Approaching Compliance with 21CFR Part 11

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Three Parts to Compliance

Administrative Controls

Policies and Plans

SOPs

Procedural Controls

Training

Various and Many

Technical Controls

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Administrative and Procedural

FDA expects you to have Administrative and Procedural Controls in place.

GET THEM DOCUMENTED!

“We’ll take enforcement discretion if you have a process in place.”

-Jennifer Thomas, CBER and Part 11 Compliance Committee

Administrative Controls

- **Allocation of Resources**
- **Company Policy**
- **Company Compliance Plan**

Procedural Controls

- **SOPs**
  - Passwords
  - Any procedures for compliance work
  - Computer Systems (back-up, recovery, etc.)
  - Tandem to Technical Controls for complete solution
- **Training**
  - Procedures
  - E-Signature is legally binding

Technical Controls

- **Q: How do we create technical controls?**
  - A: Follow your Plan
- **Q: What is our plan?**
  - A: The plan you made with your Administrative Control. It contains your approach to all three control sets, and very often a list of steps
- There are many lists. Some include Admin and Procedural Controls as the first couple of steps. Some just list steps for Technical Controls.

Stages and Steps

- **Stage 1: Create Policy**
- **Stage 2: Create Plan**
- **Stage 3: Create Procedures**
- **Stage 4: Systems Step by Step**

Stage 1: Create Policy

- **General approach to compliance**
- **Overview of requirements set by The Rule**
- **Responsibility Assignment**
  - Multi-department
- **Consistent Rule Interpretation**
  - Difficult to defend different interpretations

Stage 2 Create Plan

- **Describe Stages and Steps (or equivalent)**
- **Integration of Administrative, Procedural, and Technical Controls**
- **Include a time-line**
- **Training**

Stage 3: Create Procedures

- **Security**
  - Passwords
  - Building & Room
- **Signature**
- **Application of Plan**

Stage 4: Systems Step by Step

- Step 1: Create an equipment/system inventory.
- Step 2: Perform Coverage Assessment
- Step 3: Create Compliance List
- Step 4: Perform Gap Analysis
- Step 5: Perform Risk Analysis
- Step 6: Remediation
- Step 7: Validate

Step 1: Create an equipment/system inventory.

- Identify all relevant systems
- Err on the side of inclusion
- Note how the system is used
- Tip: Y2K list is a good starting point

Step 2: Perform Coverage Assessment

- **PREDICATE RULES**
- **Will the FDA ask for the record?**
- **Is it an Electronic Record?**
  - **What is a Part 11 E-Record?**

Step 3: Create Compliance List

- **Rule itself is a great starting point**
- **Use new guidance?**
- **Various checklists in industry**
- **Document the list**

Step 4: Perform Gap Analysis

- Compare each piece of equipment and each system with your list
- Determine the gap between the two
- Should result in matrix or report or similar documentation

Step 5: Perform Risk Analysis

- **Analyze the risk** (Step 1: How system is used)
- **Creates a priority list for remediation**
- **Equipment/Systems with highest risk done first**
- **Looking for risk:**
  - Impact on product quality
  - Consistent with other risk structures in company

Step 6: Remediation

- **Integration of Technical Controls**
- **Often includes an equipment/system specific plan**
- **Migration plan**
- **Work with vendors or around them**
  - With vendors: Make needed changes
  - Without vendors: 3rd Party, Procedural Controls
- **Best Effort**

Step 7: Validate

- Validate!

Uniqueness of Legacy Systems

- **Not designed with Part 11 in mind**
- **Many obstacles (Gaps) can exist**
- **Again, "Best Effort" is important**
  - Hybrid System
  - Procedural Controls

