

What comes to mind when
you hear the word **QUALITY**?



NORTON
HEALTHCARE

Opening Question (Live):

What comes to mind when
you hear the word
QUALITY?

Participants can vote at [slido.com](https://www.slido.com) with #435337

Use your camera and
hover over the QR
code on the screen.

Touch the Yellow
Button to go to Survey
Page



An ISO 13485 Certified In-House HTM Program?

It Can Be Done!

**Meeting Regulatory/Accreditation
Requirements Track**



Mark Cooksey, BSME, MBA, CLSSBB
Member MDSC, Norton Healthcare



NORTON
HEALTHCARE

Typical Responses

What comes to mind
when you hear the
word

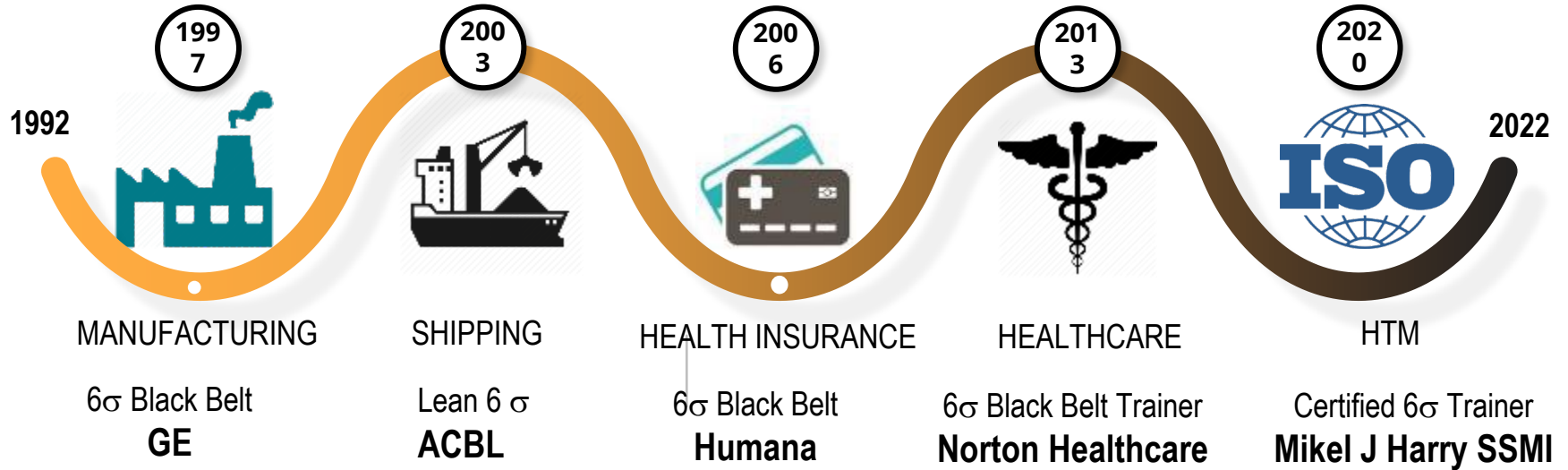
QUALITY?





ISO 13485 provides both the **guard rails** and the **steering controls**

My 30 Year Quality Marathon



ISO 13485 Success Strategies



Mark R. Cooksey
ISO 13485
Quality Leader,
Norton Healthcare

01

Why ISO 13485?

Why NHC's Clinical Engineering Group chose to make the journey

02

How does ISO 13485 Work?

A comprehensive quality management system to improve service, quality, and value

03

Strategies to overcome inertia

Changing the tire while the car is still running

04

Case Studies – Benefits from ISO 13485

See examples of new quality tools



Why are there **two parts** to quality?



How
Can
It
Be
Improved?



How
Well
Is
It
Working?

What if only OEMs were allowed to service medical equipment?



PATIENT CARE IN 2020

The Norton Healthcare system provided care at

5 HOSPITALS

7 OUTPATIENT CENTERS

16 NORTON IMMEDIATE CARE CENTERS

MORE THAN
250 PRIMARY CARE AND SPECIALTY PRACTICE LOCATIONS



1,514
staffed beds

Licensed beds: 1,907



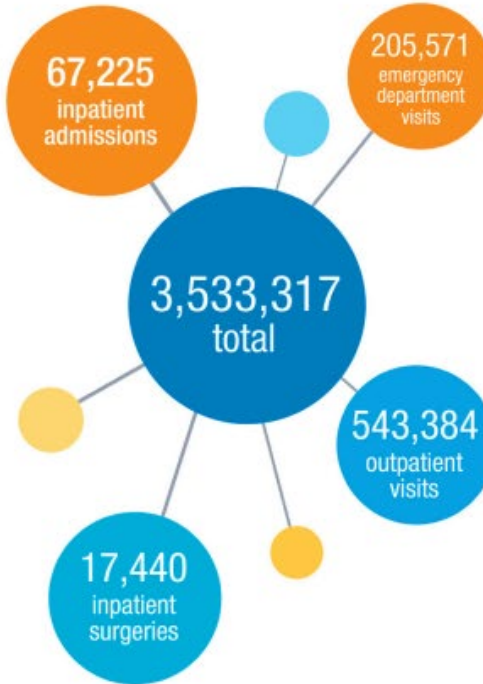
16,950
employees



1,630
providers

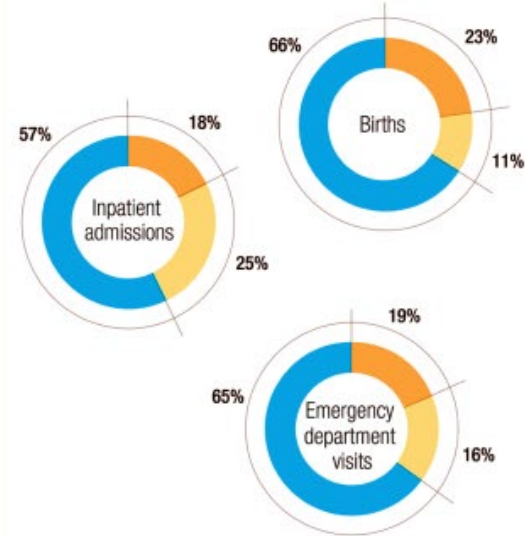
As of Dec. 31, 2020

PATIENT ENCOUNTERS IN 2020



MARKET SHARE IN 2020

Norton Healthcare continues to be the area's leading health care provider, with a large market share in some key areas.



■ Norton Healthcare
■ Baptist Health Louisville
■ UofL Health

Norton Healthcare is the leader in its market





STAY SAFE
KEEP THE
FAITH[®]



CLINICAL ENGINEERING PURPOSE STATEMENT

“Clinical Engineering *maintains and supports* Norton Healthcare’s **clinical technology** to ensure the best possible patient outcomes through risk reduction, continuous quality improvement, stewardship of resources, compliance with regulatory requirements, and exceptional customer service.”



