on the product, the accessories or packaging indicates that this device shall not be treated as unsorted municipal waste, but shall be collected separately.

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Example

EU 2017745 Article 13.3 — Regulation on Medical Devices

"Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer."

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Example

EU 2017745, EU 93/42/EEC, and FDA

Manufacturer according to EU Medical Device Directive 93/42/EEC:	Manufacturer according to FDA:
Beltone A/S Lautrupbjerg 7 DK-2750 Ballerup Denmark Tel.: +45 4575 1111 beltone.com CVR no. 55082715	**Beltone** 8001 E Bloomington Freeway Bloomington, MN 55420 USA 1-800-BELTONE beltone.com

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EU requirements (potential/partial)

- IEC/IEEE 82079-1
- ISO 3864 and ANSI Z535
- RoHS Regulations/WEEE Directive

- EMC Directive 2009/48/EU Safety on Toys
- EMC Directive 2014/30/EU relating to electromagnetic compatibility
- EMC Directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits
- EMC Directive 2014/53/EU on radio equipment
- Regulation (EU) 2016/425 relating to Personal Protective Equipment
- Regulation (EU) 2017/745 relating to Medical Devices

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UK requirements (potential/partial)

- IEC/IEEE 82079-1
- ISO 3864 and ANSI Z535
- RoHS Regulations/WEEE Directive

- BS ISO 20607
- Electrical Equipment (Safety) Regulations
- Electromagnetic Compatibility Regulations
- Radio Equipment Regulations
- Machinery Regulations
- Medical Device Regulation (EU) 2017/745
- UK MDR 2002
- UKCA marking requirements

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US requirements (potential/partial)

- IEC/IEEE 82079-1
- ISO 3864 and ANSI Z535
- RoHS Regulations/WEEE Directive

- FDA CFR - Code of Federal Regulations Title 21
- FCC regulations
- Electromagnetic Compatibility Directive (EMCD)

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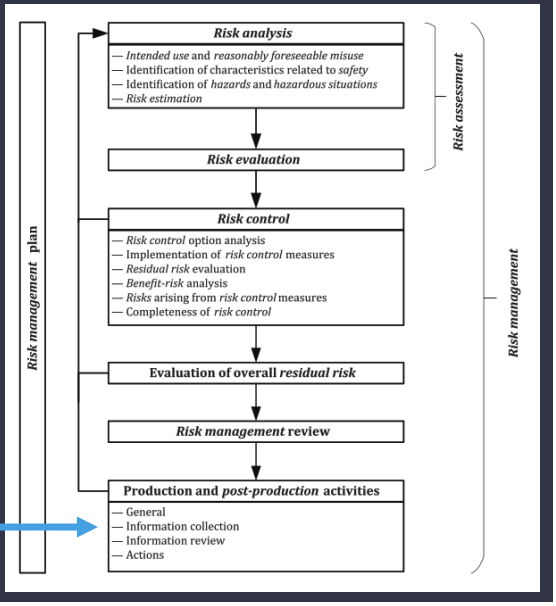
How are requirements identified?

Risk management plan

ISO 14971 Medical devices — Application of risk management to medical devices

Risks must be mitigated in product labeling, usually with an alert.



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Content development process

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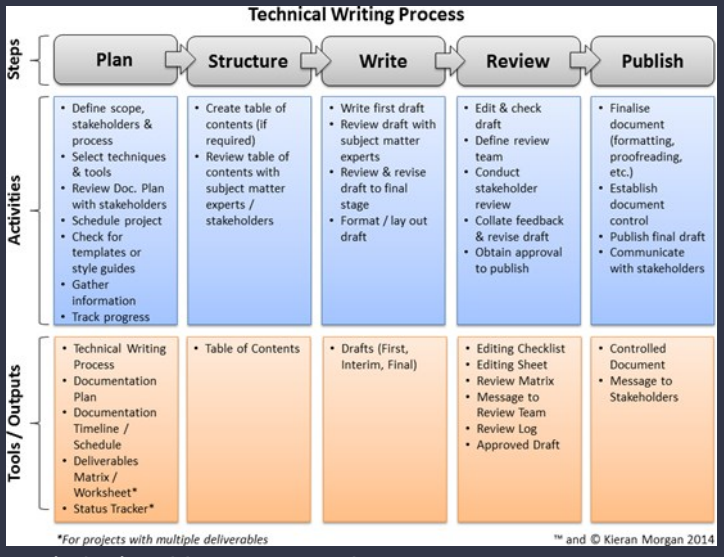
Typical technical writing process