Cost and Risk

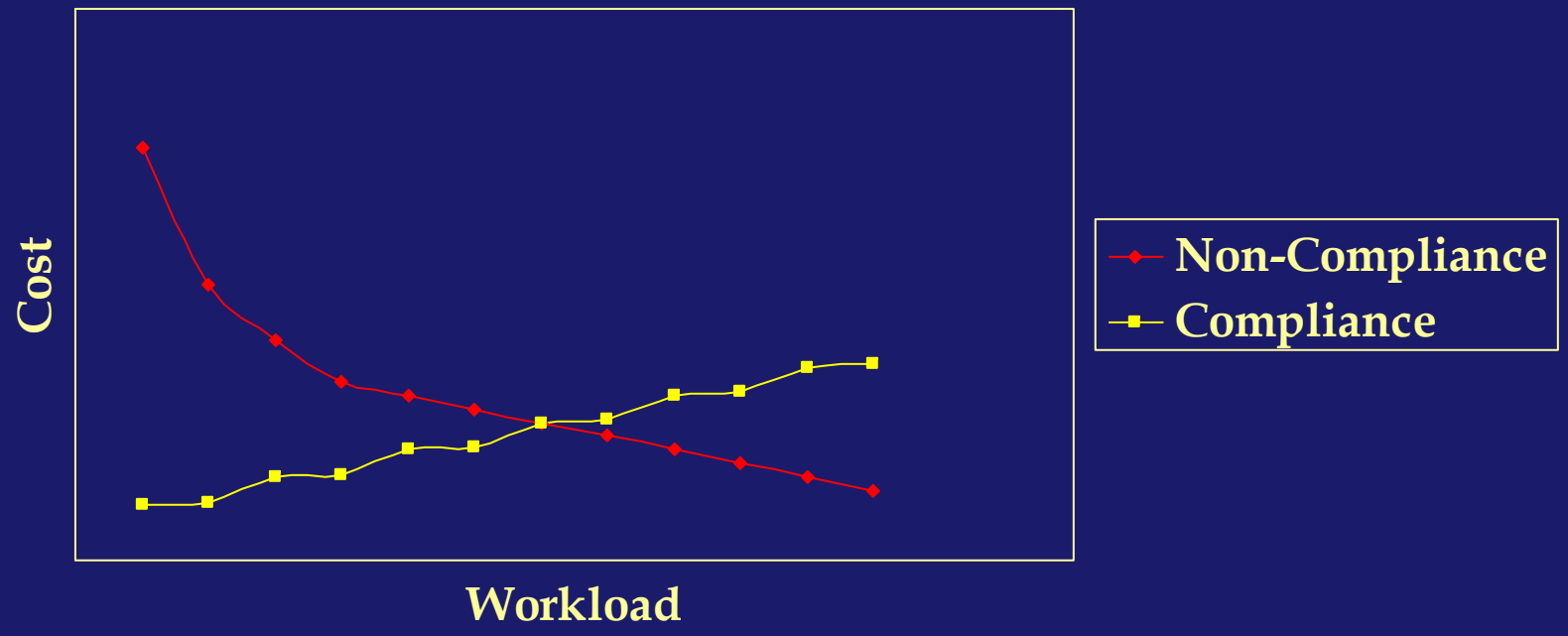
Cost of Non-Compliance

- FDA Fines (Risk Based)
- Opportunity Cost (Missed Clients)

