

The Quality System Inspection Technique (QSIT)

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REGULATIONS

code of
federal regulations

Food and Drugs

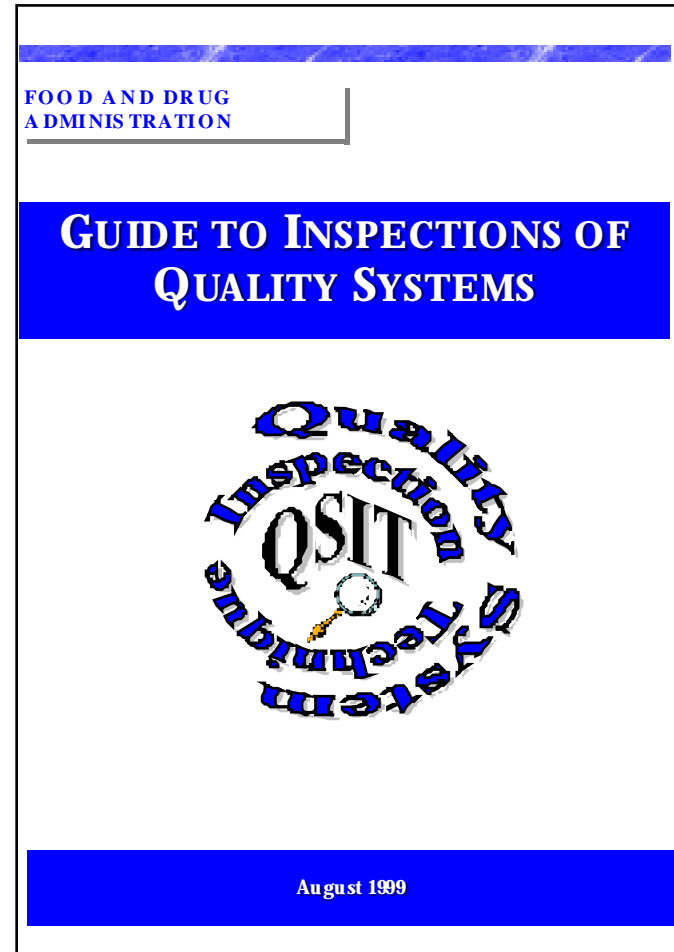
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PARTS 800 to 1299
Revised as of April 1, 1998

- Quality System Regulation
21 CFR Part 820

QSIT is an Inspection Technique

- **QSIT Guide**
 - **Purpose and Importance**
 - **Objectives**
 - **Flow charts**
 - **Narratives**
 - **Sampling Plans**