Clinical Engineering ***maintains and supports*** Norton Healthcare's **clinical technology** to ensure the best possible **patient** outcomes through

- risk reduction**
- continuous **quality improvement**
- stewardship of **resources**
- compliance with **regulatory** requirements
- exceptional **customer service**

NHC CE Purpose Statement aligns with ISO 13485



Supplier

**Provider
HTM Staff**

**V
A
L
U
E**

Customer

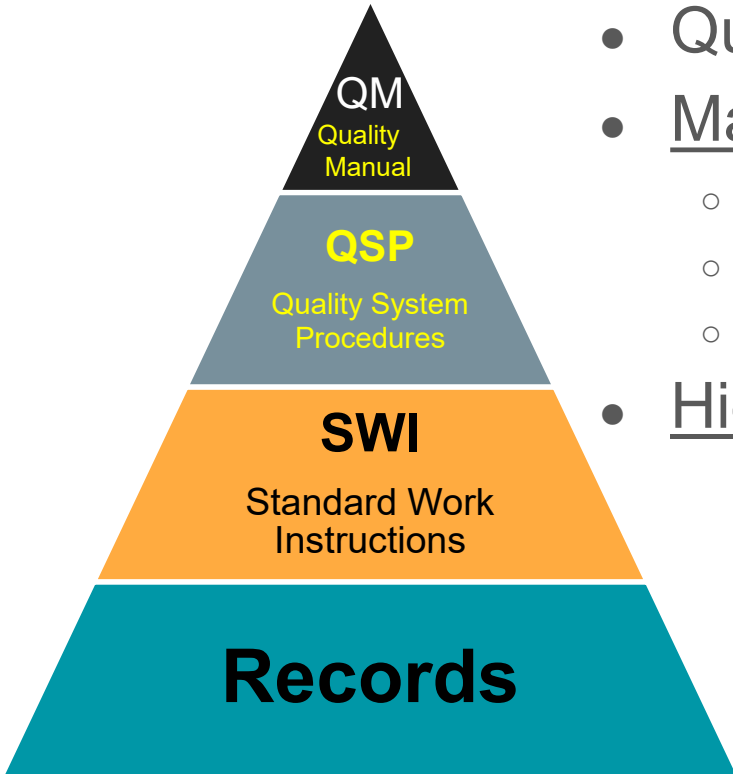
**Patient
Clinical Staff**

An **ISO QMS** promotes stakeholder **value**

Norton Healthcare's Clinical Engineering Department Achieves ISO 13485



What is **ISO 13485**?



- Quality Management System (QMS)
- Management Philosophy
 - Supply Chain
 - Risk Control
 - Continuous Improvement
- Hierarchy of “Living” QMS documentation

Specifically for **Medical Device** Manufacturers & **Service Providers**

Document It

Create QSPs,
SWIs, Records



Do It

Follow the
QMS
processes as
documented

Improve It

Analyze,
Correct,
Prevent,
Change

Prove It

Measure,
Audit, Trend,
Report



SBAR: WHY CE CHOSE ISO 13485

◆ Situation (March 2020)

- Improvement and monitoring of medical device quality is limited
- NHC Clinical Engineering (CE) does not have a Quality Management System (QMS)
- **No** one in NHC CE has **QMS experience**

◆ Background

- The FDA considering adoption of ISO 13485 for those who **service medical equipment**
- NHC CE is an in-house aftermarket servicer

◆ Analysis

- ISO is a well-respected purveyor of standards across multiple industries (e.g., ISO 9001 for manufacturing)
- Key Norton aftermarket servicers are ISO 13485 certified
- ISO 13485 is a QMS **specifically for medical devices** and complementary to existing TJC-related work

◆ Recommendation

- **Proceed** with ISO 13485:2016 implementation
- **Re-purpose** existing FTE to focus on quality as their primary function
- **Partner** with a proven consultant (Emergo) to implement **Jan 1, 2022**

Norton Corporate moved accreditation from TJC to DNV (ISO)



DNV's accreditation approach aligns (NIAHO*) standards with the ISO structure

*National Integrated Accreditation for Healthcare Organizations

Limitations of Random Audit Approach to Quality



- Rules seem arbitrary and punitive
- “Cram-for-the-Exam” audit mentality
- Fear among the hospital staff
- “Just Fix it” thinking

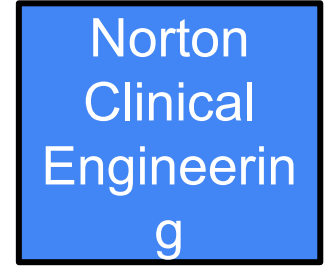


An effective QMS must improve quality, patient safety, and customer satisfaction...and be

sustainable

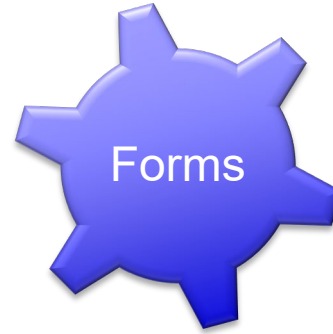


9001 is a **general** quality model for continuous improvement



13485 is a quality model for **medical devices** incorporating **risk management**

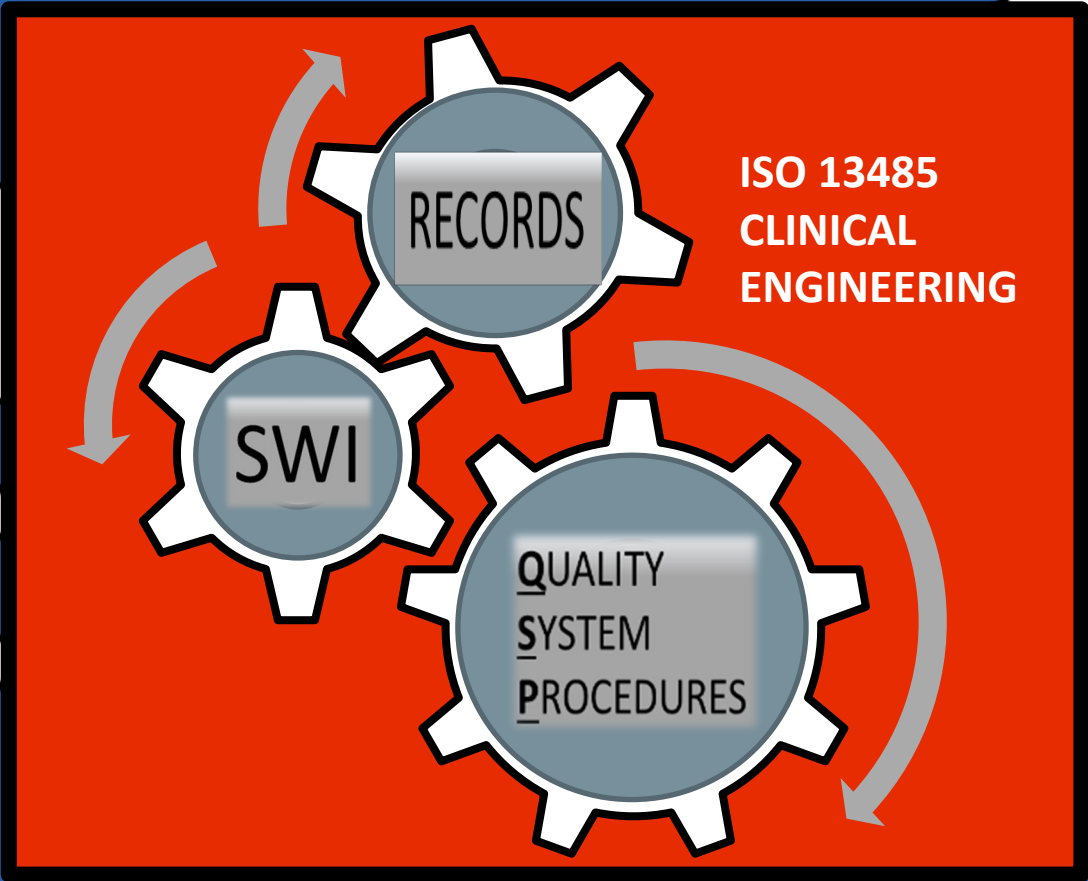
How does **ISO 13485** work?



