

How MadCap Flare Promotes Safety and Effectiveness in Service Documentation

PRESENTED BY

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MW

A little backstory...

- 2013 – Asked to create an approach to documentation that ensured consistent repair procedures
- Focus on
 - Consistent procedures
 - Consistent voice
 - Ongoing safety
- Proposed using topic-based authoring
- Brand **A** !!

Topic-based authoring – oil change analogy

- When I change the oil in my car, I always start the same way
 - Turn off the car
 - Lift the hood
- I do those things when I do other maintenance
 - Change battery
 - Add wiper fluid
 - Check the coolant level
- Why do it differently?

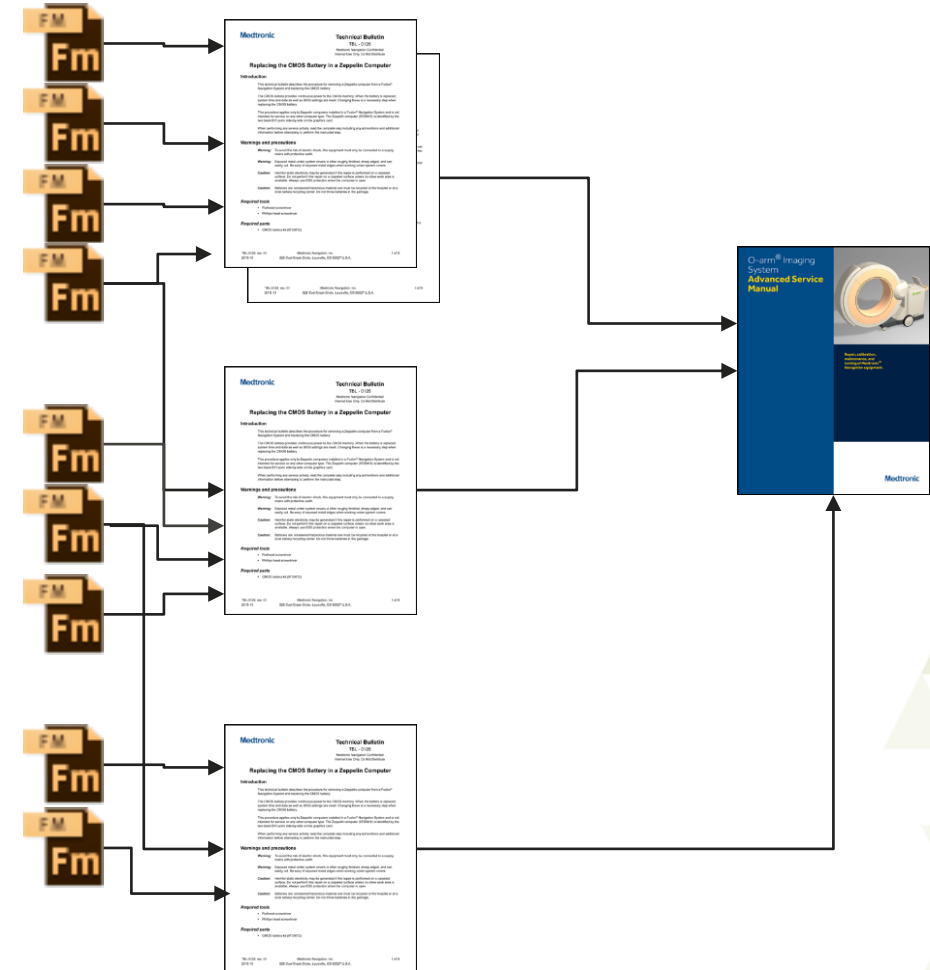
Topic-based authoring is analogous to manufacturing



- In manufacturing
 - Create the part
 - Test the individual part
 - Assemble it into the complete whole
 - Test the completed whole
 - We should take this approach with documentation
- Test the block of content
- Test the completed procedure

A little backstory...