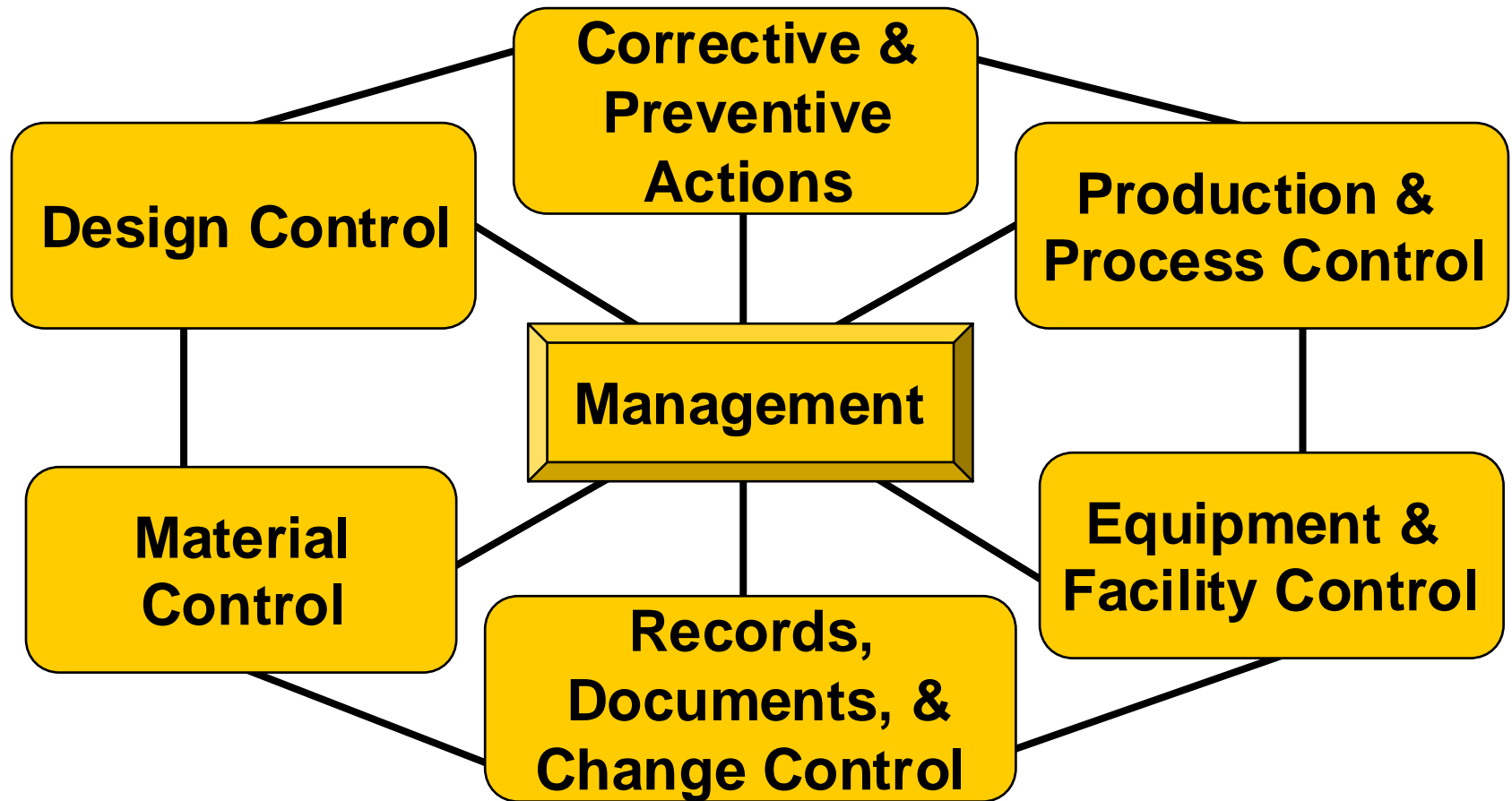
The QSIT Approach

- **QSIT focuses on evaluating whether the Quality System and subsystems have been implemented effectively.**
- **QSIT acknowledges that nonconforming product and quality problems happen.**
- **What is important is:**
 - **Did the manufacturer identify the nonconforming product or quality problem?**
 - **Did the manufacturer take effective corrective and preventive action?**

QSIT

- **QSIT is a Top down approach**
- **Key quality system sub-systems are audited**
- **QSIT provides directions for sampling of records**
- **The binomial staged sampling plans outlined in the QSIT guide help to indicate the extent of any deficiencies**

The Seven Subsystems of the Quality System



QSIT Focuses on Four Major Subsystems

- Management Controls
- Design Controls
- Corrective & Preventive Action Controls
- Production & Process Controls