Clinical Engineering **Before** ISO 13485



ISO 9001
NORTON
CORPORATE



How Does an ISO 13485 QMS Work?



LEGACY APPLICATIONS
SUPPLY CHAIN
CORPORATE POLICIES
SOPs

CLAUSE 4.0
QUALITY
MANUAL
DOCUMENT
CONTROL



CLAUSE 5.0
MANAGEMENT
RESPONSIBILITY



CLAUSE 6.0
HUMAN
RESOURCES



CLAUSE 7.0
PRODUCT / SERVICE
DEVELOPMENT



CLAUSE 8.0
QUALITY
IMPROVEMENT



CLINICAL ENGINEERING



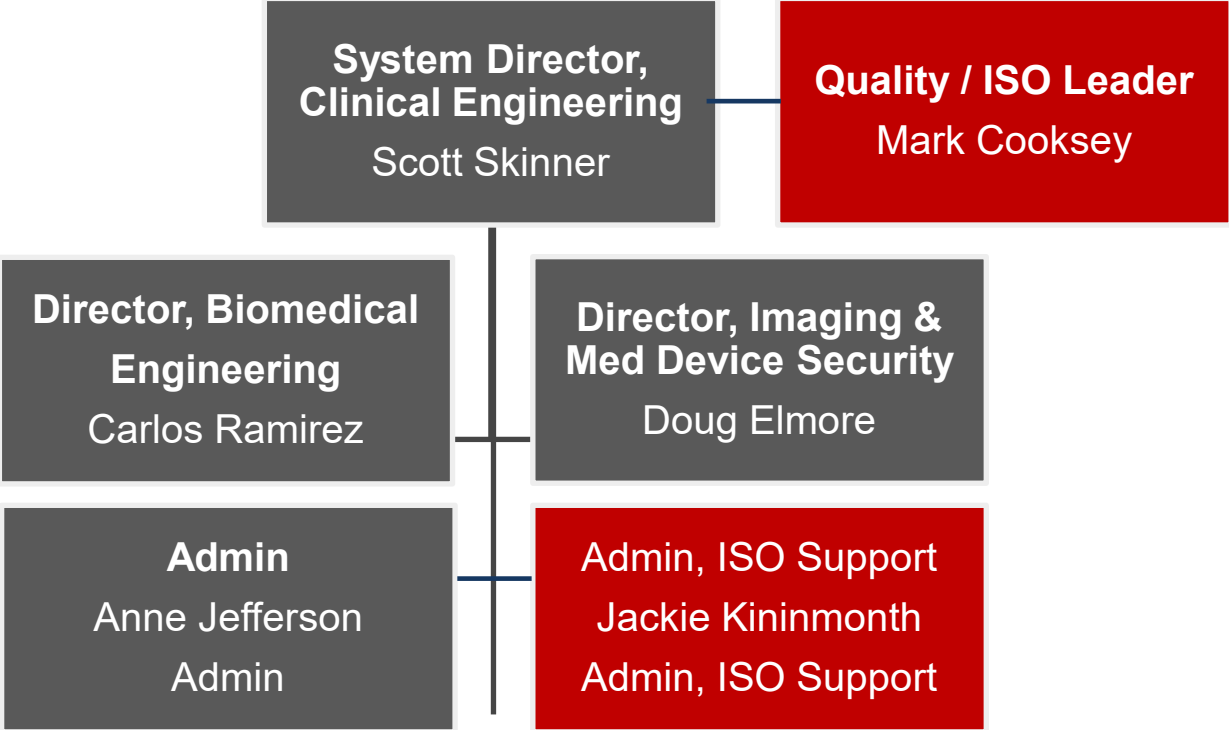
QMS

How was **ISO 13485** implemented?