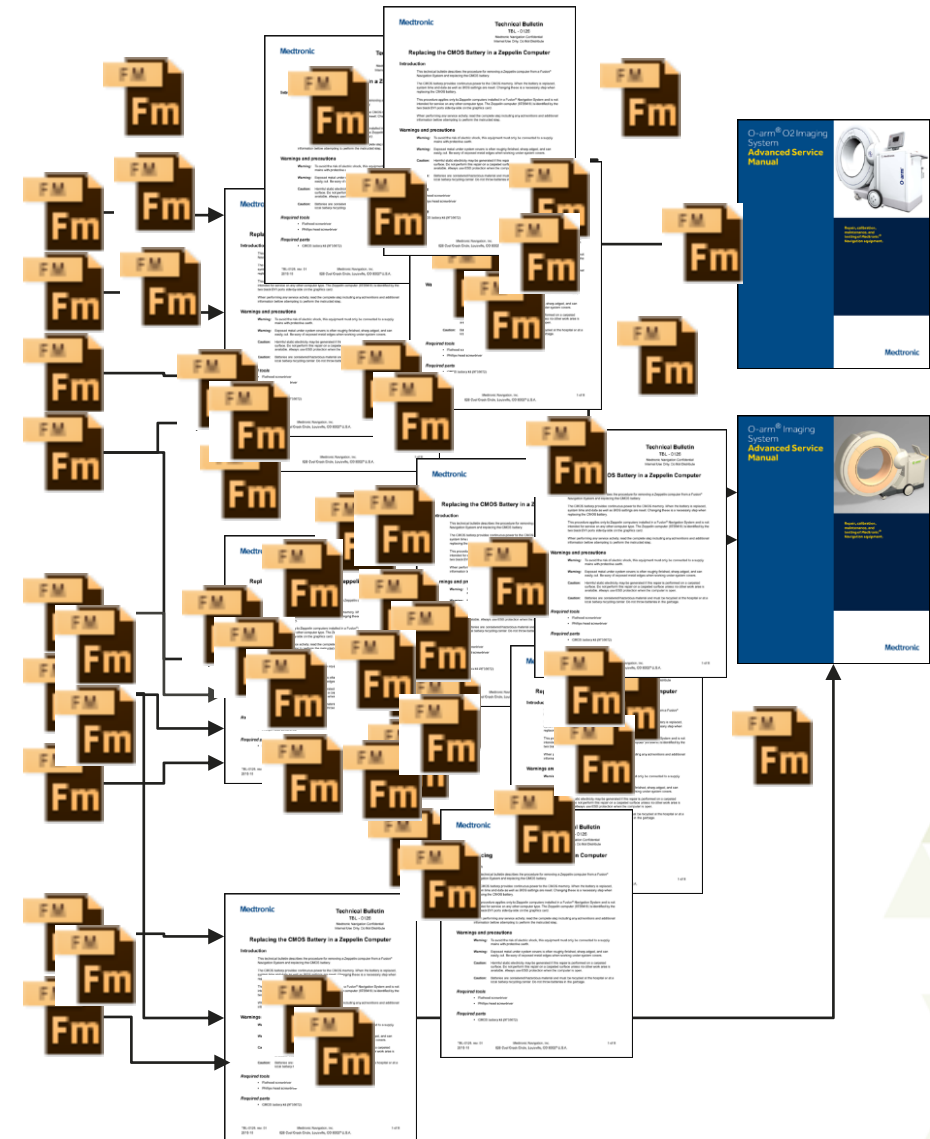
- Very effective with one manual for one product
 - 1,320 pages
 - 159 procedures
 - Parts replacements
 - Calibrations
 - Tests
 - ~80 troubleshooting procedures
 - Took almost two years



A little backstory...

