The Quality System Inspection Technique: "QSIT"

QSIT Workshops

Introduction

- ◆ **What is QSIT?**
- ◆ **How we inspect with QSIT**
- ◆ **QSIT findings**
- ◆ **Implementing QSIT**

What is QSIT?

- ◆ **Moves FDA closer to Global Harmonization guideline for regulatory auditing of quality systems of medical device manufacturers**

- ◆ **Incorporates the seven subsystems concept**

- ◆ **Provides specific guidance on auditing each subsystem**

Quality System's Sub-systems
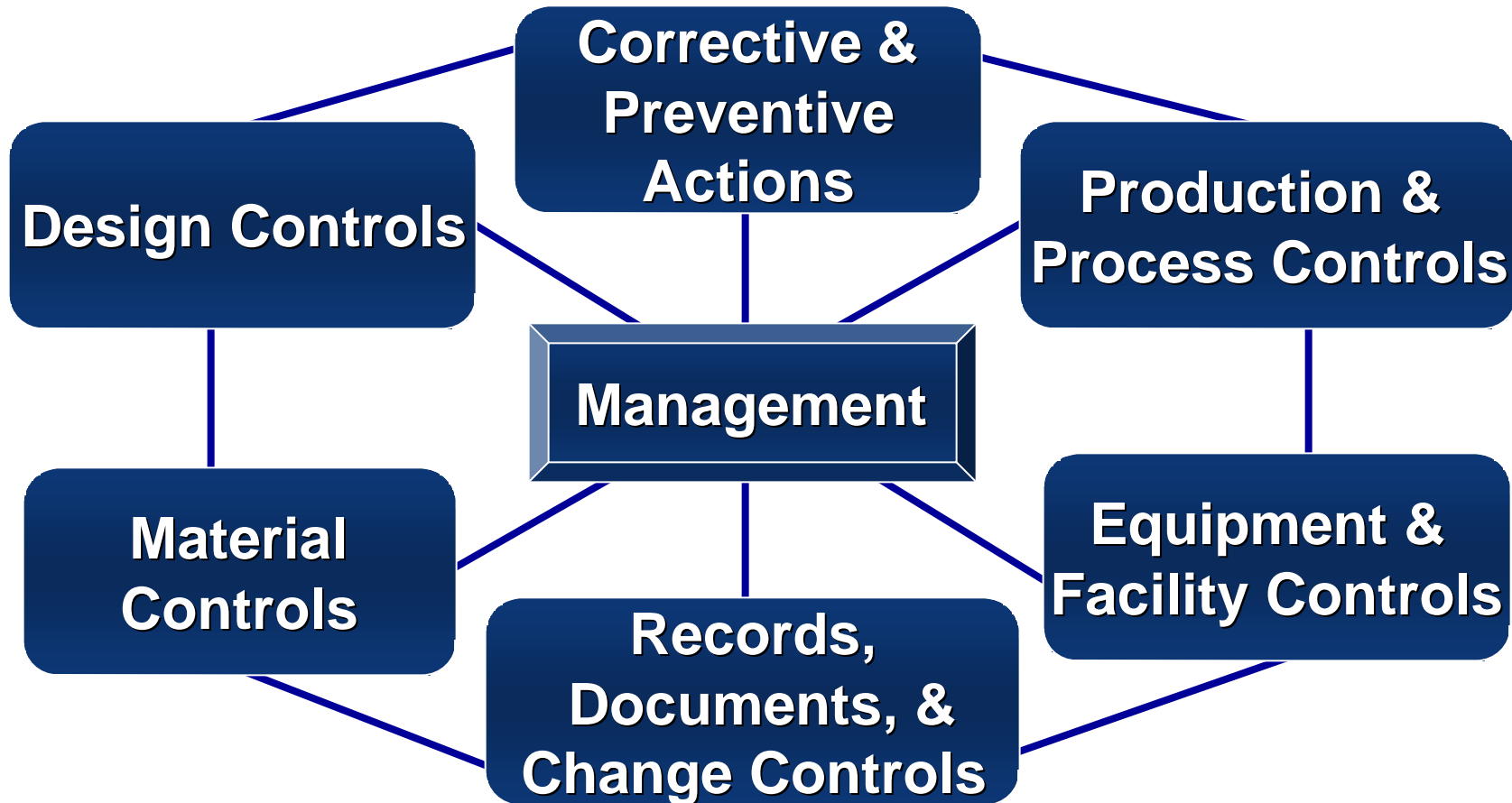
Major Themes of QSIT