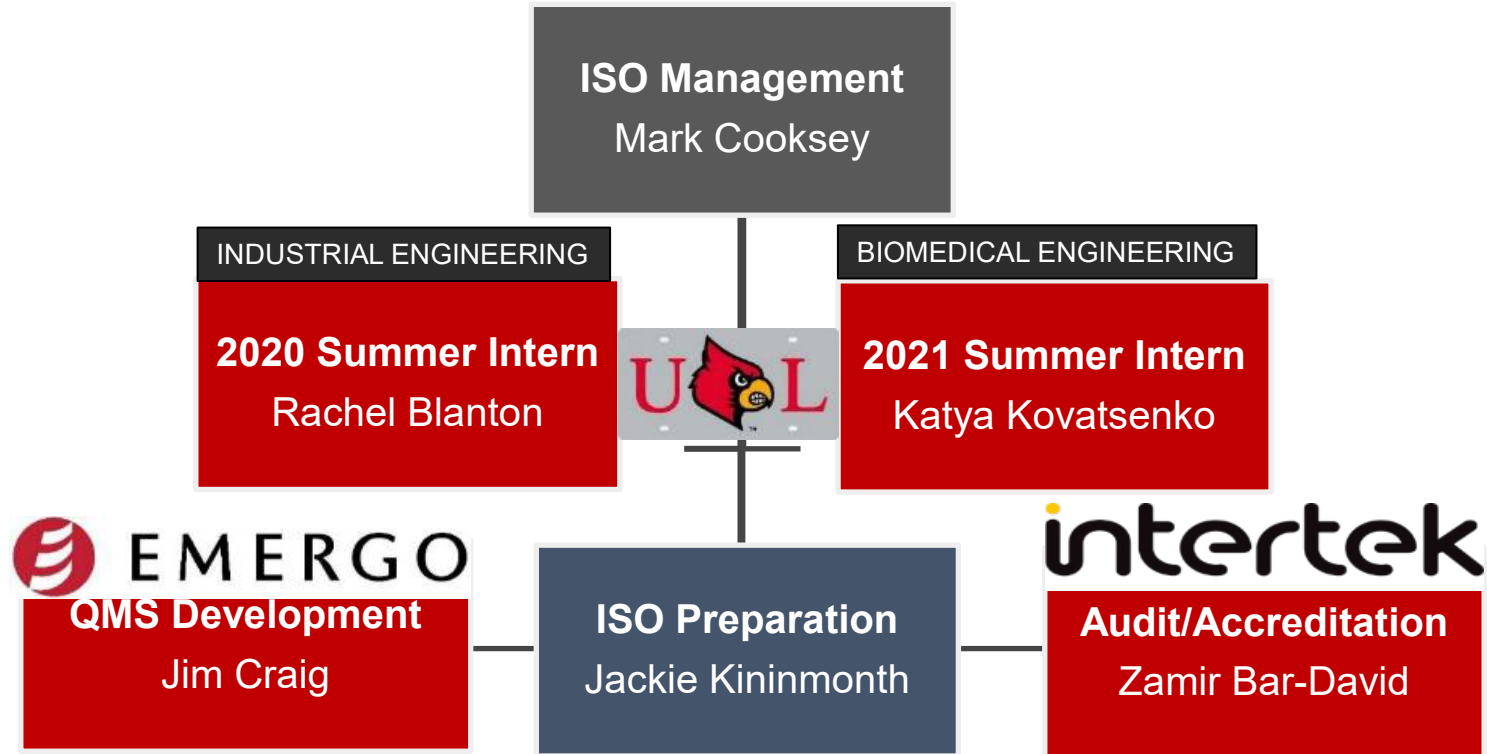
Norton's Resource Strategy

- **Realign** Resources for ISO
- Hire **Proven Change Agent** Quality Leader
- Use **ISO Consultant** as developer and advocate
- Develop **Senior Leadership** Champions
- Roll out quality training to **entire staff**

Aligned Structure to Support ISO

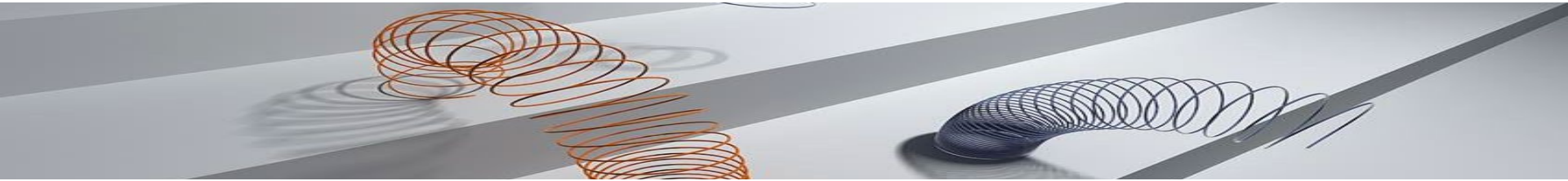


Use Temporary **External** Resources to Prepare for ISO



ISO 13485 Implementation / Certification Process

- 1 Conduct Gap Analysis
- 2 Develop ISO Compliant Documentation
KISS
- 3 Train management and techs in ISO and
Quality Improvement tools
- 4 Work with consultant to make processes
ISO 13485 ready
- 5 Internal Audit by consultant
EMERGO - UL
- 6 External Audit by certifying body
Intertek
- 7 Close Non-Conformities per
ISO Standard
- 8 Receive certification





QUALITY LEADERSHIP CONFERENCES WERE KEY TO ISO ROLLOUT



Change the **language** ...change the culture

Quality Training: Why is Change so Difficult to Accept?

Meet S.A.R.A.H

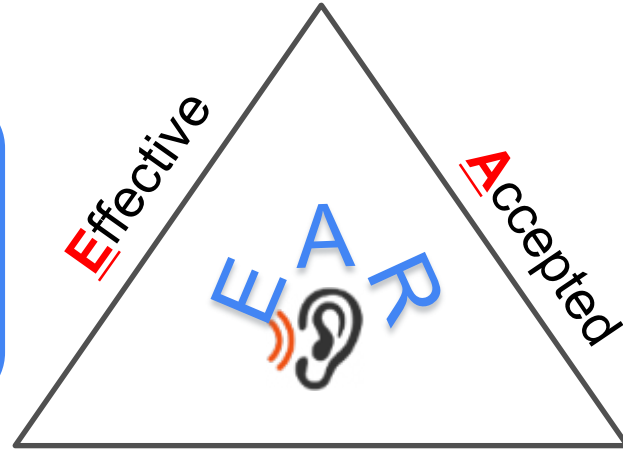


THE “EAR” MODEL PROMOTES CHANGE



It Works!

- Makes sense
- Evidence based
- Voice of all stakeholders considered



Buy-in

- Team understands the “why”
- Leader sponsored
- Aligned to vision, mission, and values



Rigorous Process

Improvements launched w/ Lean 6σ



Improvements are self-sustaining

- Launch plan: communication, education, and standard work plans in place
- Measure success with accountability (audit plan)
- **Easy to do the right thing**

Faster, Better Decision-Making



Brainstorm with Post Its
One idea per Post It, Combine Ideas,
Then multi-vote

Consensus – Fist to Five
Fist means “I’m not in the boat”
5 means “I’m in the boat paddling”



Prioritize - Impact / Effort 4 Block

Rapid Cycle Running Rules:

1. Everyone Participates
2. Respect for Everyone
3. Action Focused



Two Parts of Quality Tools



LEAN

GO TO THE GEMBA
WASTES YOU CAN “SEE”
OBSERVATION
VARY FROM STANDARD

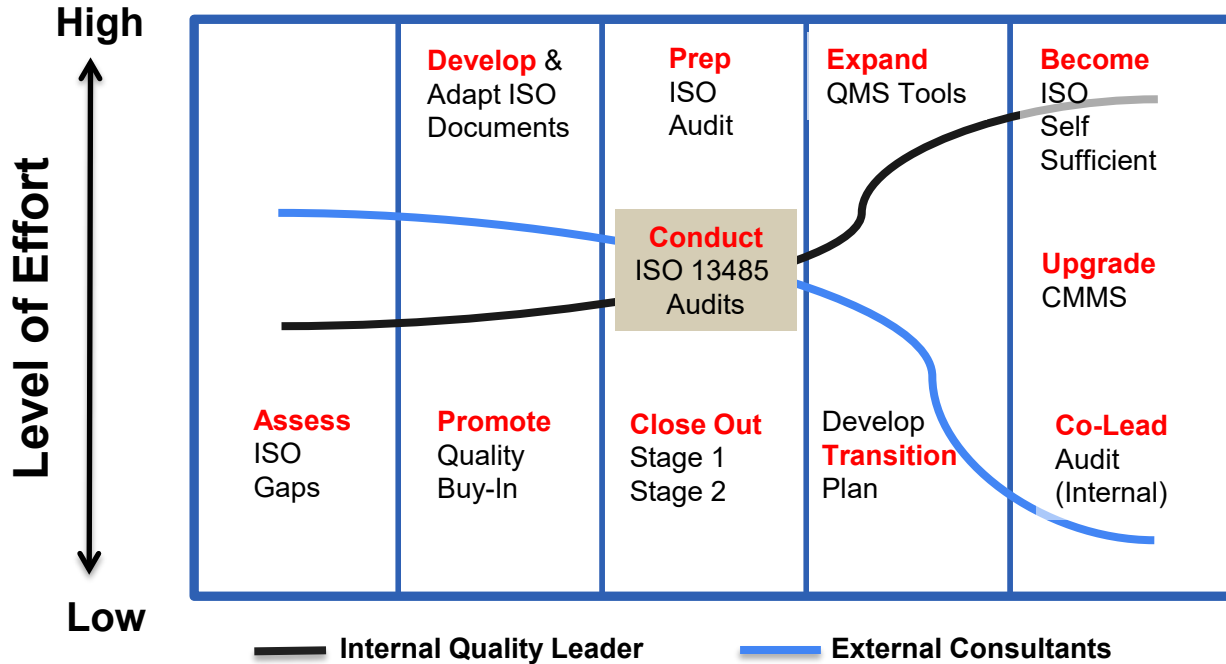
+



6 SIGMA

GO TO THE DATA
VARIATION CUSTOMERS “FEEL”
STATISTICAL INFERENCE
VARY FROM MEAN

Partner with external ISO experts to accelerate 13485 Launch



GETTING THE “DOCUMENT PYRAMID” READY FOR ISO

Gap Analysis – Review ISO Clauses and QSPs: what to **include** and **exclude**

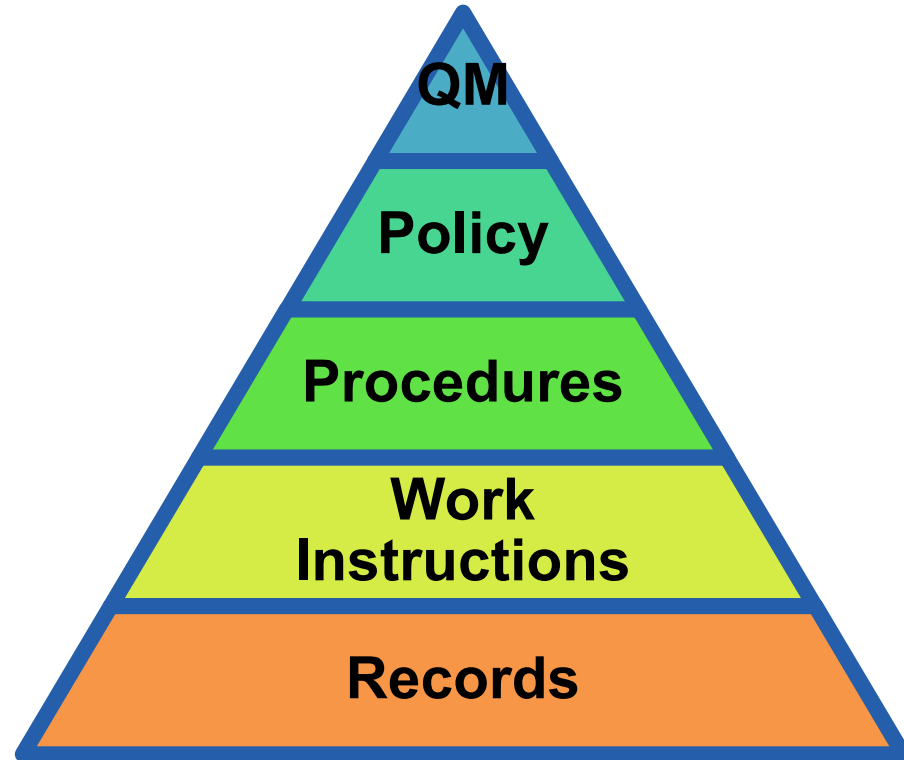
Quality Manual – **Compile** resulting ISO 13485
Quality Management System Manual

Policy – **Supplement** Legacy Corporate / CE
Policies with new ISO 13485 QMS Policies

Procedures – **Create** new ISO Quality System
Procedures (QSPs) as needed

Work Instructions – **Add** Work Instructions to
QSPs and train team in new Standard Work
Instructions (SWIs)

Records – **Link** records to show evidence of QSP
compliance (CMMS, Training Logs, etc.)



ISO 13485 DOCUMENTATION BY THE NUMBERS

ISO 13485 Clause	New Quality System Procedures (QSP)	New ISO Forms (Records)
4.0	3	9
5.0	2	1
6.0	2	
7.0	11	7
8.0	5	5
Total	23	22

Collaborated with ISO consultant to create new QSPs, Form, and Records “out of the box”

KEEP IT SIMPLE SYSTEM -

- **Build New** ISO 13485 from the ground up
 - Quality Manual
 - Quality Systems Procedures
 - Forms
 - Records



- **Leverage Existing** Infrastructure and Link to ISO
 - **Intranet** - Norton Intranet: “N Site”
 - **CMMS** Computerized Maintenance Management System
 - **EOC** Hospital Environment of Care



HOW – KEEP IT SIMPLE SYSTEM

The screenshot shows the Norton employee intranet homepage. The top navigation bar includes the following items: **NSITE**, Employee Services, Policies & Forms, **Departments** (highlighted with a red box), Applications, Email, TimeClock, Password, and a search bar labeled "Search this site". The main content area features a large banner with the text "Employee news" and a megaphone icon. Below the banner, there is a section titled "Mask guidelines" with the text "Masks now required in all facilities and offices".

All 17,000 Norton Employees
Access **SharePoint**



HOW – KEEP IT SIMPLE SYSTEM

Simple Folder
Structure
Organized
around (5) ISO
13485 Clauses

The screenshot shows the N-SITE web interface. The header includes the N-SITE logo, "Employee Services", and "Policies & Forms". Below the header, there is a "new document or drag files here" button and a search bar labeled "Find a file". The main content area displays a list of folders under "All Documents".