Added products and manuals

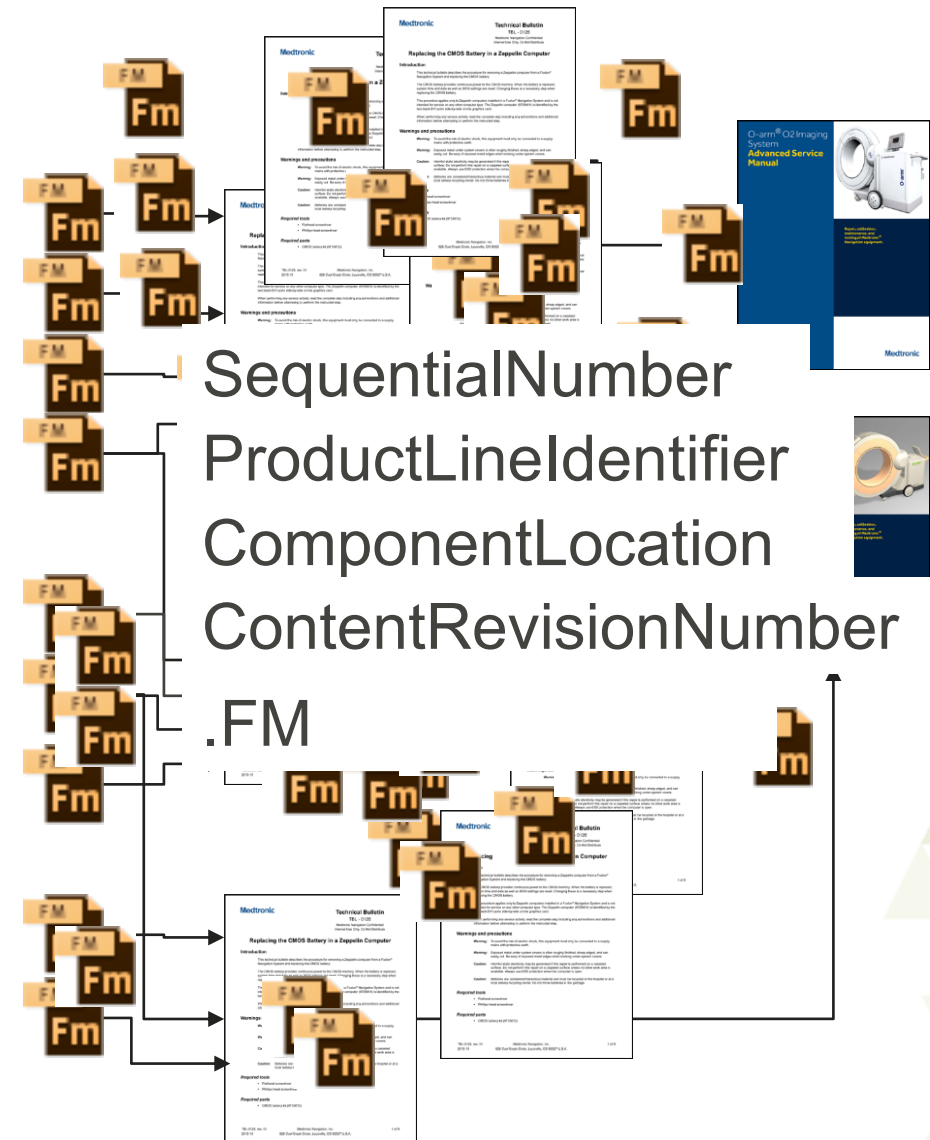
- No clear strategy for our re-use other than just “Re-Use!!”
- Bring order to the chaos



A little backstory...

Added products and manuals

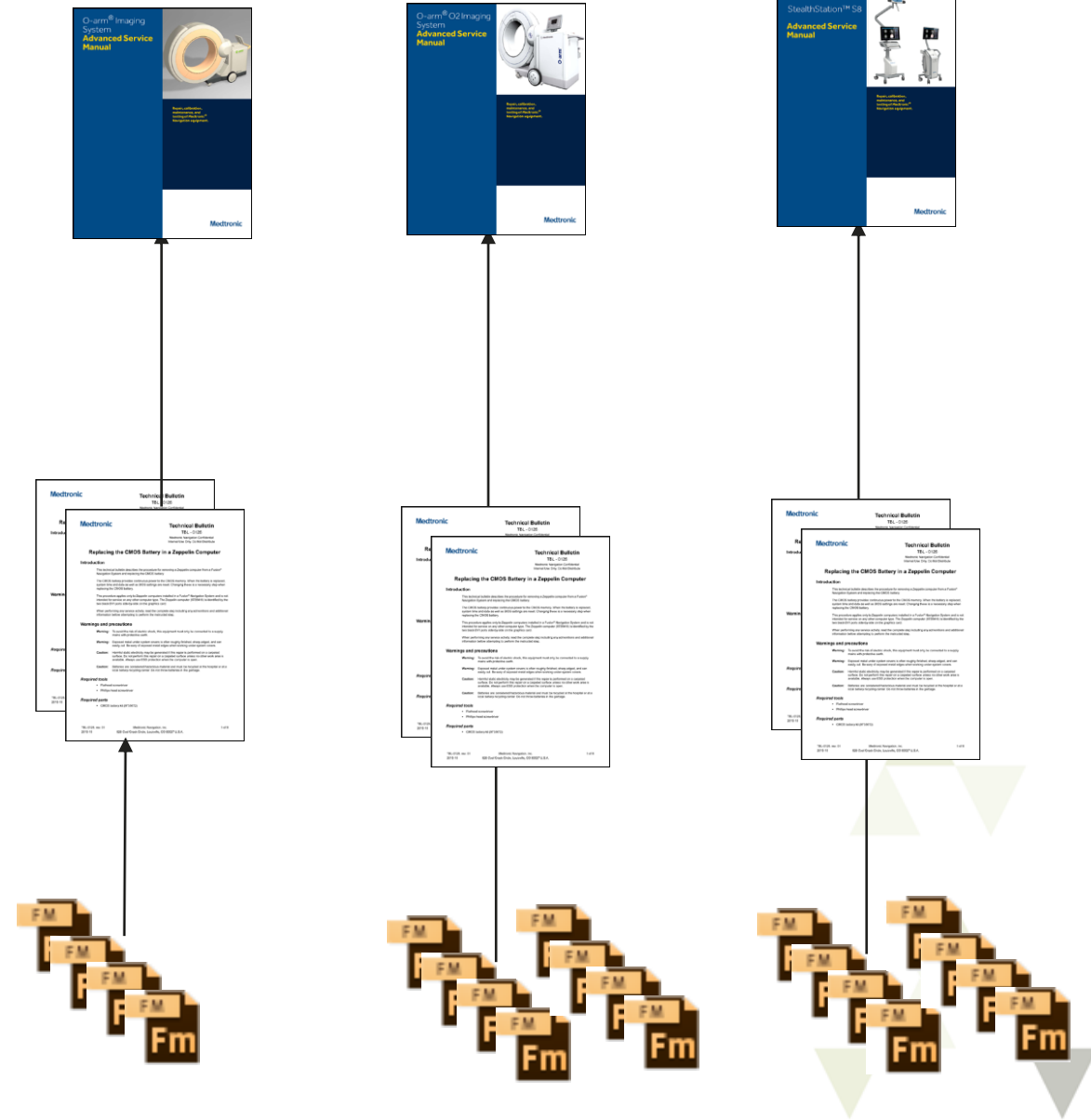
- No clear strategy for our re-use other than just “Re-Use!!”
- Bring order to the chaos
- Became a Rube Goldberg Content Management System