Theme #1 = Management

- **Management is responsible for Implementing Quality System**

- **Start & Finish with Management**

- **All product, process, design & CAPA problems can be tied to management**

Inspection Conclusion

"Did management ensure that an adequate and effective Quality System has been established?" (Mgt. #7)

Theme #2 = CAPA

◆ **We are checking the "system"**

   – **Non-conformances happen**

   – **What kind of system does the firm have?**

   – **Is the system effective?**
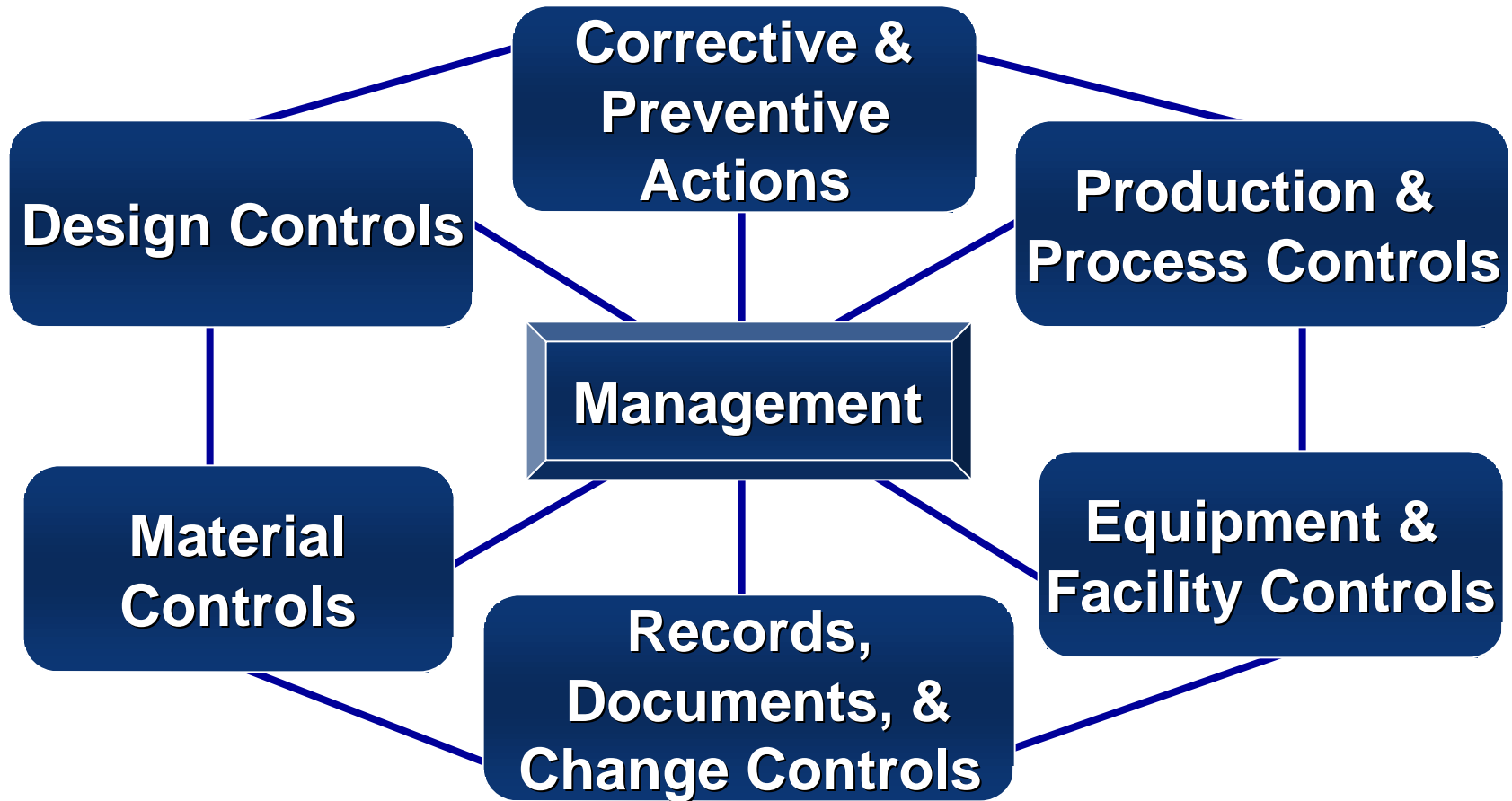
Management

