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
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 vs. Workload

- Non-Compliance
- Compliance
Cost and Risk

Cost

Workload

Combined
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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