✓	📁	Name	...	Modified	Modified By
		4.0 Quality Management System	...	March 01	<input type="checkbox"/> Cooksey, Mark
		5.0 Management Responsibilities	...	March 01	<input type="checkbox"/> Cooksey, Mark
		6.0 Resource Management	...	March 01	<input type="checkbox"/> Cooksey, Mark
		7.0 Product Realization	...	March 01	<input type="checkbox"/> Cooksey, Mark
		8.0 Measurement Analysis and Improvement	...	March 01	<input type="checkbox"/> Cooksey, Mark



HOW – KEEP IT SIMPLE SYSTEM

NSITE Clauses

+ new document or drag files here

All Documents ... Find a file

- 4.0 Quality Management System
- 5.0 Management Responsibilities
- 6.0 Resource Management
- 7.0 Product Realization
- 8.0 Measurement Analysis and Improvement**
- ISO - SUPPORT ONLY FILES
- Customer Quality Log
- ISO NC-CAPA-CR MASTER LOG
- QMS MASTER DOCUMENT LIST

NSITE Documents

+ new document or drag files here

All Documents ... Find a file

Name	Modified	Modified By
8.0 FORMS	March 02	Cooksey, Mark
8.0 QSP Measurement Analysis and Improvement	March 01	Cooksey, Mark
8.0 RECORDS		

NSITE Records

+ new document or drag files here

All Documents ... Find a file

Name	Modified	Modified By
RECORDS 8.2-2 Complaint Handling	May 06	Cooksey, Mark
RECORDS 8.2-4 Internal Audit	April 01	Cooksey, Mark
RECORDS 8.5-2 Corrective and Preventative Actions	March 23	Cooksey, Mark

What are some of the benefits?



Created a Quality Improvement Mindset

- Audits/complaints are **opportunities for improvement** (OFIs)
- **No Excuses** to addressing non-conformities
- **Train in New Quality Tools**: Root Cause Analysis / Lean 6 Sigma
- **New ISO tools**: Corrective and Preventative Action (CAPA)
 - **Major** – Impact Patient Care
 - **Minor**- Impact Efficiency/Effectiveness of QMS
 - **OFI** - EE Improvement Ideas - OFI

75% of the staff have become certified Lean 6 Sigma White Belts





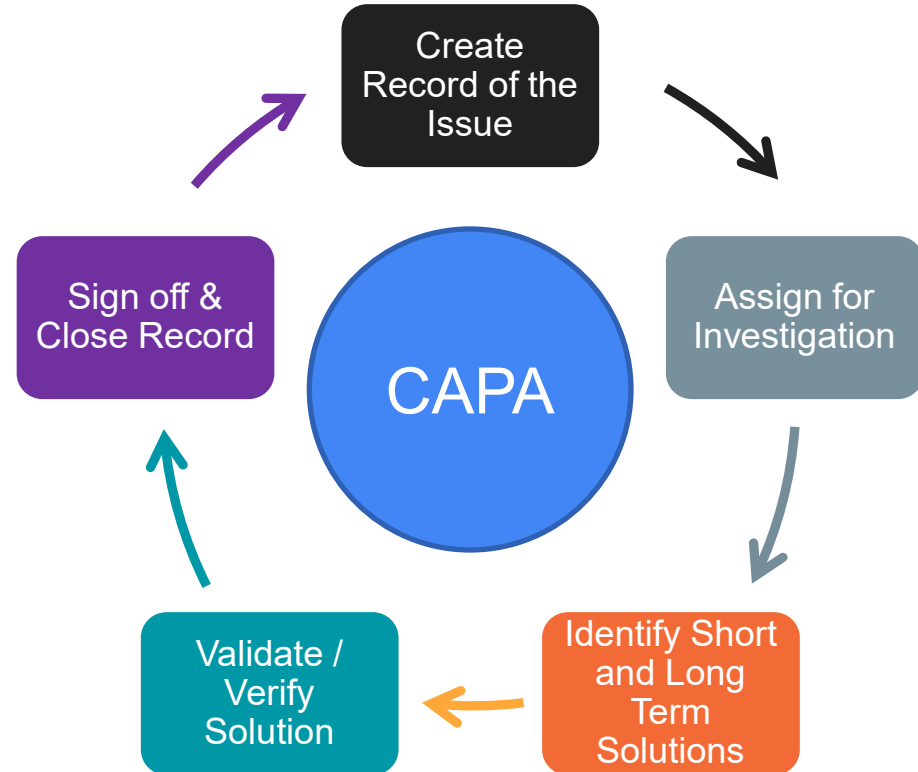
CAPAs: A new way to approach Continuous Improvement

Identify, Assess, Non-Conformities

- Audit Findings
- Vendor Issues / Recalls
- **Customer Complaints**

Create Opportunities for Improvements

- **Implement Lean 6 Sigma Projects**
- Standardized Processes
- Improved “Goof Proof” Work Flows
- 5S Visual Management
- Material Cost Savings



CE ISO 13485 Update / Timeline

Hire Quality Leader to Develop ISO compliant Quality Management System

Quality Conference

- ✓ ISO 13485 Certified!
- ✓ Passed DNV GL Audit – **0 NCs**
- Conformance Audit - *UL*
- Surveillance Audit - *Intertek*
 - Downtown
 - Imaging

Fully Self - Sufficient with trained Internal ISO auditors



Complete ISO audits:
Readiness - *UL*
Certification - *Intertek*



CE Auditor Training - *UL*
Conformance Audit - *CE*
Surveillance Audit #3 - *Intertek*

Case #1: ISO tools used to Improve internal work flow

EXTREME

5S

MAKEOVER

Clinical Engineering Edition



5S APPLIED TO THE ENTIRE IMAGING DEPARTMENT



2021 Summer Intern
Katya Kovatsenko
U of L Biomedical Engineer, Pre-Med
Fulbright Scholar

KEEP ONLY WHAT YOU NEED



BEFORE



AFTER

GET RID OF MONUMENTS CREATE NEW WORKSPACE



BEFORE



AFTER

CLEAN UP “MAIN STREET”