Technical Writing Process, Kieran Moran 2014

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Typical process: issues

- Requirements identified during review
- Reviewer must determine what's missing or incorrectly formatted

Results

- Not traceable (content management, audits)
- Reviews are extremely tedious and time consuming
- Can cause large scale additions/modifications
- Must be repeated with every update

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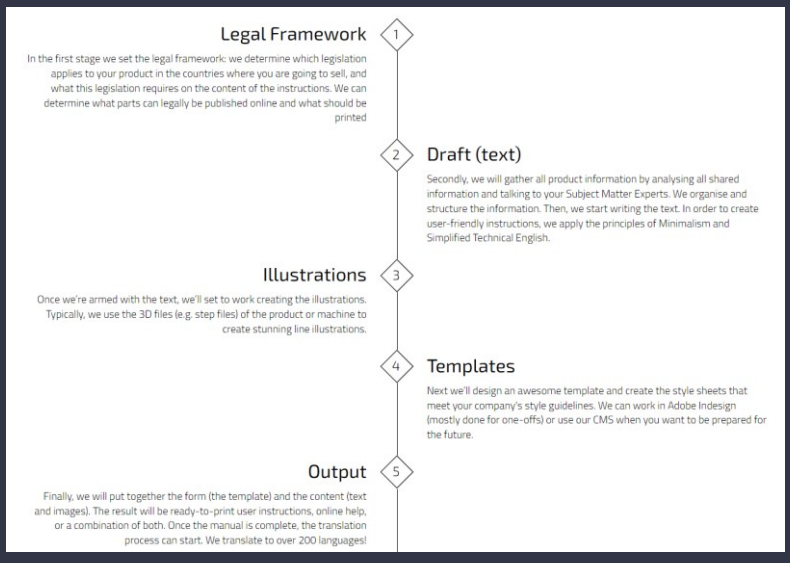
Requirements-based process



Instrktiv.com

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Requirements-based process

- Requirements identified before content is created
- Content and formatting defined by requirements

Results

- Traceable (content management, audits)
- Reviews are streamlined: focus on verifying rather than identifying
- Additions/changes are usually minor
- Updates can focus on new and revised content/regulations

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Developing a requirements-based process

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How to develop a requirements-based process

- Identify requirements
- Create a requirements list/database
- Involve risk assessment team before content is developed
- Outline content based on requirements
- Match requirements to content
- Review based on checklists
- Manage requirements list/database

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Identify requirements

Known and potential requirements
- meet with risk assessment team

Product/industry requirements
- analyze current and competitor documentation

Sales region requirements
- meet with product management/sales

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Create a requirements list/database

Goals
- Shared/accessible
- Searchable
- Match requirements to required/sample content
- Match requirements to products

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Requirements list/database example

Requirement¤	Requirement·Text¤	Resolution¤	Product·A¤	Product·B¤
WEEE·Article·14.4¤	"With·a·view·to·minimising·the·disposal·of·WEEE·as·unsorted·municipal·waste·and·to·facilitating·its·separate·collection,·Member·States·shall·ensure·that·producers·appropriately·mark·—·preferably·in·accordance·with·the·European·standard·EN·50419·(1)·—·EEE·placed·on·the·market·with·the·symbol·shown·in·Annex·IX.·In·exceptional·cases,·where·this·is·necessary·because·of·the·size·or·the·function·of·the·product,·the·symbol·shall·be·printed·on·the·packaging,·on·the·instructions·for·use·and·on·the·warranty·of·the·EEE."¶  ¤	 ¶ The·symbol·on·the·product,·the·accessories·or·packaging·indicates·that·this·device·shall·not·be·treated·as·unsorted·municipal·waste,·but·shall·be·collected·separately.¤	YES¤	YES¤
EU·2017745·Article·13.3¤	"Importers·shall·indicate·on·the·device·or·on·its·packaging·or·in·a·document·accompanying·the·device·their·name,·registered·trade·name·or·registered·trade·mark,·their·registered·place·of·business·and·the·address·at·which·they·can·be·contacted,·so·that·their·location·can·be·established.·They·shall·ensure·that·any·additional·label·does·not·obscure·any·information·on·the·label·provided·by·the·manufacturer."¤	Manufacturer·according·to·EU·Medical·Device·Directive·93/42/EEC:·¶ Beltone·A/S·¶ Lautrupbjerg·7·¶ DK-2750·Ballerup·¶ Denmark·¶ Tel.:·+45·4575·1111·¶ beltone.com·¶ CVR·no.·55082715·¶ ¶ Manufacturer·according·to·FDA:¶ Beltone·¶ 8001·E·Bloomington·Freeway·Bloomington,·MN·55420·USA·¶ 1-800-BELTONE·¶ beltone.com¤	YES¤	YES¤