A little backstory...

Lessons learned

- Know your content.
Understand how much content will actually be re-used.
- Silos aren't a bad thing.
They are a legitimate way to limit scope
- If you have to test, scope re-tests across all procedures.



A little backstory...



2016

Converted our entire documentation set from Brand **A** to Madcap Flare

- Seven product lines
- 65 documents in the wild
- +1,300 blocks of content
- Fiscal year 2017 we published how many pages?

Our implementation today

- MadCap Flare 2017
- High definition digital cameras to record procedures
- Adobe Photoshop and Illustrator for image preparation
- Capture for callout numbers
- All sits on top of an SVN repository
 - Already set-up from our old architecture

*The Practicality of
“Safe” and “Effective”*

Medtronic – What we do

- External defibrillators
- Pacing Systems
- Heart Valves
- Guide Wires
- Shunts
- Spinal Cord Neurostimulation Systems
- Balloon Sinus Dilation



Medtronic – What we also do

Fusion™ ENT Surgical Navigation System

“...real-time positioning information that can help you navigate in and around the sinuses and way from critical structures during removal of diseased tissue.”



Medtronic – What we also do

StealthStation™ S8 Navigation System

“...offers both optical and EM tracking capabilities....for neurosurgery and spine procedures including biopsy, tumor resection, and treatment of spinal trauma...”



Medtronic – What we also do

O-arm™ Surgical Imaging System

“...a mobile x-ray system designed for 2D fluoroscopic and 3D imaging for adult and pediatric patients.”



Super-heroic!!



Doctor Strange. Dir. Scott Derrickson. Perf. Benedict Cumberbatch, Rachel McAdams. Marvel Studios, 2016. Film.

The FDA – Safe and Effective

- The Food and Drug Administration is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices.
 - U.S Food & Drug Administration, FDA Fundamentals

Medtronic Global Service Operations

– *What we do*

- Service documentation for these capital systems
 - Service documentation describes the repair, calibration, maintenance, and testing of Medtronic Navigation equipment.
 - Service documentation does not describe the use of Medtronic Navigation equipment in a clinical setting or a therapeutic manner.
- How do you take the system apart, affect a repair, and return it to service for a customer.

What we do

- When you take them apart medical devices have more in common with industrial equipment
- Common hazards for service engineers
 - Unfinished edges that easily cut skin
 - Crush or amputation injury
 - Extremely high voltage
 - Exposure to ionizing radiation
 - Exposure to laser radiation (permanent injury in milliseconds)

Creating Safe and Effective documentation

- Our service procedures should be safe.
 - Admonish the engineer of all hazards in all situations
 - Assure easy access to information in safety sections
 - Account for common failure modes
 - Provide consistent warnings and cautions

Creating Safe and Effective documentation

- Our instructions should be effective
 - Consistency from procedure to procedure
 - The procedure should do what we say it does.
 - Nothing more. Nothing less.
 - Procedure not technique
 - Procedures have all the steps from 1 to the end
 - Common tools throughout all procedures





Promoting safety

Common hazards



- Disassembled medical devices have much in common with industrial equipment
- Warning versus Caution
 - Warning:** Failure to observe a warning may result in physical injury to a patient, the operator, the field service engineer, or by-standers.
 - Caution:** Failure to observe a caution could result in damaged equipment, forfeited time or effort, or the need to abort use of the system.