Design Controls

Production & Process Controls

Corrective & Preventive Actions

Material Controls

Equipment & Facility Controls

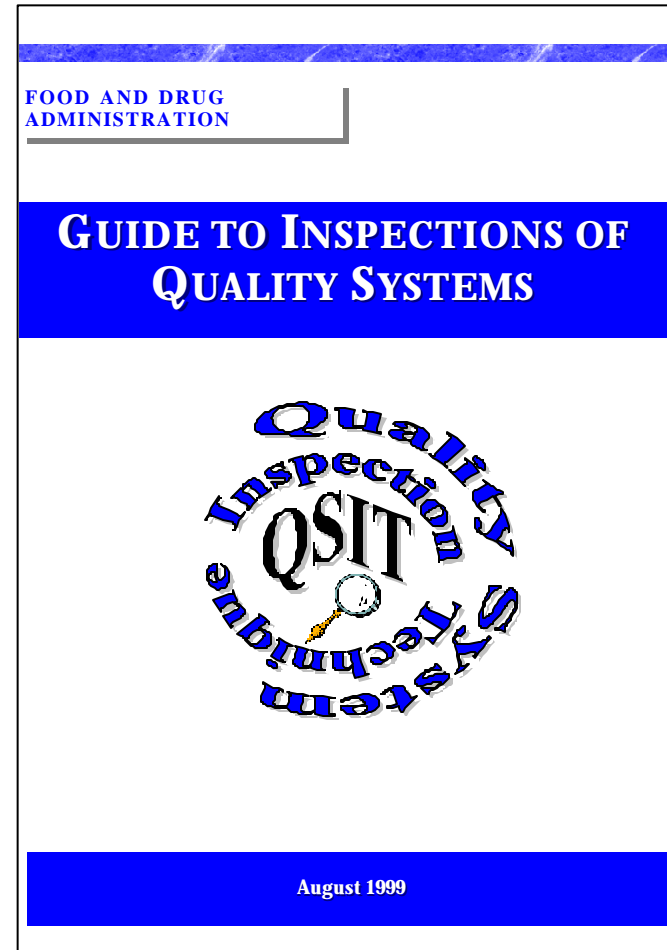**Records, Documents, & Change Controls**

Controls

The Inspection Approach

- ◆ **Top-down (versus Bottom-up)**
- ◆ **Sampling records (use tables)**
- ◆ **Pre-inspection activities (ask for and review documents)**
- ◆ **Start and end with Management**

How Will Each Subsystem be Inspected?

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

FOOD AND DRUG ADMINISTRATION

GUIDE TO INSPECTIONS OF QUALITY SYSTEMS

QSIT

August 1999

Establish - [21CFR 820.3(k)]