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Involve risk assessment team before content is developed

Benefits

- Shared responsibility
- Content developer can help ensure requirements are met
- Less time/stress for risk assessment team to review

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Outline content based on requirements

- Review requirements database/list
- Identify and add applicable requirements
- Fill “gaps”
- Identify required content in outline

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Match requirements to content

Use “identifiers” to match content to requirements

Potential options

- Data attributes
- IDs
- Meta tags
- Concept markers

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Match requirements to content: example

Content developer

- Add requirement concept markers to content
- Create a “Requirements Met” topic using a concept proxy
- Include the Requirements Met topic in review PDF

- popularized by Madelyn Boudreaux

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Review based on checklists

Reviewer

- Use Requirements Met topic to approve included requirements
- Use requirements database/list to identify missing requirements

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Manage requirements list/database

Risk assessment team

- Update requirements list/database based on updates to regulatory documents
- Update applicable products

Content developer

- Add new resolution content
- Update resolution content as needed

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Potential improvements

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Discussion

Requirements list improvements

Requirement¤	Requirement·Text¤	Resolution¤	Product·A¤	Product·B¤
WEEE·Article·14.4¤	"With·a·view·to·minimising·the·disposal·of·WEEE·as·unsorted·municipal·waste·and·to·facilitating·its·separate·collection,·Member·States·shall·ensure·that·producers·appropriately·mark·—·preferably·in·accordance·with·the·European·standard·EN·50419·(1)·—·EEE·placed·on·the·market·with·the·symbol·shown·in·Annex·IX.·In·exceptional·cases,·where·this·is·necessary·because·of·the·size·or·the·function·of·the·product,·the·symbol·shall·be·printed·on·the·packaging,·on·the·instructions·for·use·and·on·the·warranty·of·the·EEE."¶  ¤	 ¶ The·symbol·on·the·product,·the·accessories·or·packaging·indicates·that·this·device·shall·not·be·treated·as·unsorted·municipal·waste,·but·shall·be·collected·separately.¤	YES¤	YES¤
EU·2017745·Article·13.3¤	"Importers·shall·indicate·on·the·device·or·on·its·packaging·or·in·a·document·accompanying·the·device·their·name,·registered·trade·name·or·registered·trade·mark,·their·registered·place·of·business·and·the·address·at·which·they·can·be·contacted,·so·that·their·location·can·be·established.·They·shall·ensure·that·any·additional·label·does·not·obscure·any·information·on·the·label·provided·by·the·manufacturer."¤	Manufacturer·according·to·EU·Medical·Device·Directive·93/42/EEC:·¶ Beltone·A/S·¶ Lautrupbjerg·7·¶ DK-2750·Ballerup·¶ Denmark·¶ Tel.:·+45·4575·1111·¶ beltone.com·¶ CVR·no.·55082715·¶ ¶ Manufacturer·according·to·FDA:¶ Beltone·¶ 8001·E·Bloomington·Freeway·¶ Bloomington,·MN·55420·USA·¶ 1-800-BELTONE·¶ beltone.com¤	YES¤	YES¤

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Discussion

Requirements list improvements

- Filter based on product type, product, etc.
- Identify new and modified requirements
- Link to requirements documents
- Create "snippets" for resolutions and provide links (single source)
- Use the same application for requirements list and content

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Thank you!

Scott DeLoach

ClickStart
scott@clickstart.net

Thomas Bro-Rasmussen

GN Hearing A/S
tbrasmussen@gnhearing.com