Common hazards

- Common hazards
 - Unfinished edges that easily cut skin
 - Crush or amputation injury
 - Extremely high voltage
 - Exposure to ionizing radiation
 - Exposure to laser radiation (permanent injury in milliseconds)

Hazards you might not have considered



- Consider damage to the system or surrounding property to be hazards as well
- Other warnings and cautions
 - Use a spotter when moving the system to avoid damage to facility walls and doors
 - The part is heavy and may be damaged if allowed to fall after the last fastener is removed
 - The Ethernet cable may be damaged without sufficient strain relief resulting in data interruptions

Writers create a consistent voice



- Admonitions provide a consistent message

Three part admonition structure

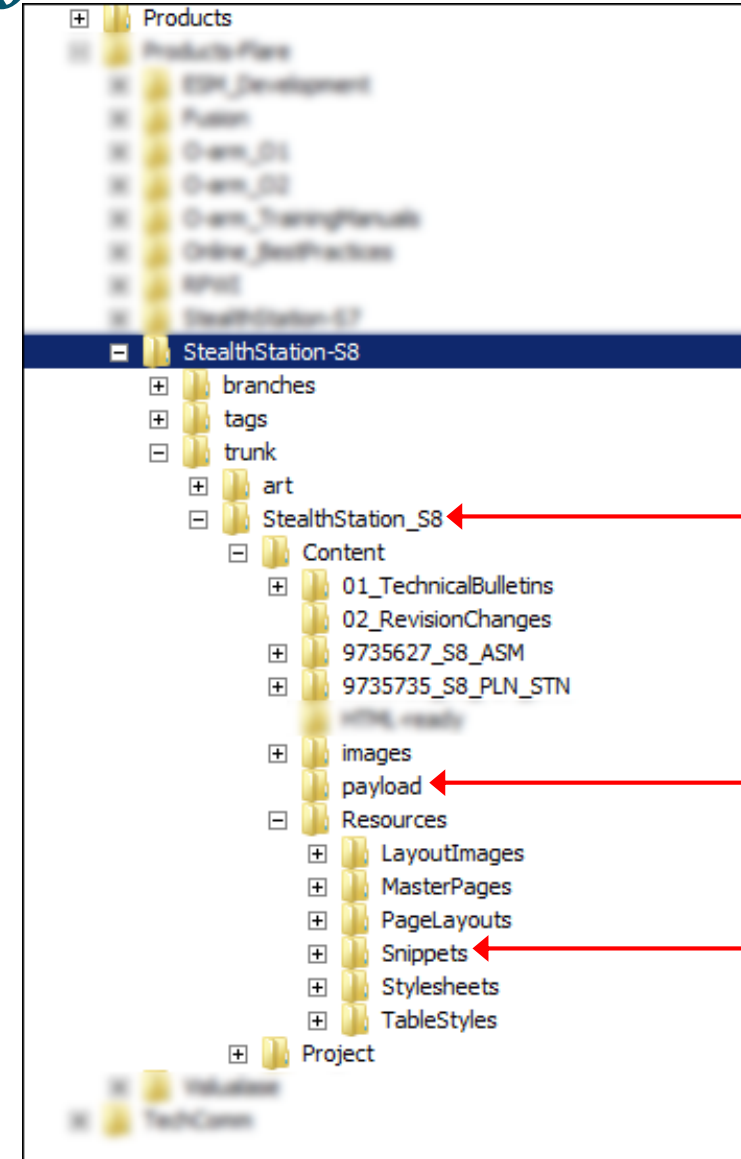
Signal Word: Description of the hazard. Potential harm resulting from ignoring the admonition. Methods to mitigate the hazard.