BEFORE



AFTER

TOOL CABINET: A PLACE FOR EVERYTHING AND EVERYTHING IN ITS PLACE



BEFORE



AFTER

GOOF PROOF: “KAIZEN FOAM” ON TOOL CART

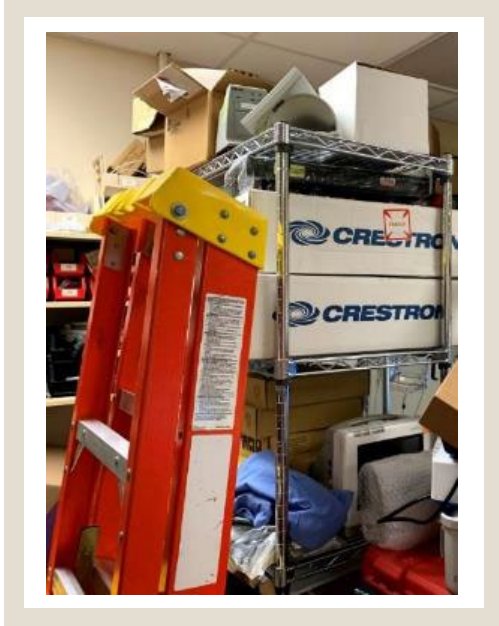


BEFORE

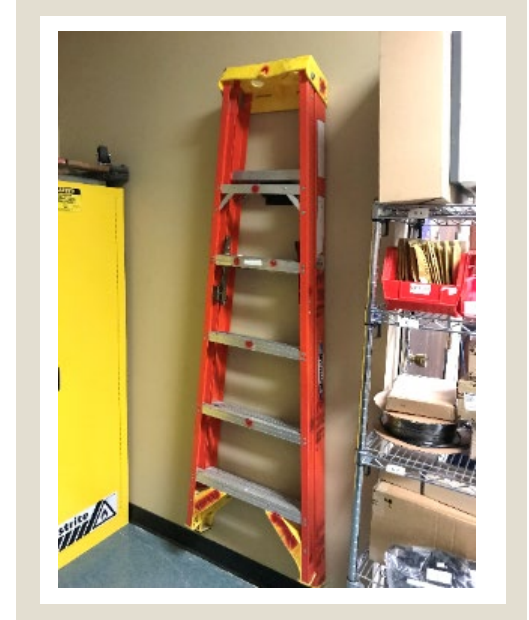


AFTER

DESIGNATED LOCATIONS FOR LADDERS

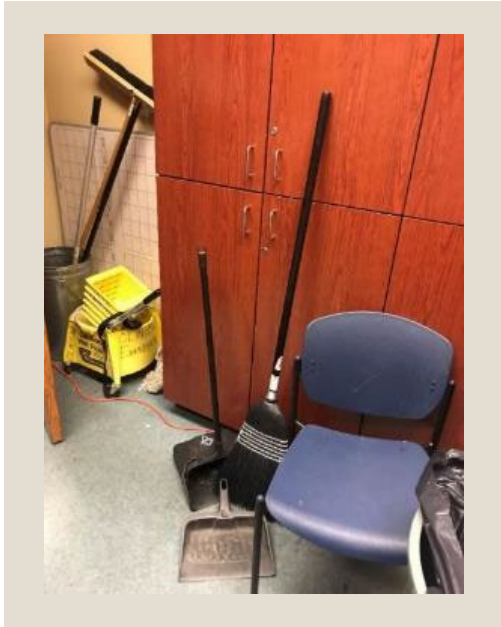


BEFORE



AFTER

CLEAN UP CLEANING SUPPLIES



BEFORE



AFTER

ORGANIZE THE “WAREHOUSE”



BEFORE



AFTER

REORGANIZE “THE SUPERMARKET”



BEFORE



AFTER

5S FEVER IS EVERYWHERE!



IMAGING

5S sustained after two years



224 Bldg

5S station for IS equipment



224 Bldg

Matt and Travis have 5S'd "Warehouse" and Workstation

Presentations from Biomed/Imaging Techs at Oct 2022 Quality Conference

Case #2: ISO tools used to
improve customer
satisfaction and reduce
costs

Complaint → CAPA → Rapid Cycle → Change Request (CR)

CE called to lead team to solve issues with Vital Sign Monitor (VSM) Accessories



Hospital: Patient safety Impacted by unavailable VSMs. **Stressed Staff**



Clinical Engineering: chasing "no defect found" **Wasting resources**



Supply Chain: Nurse Managers stash away **\$700,000 in VSM accessories.**

© AAMI 2022 aami.org/ieXchange



**Rapid Cycle Solution
Created Accessories
"SUPERMARKET"**

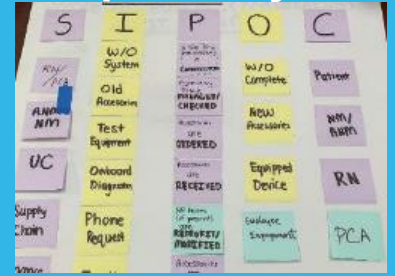
Lean 6 σ Tools Applied to Patient Monitor Accessories Project

- Time Studies / Bottlenecks
- Kanban
- Pull 1 piece flow
- Improve Standard Work
- Poke-yoke (mistake proof)
- Golden Sample
- Voice of Customer
- SIPOC
- Process Mapping
- Fishbone diagram / 5 Whys
- DOWNTIME wastes
- Pareto Analysis
- 5S / Visual Management
- Baseline vs Benchmark
- CAPA