The Three Other Subsystems

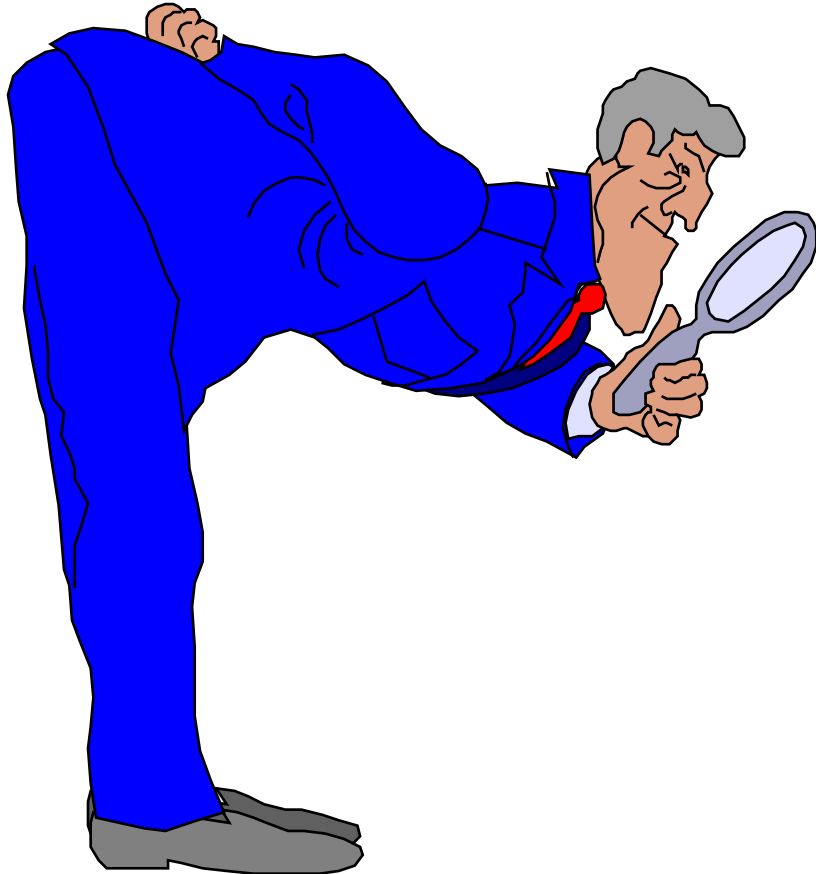
- Facility & equipment controls
- Product controls
- Documents, records & change controls

Satellites

- Sterilization Process Controls may be evaluated during inspection of Production and Process Controls
- Compliance with Medical Device Reporting, Reports of Corrections and Removals, and Medical Device Tracking is evaluated during inspection of CAPA



Using QSIT-



- Sample
- Review
- Confirm
- Verify

Management Controls - Purpose

- Provide adequate resources for device design, manufacturing, quality assurance, distribution, installation and servicing
- Assure proper function of quality system
- Monitor quality system
- Make necessary adjustments

Management Controls - Inspectional Objective Example

- 1. Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined & documented.

Design Controls-Purpose

- **Control the design process to assure that devices meet:**
 - **user needs**
 - **intended uses**
 - **specified requirements**



Design Controls - Inspectional Objective Examples

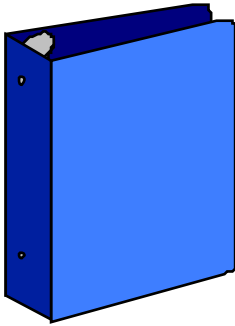
- 1. Select a single design project.
- 2. For the design project selected, verify that design control procedures that address the requirements of Section 820.30 of the regulation have been defined and documented.

Sampling for Confidence

- Using Table 1 and reviewing a population of 35 randomly selected records of one type (DHR) and finding one deviation means . . . the investigator can be 95% certain that no more than 15% percent of the set of records contain unrecognized non-conforming data points (test results).

Note: Even 1 deviation may be unacceptable.

"Top Down"



Review Design Control Procedures

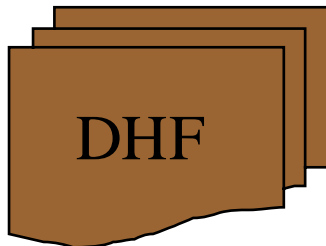


Table 1

Binomial Staged Sampling Plans
Binomial Confidence Levels

Confidence Limit		0 out of:	1 out of:	2 out of:
$.95 \leq$				
A	.30 ucl*	11	17	22
B	.25 ucl	13	20	27
C	.20 ucl	17	26	34
D	.15 ucl	23	35	46
E	.10 ucl	35	52	72
F	.05 ucl	72	115	157

Sample Design Control Records



Review Design Control Records

A "Top Down" Example...