Most basic safety information

- Safety sections
 - Overall hazards
 - Personal Protective Equipment
 - Cross-reference or re-used content?
- Admonitions
 - Warnings and cautions at the point of use
 - Snippet vs blocks of content

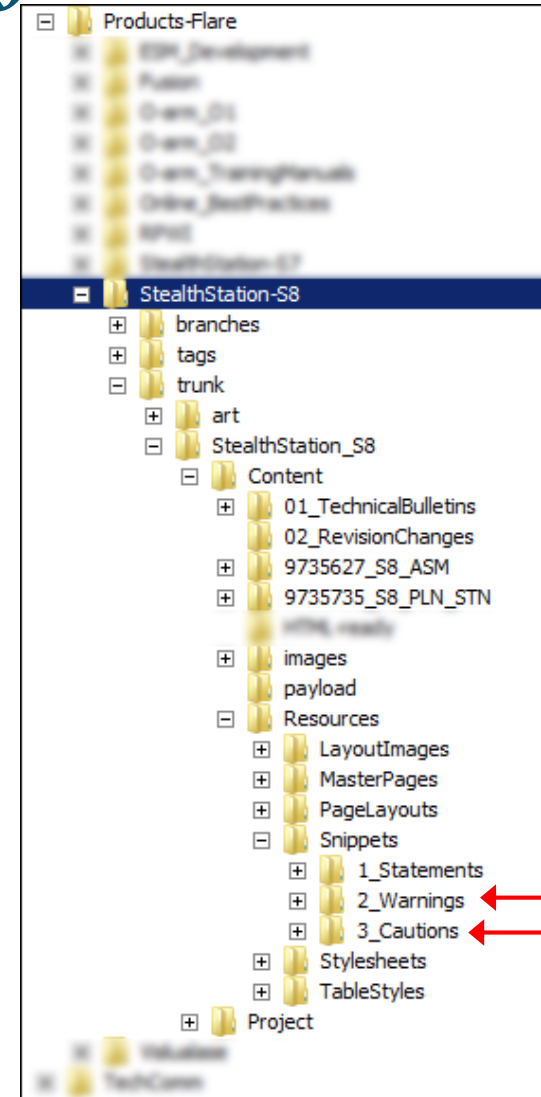
Structuring admonition information

- SVN Trunk
 - Payload contains all re-usable content
 - Sibling of the individual documents to promote re-use



Structuring admonition information

- Snippets directory
 - Segregated by admonition type
 - Resources is still a sibling of the other documents so re-use is not affected.
 - Admonitions can be connected or disconnected.



Admonitions as connected snippets

- Pros
 - Easy to re-use the content
 - Easy to share across documents in a product silo or project
 - Easy to create a Warnings and cautions section.
- Cons
 - Admonitions are often slightly different from usage to usage.
 - Links in the snippets are difficult
 - Difficult to output for review
 - Formatting doesn't always shine through.

Admonitions as disconnect snippets

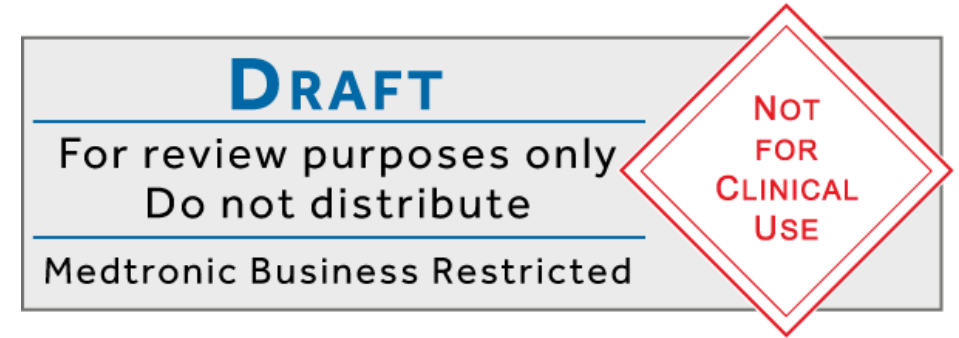
- Pros
 - Good starting point for a new admonitions
 - Can be customized to the individual usage
- Cons
 - Effectively becomes cut and paste
 - Impossible to update universally
 - Links are difficult
 - Difficult to output for review

Safety information as content block

- Pros
 - Follows our re-use strategy
 - Links are easy
 - Formatting is obvious
 - It's just more content
- Cons
 - Difficult to imbed in other content blocks
 - Difficult to customize for specific implementation

Watermarks

- Every draft is marked as “Not for clinical use.”
- Reviewers are field personnel
- Potential for an untested procedure to be released into the wild
- Every document has the business classification
- Supported by multiple targets for multiple review cycles





Promoting effectiveness

What is effectiveness?

- Do the procedures do what we say they do?
- Do the procedures have all the steps necessary?
 - Branch steps
 - Do/until
 - If/then/else
- Applies to all revisions of the system
 - Major updates
 - Minor change
- Anticipated failure modes

How do we measure effectiveness?