Gather Data



Rapid Cycle



Pilot Solution



Get Buy In



SOLUTION HIERARCHY – ACCESSORIES MANAGEMENT

EASY CONTROL

(1) KIOSK
KANBAN



Easy to do the
Right Thing



SUPPLY CHAIN
MANAGES



CE MANAGES
STOCK

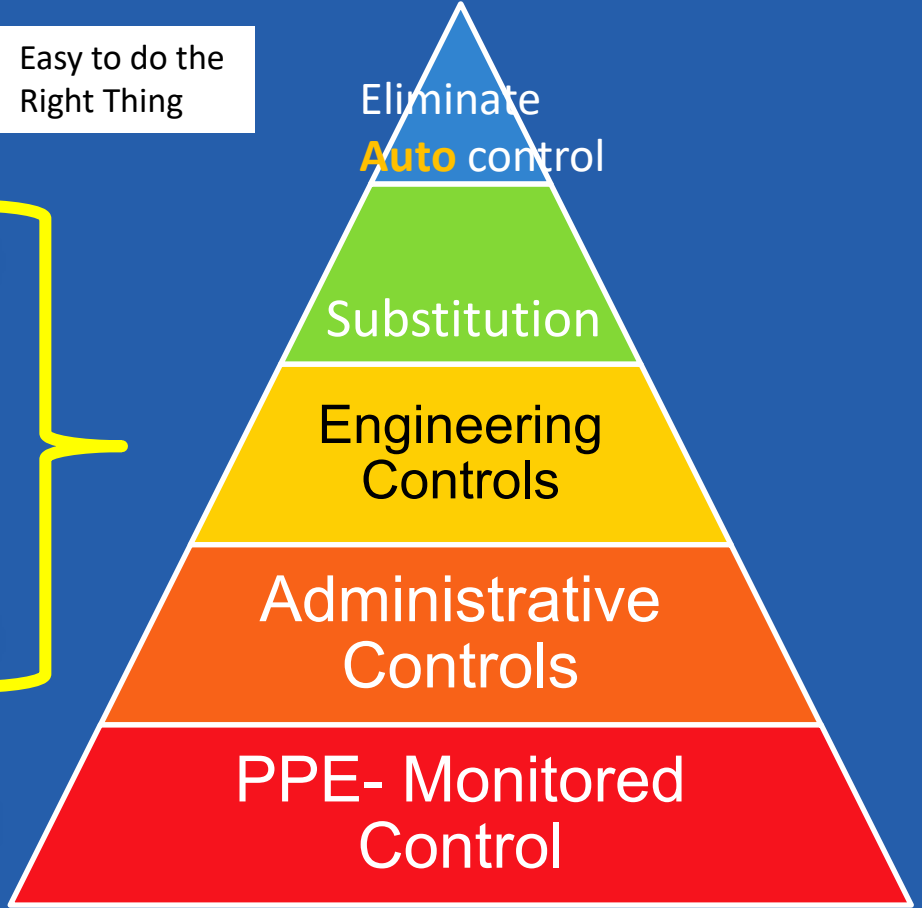


(17) ANM
STOCK
LOCATIONS



POOR CONTROL

PCA SOPs
CE WEBSITE



Closed Loop Replenishment Concept



**CLINICAL STAFF
PULLS FROM
"SUPERMARKET"**



**SUPPLY CHAIN
PULLS FROM
"WAREHOUSE"**

Location	Lawson Number	Item Description	Reference Number
SC1	081647	Adult pressure interconnect cable 3.0m	M1599B/ 989803104341
SC2	081650	sp02 adapter cable 1.1m	M1943A
SC3	153943	5 lead set icu grabber 1.6m (5.3ft.)	M1968A (989803125841)
SC4	153945	mx40 reusable 5 leads with sp02	989803171851
SC5	081651	3 lead ECG trunk cable 2.7m (9ft.)	M1669A
SC6	153941	5 lead ECG trunk cable 2.7m (9ft.)	M1668A (989803145061)
SC7	110110	3m Nellcor sp02 cable (9ft.)	M1943NL
SC8	136198	Foley cath temp sensing cable 12ft.	DYND110102
SC9	152859	cable truwave reuse px1800	PX1800
SC10	154864	Covidien DL adapter 5 lead with cover	33526TN (contact christy.kennedy@cardinalhealth.com)
SC11	154251	Cardiac output cable	M1642A/ 989803104611
SC12	154252	Cardiac temp probe cable	989803101031
SC13	014904	Adult sp02 sensor	DS100A1
SC14	051843	Flexiport reusable adult 11 cuff	W-AREUS11 (order from medline)
SC15	049305	Adult reusable sp02 sensor	M1191B
SC16	110109	leadset cable 3 m1671A	M1671A
SC17	154845	Bili Cal	989805607841
SC18	154865	Covidien DL adapter 5 lead without cover	33541 (contact christy.kennedy@cardinalhealth.com dir
SC19	154122	oral temperature probe	02895-000/ 989803143381
SC20	109238	Adult reusable sp02 sensor	M1196A
SC21	097018	Set 5 Lead Grab	989803152051
SC22	154526	Reusable ext hose	91824
SC23	154525	Cable Interconnect Mol	39825
SC24		3 lead detachable child	989803153031

**SUPPLY CHAIN
REORDERS FROM
"E-STORE"**

PULL

RESTOCK



5S visual management features

- Green Zip Tie signals replenishment
- “Golden Sample” – pick the right accessory
- 5J6 label – WAREHOUSE stock location
- PHILIPS label – used by SUPPLY CHAIN
- 5 LEAD ECG TRUNK CABLE 2.7 m (9ft) is the VENDOR label
- Badge Reader + camera controls usage

New Replenishment Process: Everybody Wins

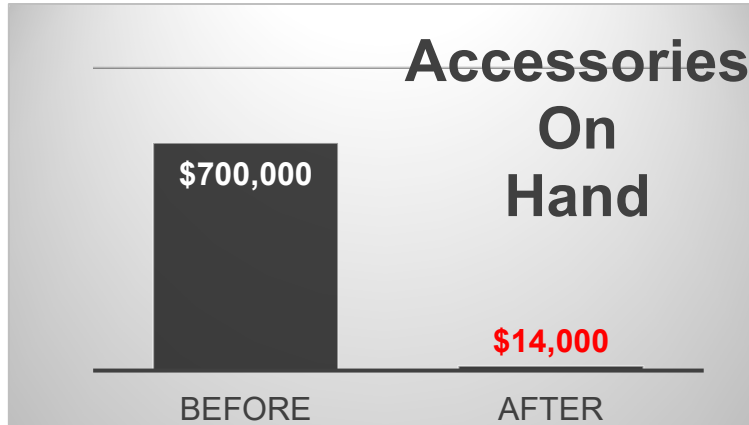
STAKEHOLDER BENEFITS	OPERATIONAL EXCELLENCE FEATURE
PCA	-GRAB-N-GO single location! -VSM Accessories always available
ANM	- No ANM ordering!
CE TECH	- Fewer accessory-related work orders!
SUPPLY CHAIN	-Closed Loop / goof proof visual management -Simple signaling – like “crash cart” -Multi-level communication Golden Sample, Picture, Part, Model #, Description, Inventory Location
C-SUITE	-Improved VSM availability = patient safety -Reduced inventory by 94% -Better cost/usage tracking - Streamlined process
OTHER HOSPITALS	Replicated solution to other hospitals



Vital Signs Accessories Management Optimization

Results

- Simplified Replenishment Process
- Centralized Visual **Cost Control**
- Reduced Storage Locations by **94%**
- Reduced Supplies on hand by **98%**
- Improved **Availability** of Supplies



Vital Signs Accessories Management Optimization

DEFINE

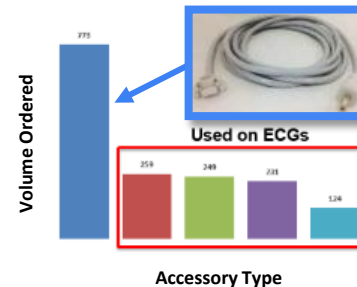


>\$700K Spent in Past 3 Years

MEASURE



ANALYZE



IMPROVE / CONTROL

Better Accessibility

Improved Tracking

Streamline

Potential Savings

What Will I Take Back?



NORTON'S LESSONS LEARNED ISO 13485

- Plan the Work, Work the Plan, **Audit the Work**
- Use **risk** to triage improvements
 - Customer Complaints, Supplier Issues, OFIs
 - Generate CAPAs and Change Requests
- All processes are **actively linked**
 - Policies→QSPs→SWIs→Forms→Records

Why Now? Why Me?

ISO 13485 supports
your Right to
Repair!



Closing Thoughts: You Can Do This!



C-Suite Sponsorship of ISO



Lean 6 Sigma Training



Consulting Advocacy



ISO Certification



Quality Evangelism



SoCal 2022 Quality Success Strategies Takeaways



Mark R. Cooksey
ISO 13485
Quality Leader,
Norton Healthcare

01

What ISO 13485 is

A QMS with quality improvement at its core

02

Why your company needs it

Supports your company's right to repair

03

How to launch ISO 13485

Allocate resources (employees with external consultants)

Use the EAR model to drive effectiveness, acceptance, and rigor

04

Benefits of ISO 13485

Create a company with a quality culture



NORTON
HEALTHCARE



THANK YOU.

Mark Cooksey

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