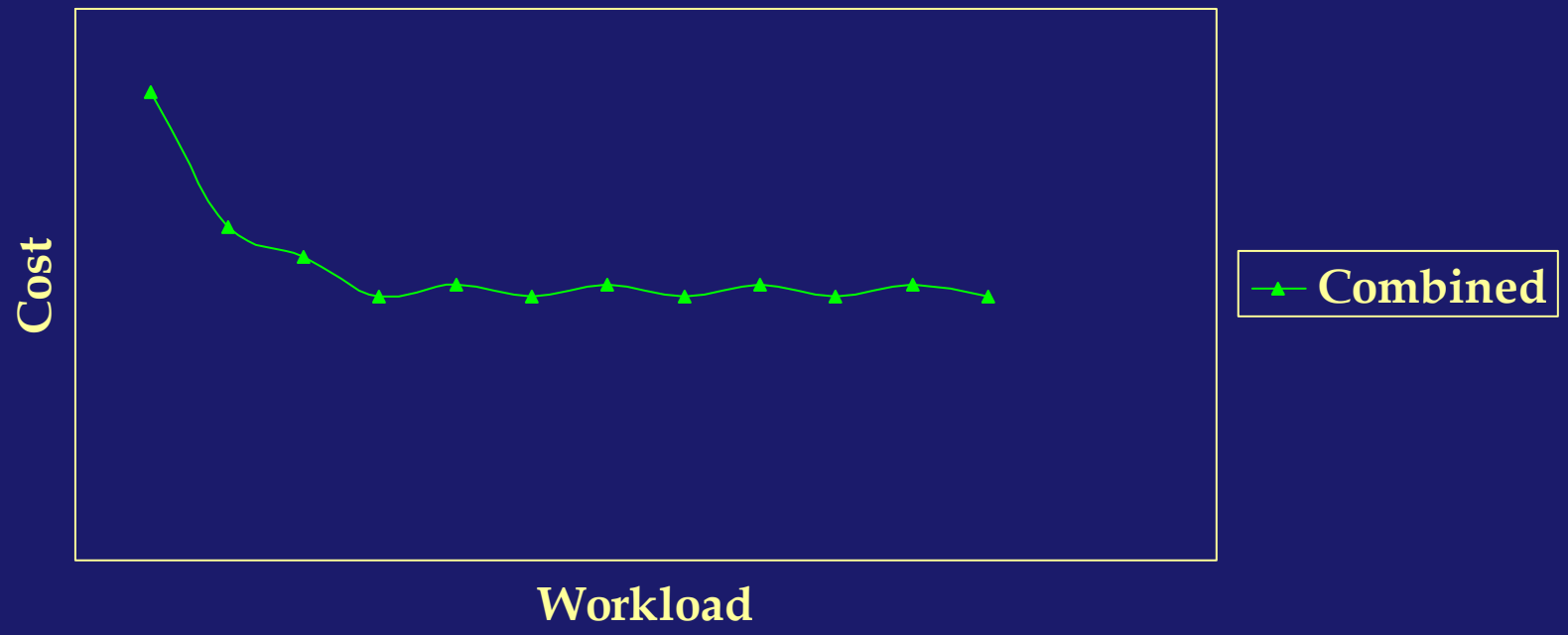
Cost of Compliance

- Technical Controls
- Personnel costs

Cost and Risk



Cost and Risk



NEW GUIDANCE!!!!

- **The source of the issue: New Initiative**
- **Transfer of Part 11 to CDER**
- **“FDA is re-examining part 11 as it applies to all FDA regulated products”**
  - **–Scope and Application Guidance**

FDA Says

- **"We anticipate initiating rulemaking to change part 11"**
- **"…we will narrowly interpret the scope of Part 11."**
- **"…we do not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 …"**

Important points

- **“Re-examination” NOT “Withdrawal”**

“…exercise enforcement discretion”

- **Narrow Interpretation of Scope (P11 doesn’t apply if)**
  - Use computers to generate paper printouts of e-records
  - AND paper records meet predicate rules
  - AND persons rely on the paper records

Important points continued

- **“Part 11 Records” Definition**
  - Predicate rules require
  - Electronic in place of paper
  - Electronic used to perform regulated activities

- **The “Enforcement Discretion” List (EDL)**

EDL 1. Validation

- **Rule (sect. for ED): Validation of systems to ensure:**
  - Accuracy
  - Reliability
  - Consistent intended performance
  - Ability to discern invalid or altered records
- **Must still comply with predicate rules for validation**
- **FDA recommends validating higher risk systems even if not under predicate rule**

EDL 2. Audit Trail

- **Rule (sect. for ED):**
  - Secure, computer-generated, time-stamped
  - Independently record the date and time
  - Changes not obscure previous information
- **Must still comply with predicate rules for sequencing**
- **FDA recommends audit trails for higher risk systems even if not under predicate rule**

EDL 3. Legacy Systems

- Grandfather clause
- Criteria for “enforcement discretion”:
  - “The system was operational before the effective date”
  - “The system met all applicable predicate rule requirements before the effective date”
  - “The system currently meets all applicable predicate rule requirements”
  - “You have documented evidence and justification that the system is fit for its intended use…”

EDL 4. Copies of Records

- **Rule (sect. for ED):**
  - Generate accurate and complete copies
  - In human readable and electronic form
- **Predicate rules on record inspection**
- **Conspicuous exclusion of “electronic form” in guidance**
- **FDA recommends “common formats” for copies**

EDL 5. Record Retention

- **Rule (sect. for ED):**
  - Accurate and ready retrieval through retention period
- **Predicate rules on record retention and availability**
- **Justified and documented risk assessment**
- **FDA does not intend to object to archiving records to microfilm, microfiche, paper, or PDF**
- **Hybrid systems are okay if predicate rules covered**

Thank You for Listening

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