- Reviews
 - SME reviews
 - Dry-run testing
 - Verification testing
 - All documented and recorded
- Can we follow the procedures?



Effectiveness of reusability

- Write once. Use Many.
- Determine the best possible approach
- Re-use that approach for similar procedures
- Re-used, tested across multiple procedures is effective

Effectiveness of reusability

- Everything you need from step 1 to the end
- Massive procedures, but each component is tested repeatedly
- Single voice across documents
- Consistency of approach
 - Wrench vs Driver
 - Screw vs Bolt vs Fastener
 - Screw vs Tighten

Effectiveness of reusability

- Who knows what these are?
 - Channellocks[®]
 - Irwin Tools[®] Vise-Grip
 - Irwin Tools[®] Groove Joint
 - Milwaukee[®] Torque Lock Locking Pliers
 - Husky[®] Straight Jaw Locking Pliers



Disadvantages

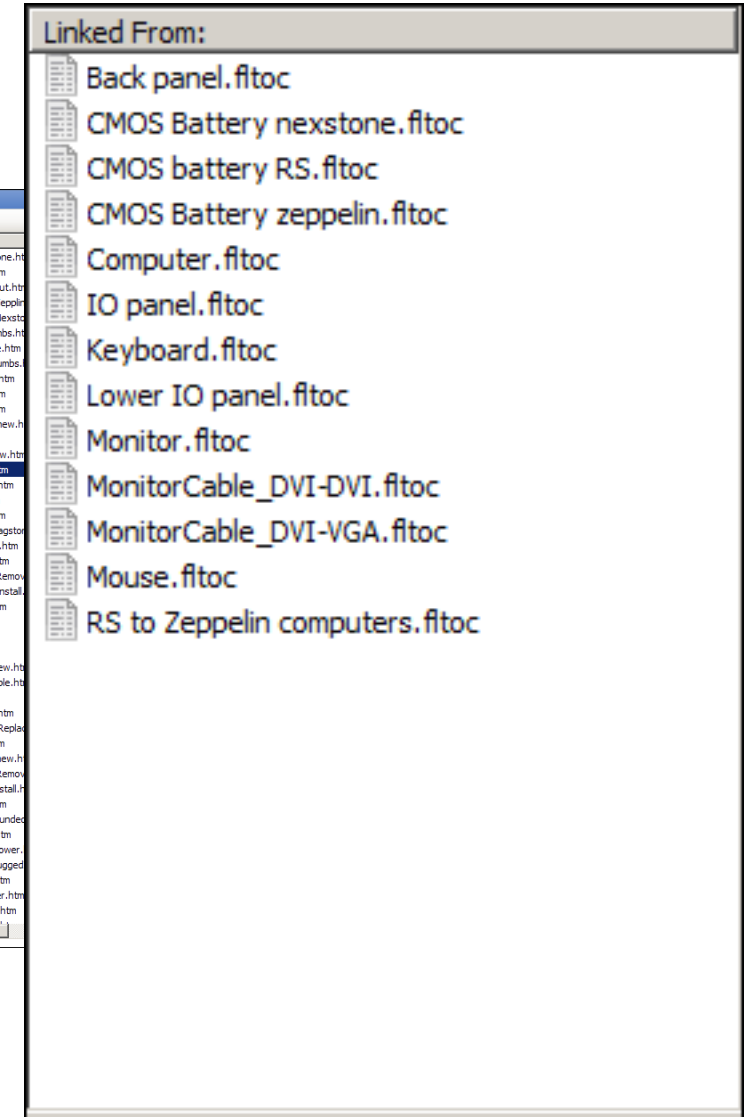
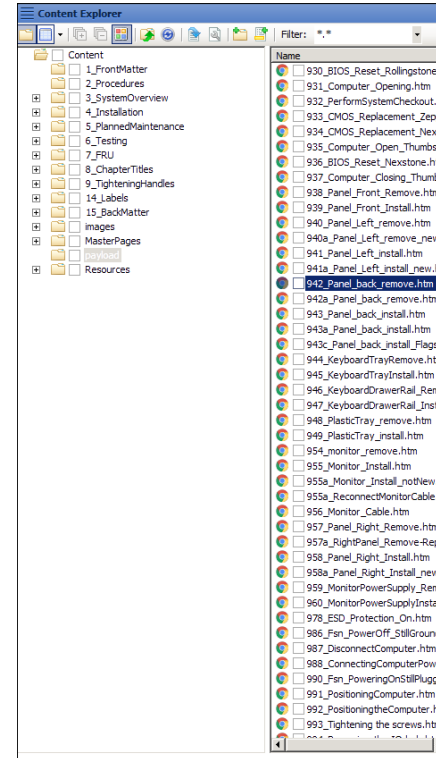