**Were Design Verification Procedures
Defined? Documented?**



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Binomial Staged Sampling Plans
Binomial Confidence Levels

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Sample Design Control Records



**Do verification activities confirm
that design output meets design
input requirements? Does the DHF
contain the required information?**

"Vertical Probes"

Design Input

Design Output



Design Verification



Design Validation

Design Change

Design Review



Design Transfer

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Corrective and Preventative Action - Purpose

- Collect and analyze information
- Identify and investigate actual and potential product and quality problems
- Take appropriate and effective corrective action to correct existing quality problems and preventive action to prevent occurrence of potential quality problems

CAPA - Inspectional Objective Example

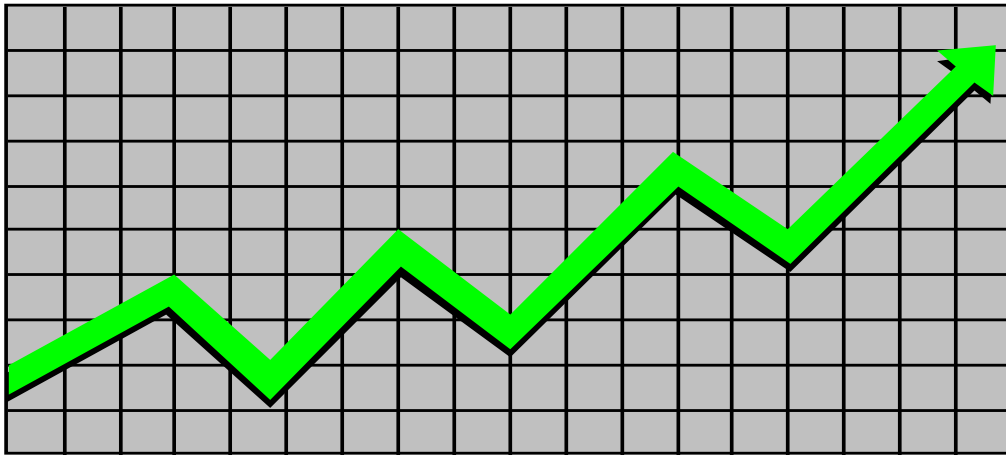
2. Determine if appropriate sources of product and quality problems have been identified. Confirm that data from these sources are analyzed to identify existing product and quality problems that may require corrective action.

CAPA satellite systems

- Medical Device Reporting (MDR)
 - sampling tables are used
- Reports of Corrections and Removals (recalls)
 - sampling tables are used
- Medical Device Tracking

Production & Process Controls - Purpose

To manufacture devices that meet specifications



P&PC-Inspectional Objective Example

- 4. If the results of the process reviewed cannot be fully verified, confirm that the process was validated by reviewing the validation study.

At the conclusion of the inspection...

7. Evaluate whether management with executive responsibility has ensured that an adequate and effective quality system has been established and maintained.

Closing the Inspection

- Discussion With Management
- Participants
- No Surprises
- List of Inspectional Observations (FDA-483)
- Annotations (Be Prepared)
- Response to FDA-483 (What, Where, When)

FDA-483 Annotation

- Reported corrected, not verified
- Corrected and verified
- Promised to correct
- Under Consideration

Preparation and FDA Transparency

- FD&C ACT
- Investigations Operations Manual (IOM)
- Compliance Program 7382.845
- Quality System Inspection Technique
- Medical Device Reporting, 21 CFR Part 803
- Reports of Corrections & Removals, 21 CFR Part 806
- Electronic Records and Signatures, 21 CFR Part 11

Presentation of History of Business Information

- Organizational Charts
- Who We Are and What We Make
- Product Catalog, Labeling, Demos
- Registration and Listing File
- 510(k) New Products, New Processes
- Corrections to Previous FDA-483 Observations

FDA WEB RESOURCES

- **Medical Device Quality Systems Manual**
- <http://www.fda.gov/cdrh/qsr/contnt.html>

- **QSIT "Guide":**
- http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm

- **18. Factory Inspections**
- <http://www.fda.gov/cdrh/qsr/18inspn.html>

- **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers**
- <http://www.fda.gov/cdrh/ohip/guidance/1128.html>