- ◆ **Define**
- ◆ **Document**
- ◆ **Implement**

The "Establish" Test

- ◆ **Proof of "Establish"**
  - – **Is the firm doing what regulation says?**
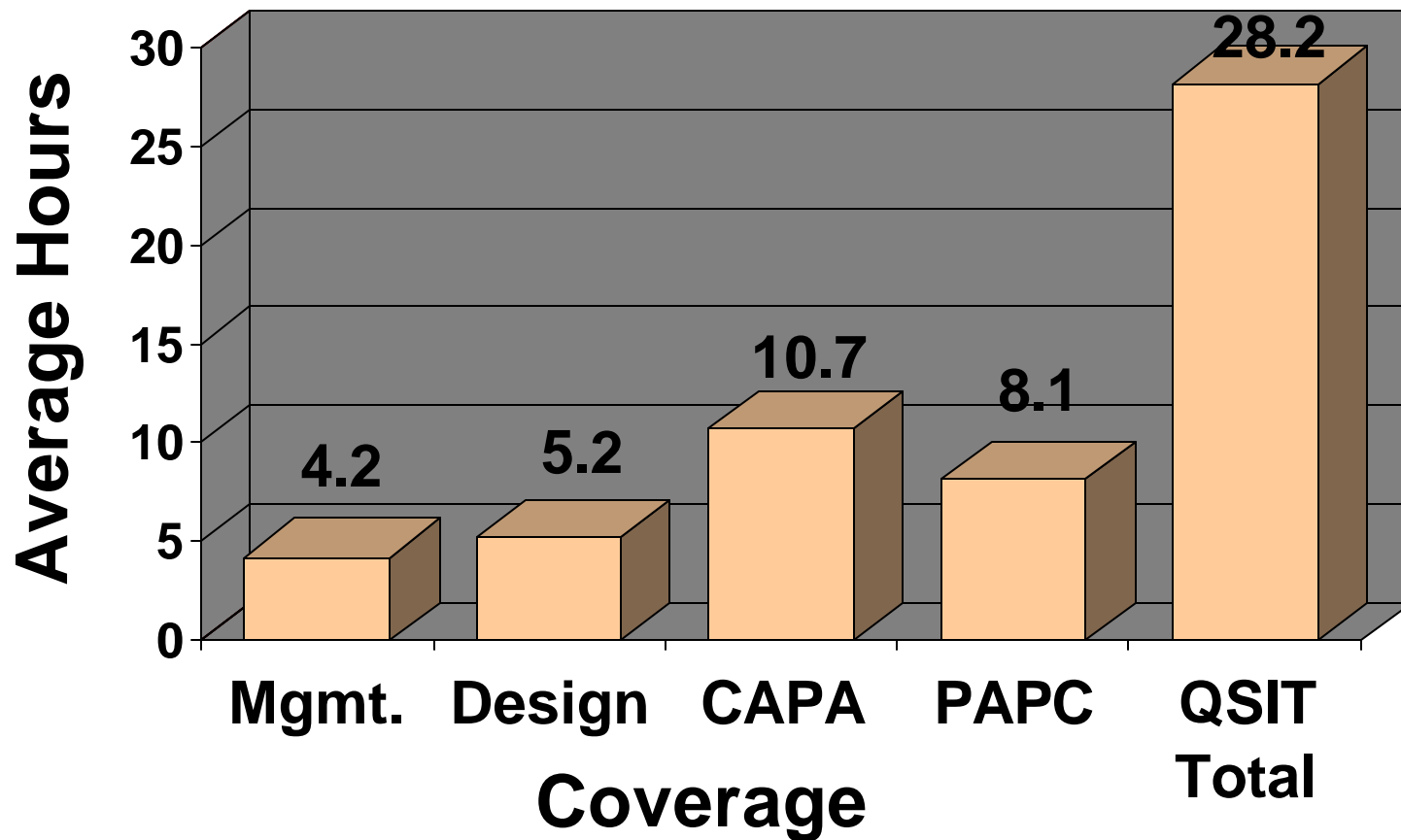 - – **Is the firm doing what their procedure says?**