Disadvantages

- Difficult concept because it diverges from the traditional authoring approach
- Easy to get overwhelmed by the amount of content and the places it is used
- Rigorous approach to assembly and tracking where content is used

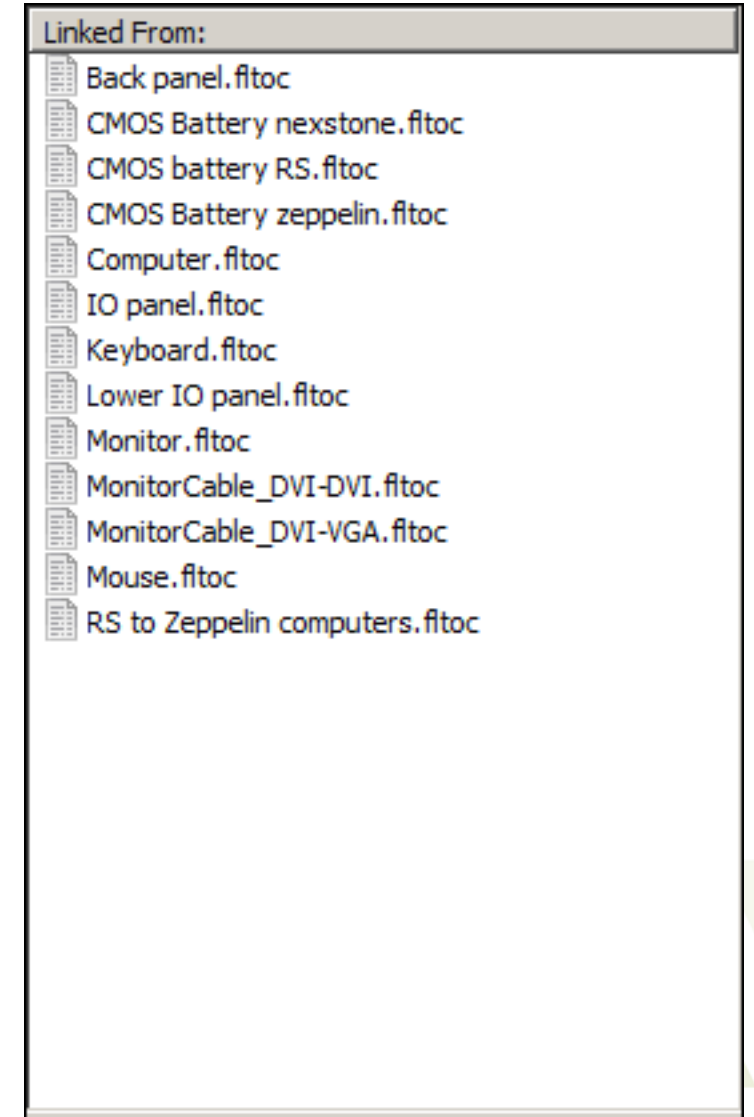
Disadvantages

- Minor changes to content require additional cross-checks. No such thing as “just change that line.”
 - What other procedures or documents are impacted?
 - Does the change drive a re-test?



Disadvantages

- **ENHANCEMENT REQUEST:** Make “Linked From” an exportable report.



Disadvantages

- Easy to outpace your support
 - Get ahead of the project
 - Work faster than your SMEs can review
 - Team looks idle when in fact they are just awesome.



In closing

Supporting “Safe and Effective”

- Safe and effective
 - Safe, protects the engineer, by-standers, property, and the system
 - Effective, completes a repair and stays on point

Supporting “Safe and Effective”

- Safety
 - Re-usable admonitions provide consistency
 - Re-usable admonitions support a common voice and message
 - Common targets support multiple review cycles

Supporting “Safe and Effective”

- Effectiveness
 - One way of doing things
 - One language
 - Easy to distribute writing responsibilities across multiple procedures
 - Even massive procedures can be broken down to easily to scope and implement writing tasks

Creating Efficiency

- Write once, Use Many
- Universal updates
- Hockey-stick productivity curve
- A measure of efficiency:
 - In fiscal year 2016, three writers published only 806 pages using Brand **A**
 - In fiscal year 2017, three writers published almost 11,000 pages of documentation using MadCap Flare.



Questions