The "Establish" Test

◆ **Proof of "Establish"**

 – **Is the firm doing it adequately?**

 – **Bore down…using:**
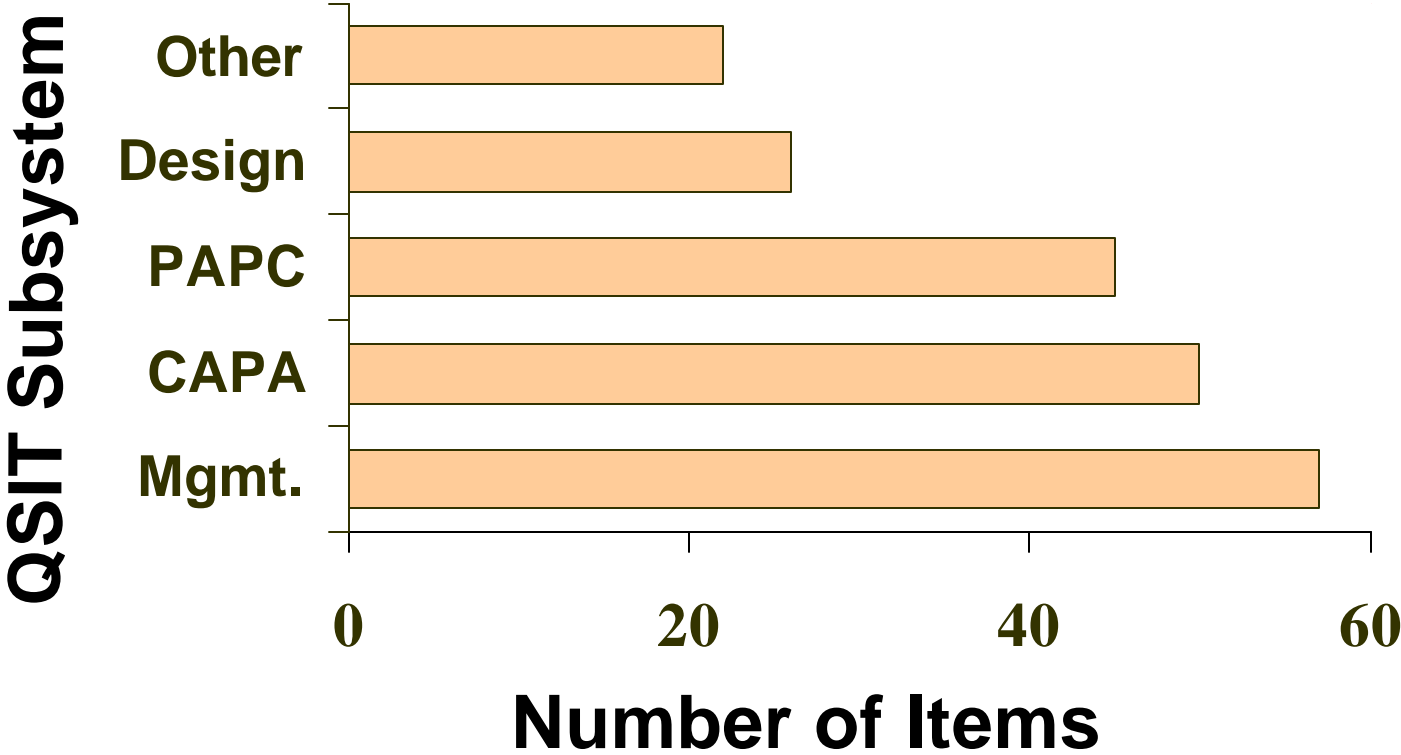
  » **Vertical Probes**

  » **Sampling**

Order of Systems

- ◆ **Management**

- ◆ **Design**

- ◆ **CAPA**

- ◆ **Production & Process Controls**

- ◆ **Conclude with Management**

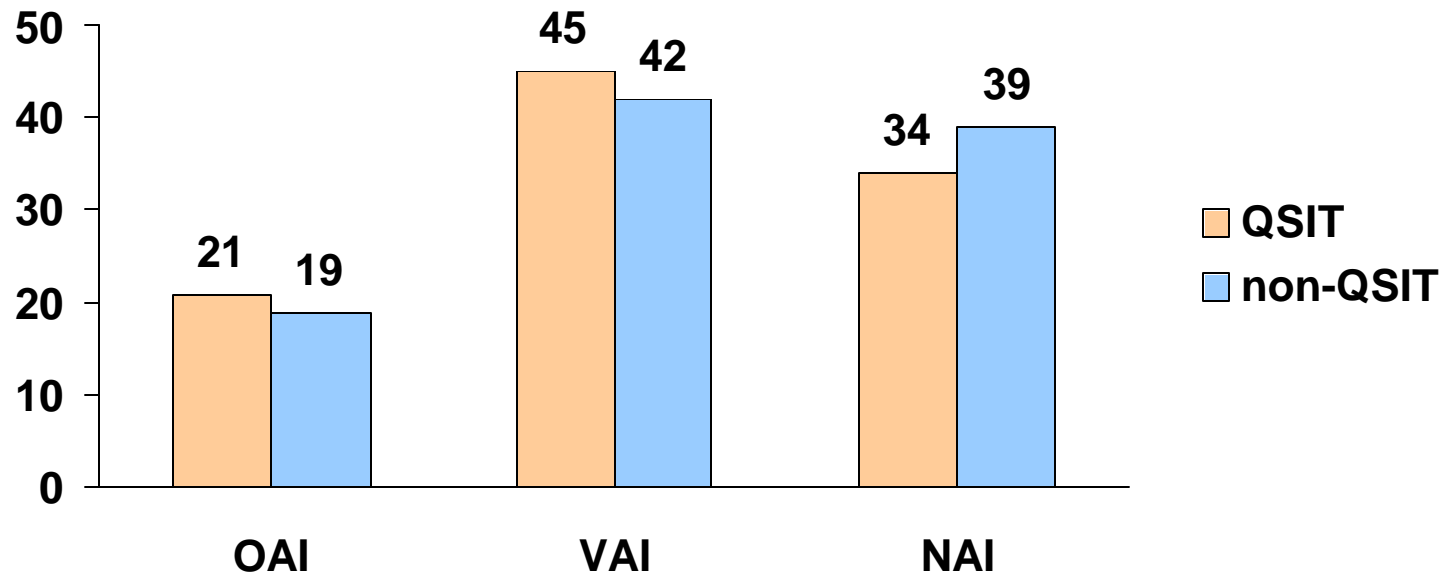# QSIT Findings In-Plant Time

QSIT FDA 483's

200 Total (FDA 483) Items

QSIT Inspection Classifications

Implementing QSIT

- ◆ **Training on-going**
- ◆ **Compliance Program**
- ◆ **Industry Workshops**
- ◆ **Monitoring and Improvements**

Compliance Program

- ◆ **Incorporates Several Program areas**

- ◆ **Utilizes QSIT**

- ◆ **Uses Three Levels of Inspection**

- ◆ **Establishes OAI**

SUBJECT:	IMPLEMENTATION DATE
INSPECTION OF MEDICAL DEVICE MANUFACTURERS	Upon Receipt of Final Document
	COMPLETION DATE

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
73-91	82830L 42830L -- All Level 1 (Routine) Inspections
	82830C 42830C -- All Level 2 (Initial or Comprehensive) Inspections
	82830F -- All Level 3 (Compliance Follow-up) Inspections
	82830A -- Report Time spent on Assessment of Firm's Sterilization processes
	82830B -- Contract Sterilizers Inspections
	81011 -- Report Time spent on Assessment of Firm's MDR Practices
	(To Be Assigned) -- Report Time spent on Assessment of Firm's Tracking Practices
	(To Be Assigned) -- Report Time spent on Assessment of Firm's Corrections and Removals Practices

Field Reporting Requirements

483s. A copy of all FDA 483s issued as a result of inspections conducted under this program should be sent to HFZ-306 for entry into the national 483 database.

EIRs. All EIRs and administrative/regulatory action recommendations should be sent to HFZ-306. ??????
Send an EIR to CDRH, HFZ-306, **only** if the inspection resulted in an OAI classification.

Warning Letters. A copy of all Warning Letters should be sent to HFZ-306 and HFC-210.

One Last Item……………..

◆ **HACCP vs. QSIT**

    – **QSIT is NOW**

    – **HACCP is FUTURE**

        » **HACCP is being tested.**

        » **Possible role is……….**

For Further Information

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For Further Information

◆ **QSIT Website:**
  – **www.fda.gov/cdrh/gmp/gmp.html**

◆ **QSIT Study:**
  – **www.fda.gov/cdrh/gmp/qsit-study.pdf**

◆ **QSIT "Guide":**
  – **www.fda.gov/cdrh/gmp/qsitbook.html**
    » **Changed to…….**

Thank You