Part 11 Validation Approach for Paperless (Electronic) Chart Recording Systems

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on behalf of

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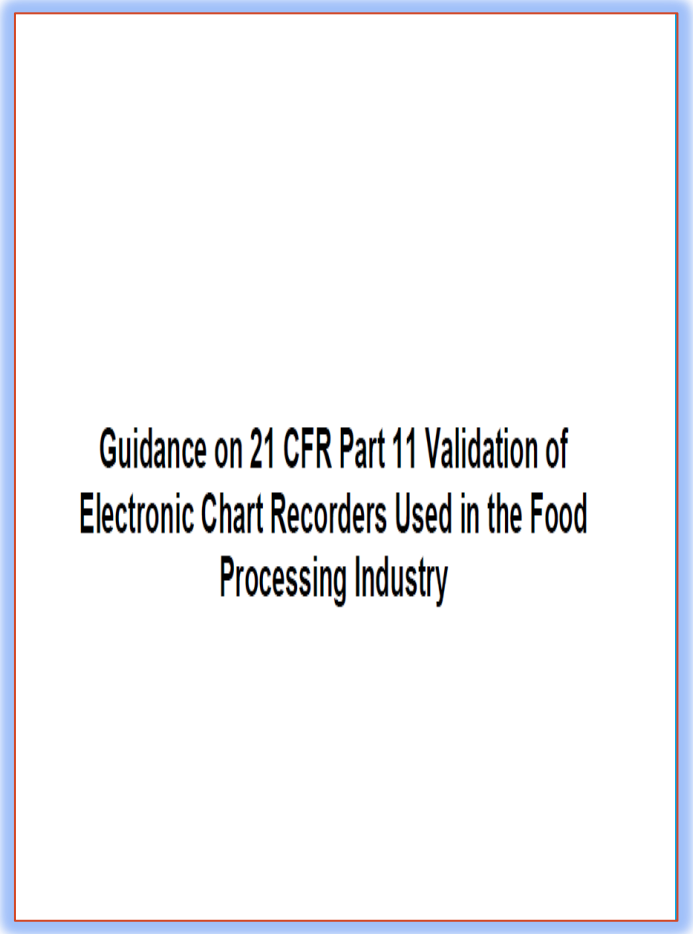
Industry Guidance: Scope and Objective

- Provide guidance on the validation of paperless chart recording Systems to meet FDA regulation on Electronic Records and Signatures, 21 CFR Part 11
- Focus on paperless chart recording system used in the food processing industry to create and maintain records required by the FDA
- Does not ensure compliance, but rather intends to outline a validation approach that can be used and adapted to meet 21 CFR Part 11 requirements
- Should be considered as best practice for any food manufacturing operations that intend to utilize paperless recording systems



Disclaimer

- The presented guidelines are not the opinions of the companies that employ the Ad Hoc committee members and reviewers
- Reference to any specific commercial product, process, trade name, trademarks, and manufacturer, or otherwise, do not constitute or imply its endorsement and/or recommendation by the Institute for Thermal Processing Specialists (IFTPS)
- The validation approach outlined in the guidance document shall be considered “voluntary” to enable compliance with the regulation

Definitions

Predicate rule: Rules/Regulatory requirements (e.g., 21 CFR Part 113) that must be met

Electronic Records: Records that are required to be maintained under predicate rule requirements; that are maintained in electronic format *in place of paper format* and that are relied on to perform regulated activities

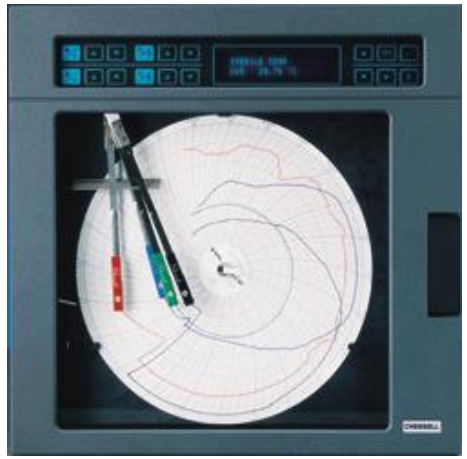
Electronic Signatures: Electronic signatures that are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules

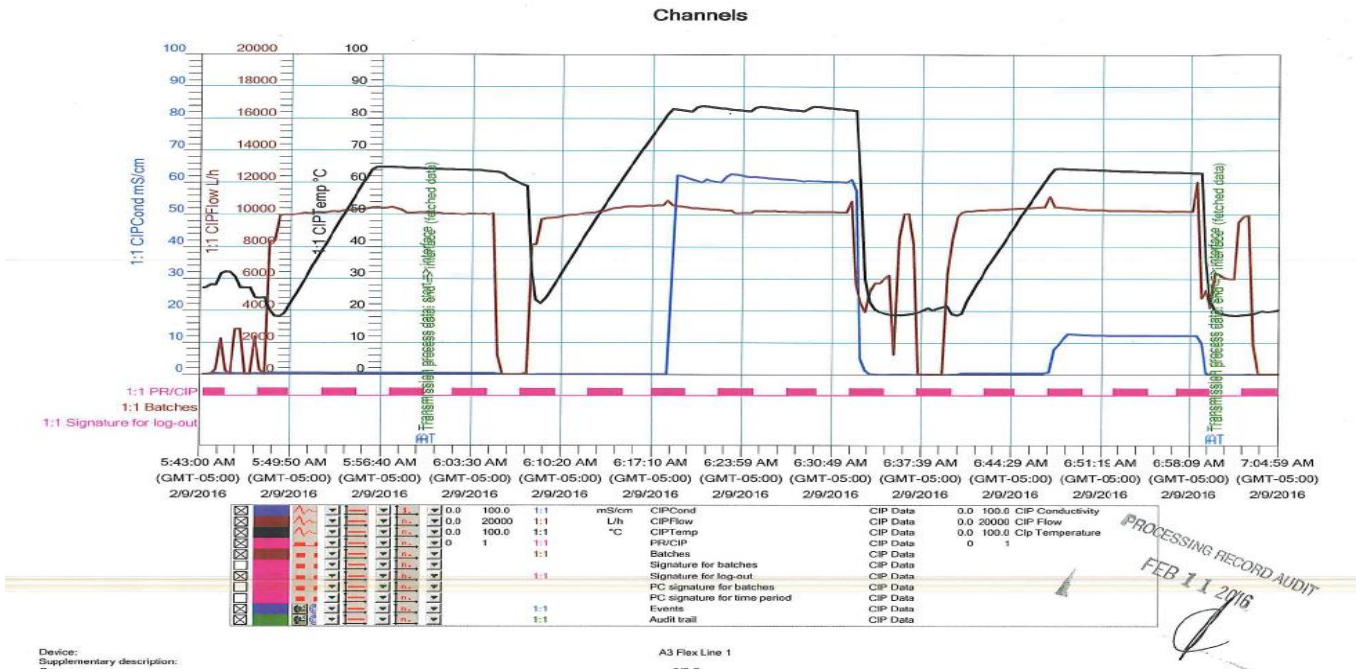
Overview of 21 CFR Part 11 Requirements

Part 11 Requirement	Main Point
Data Security and Data Access	• Electronic records must be protected to enable accurate and easy retrieval. • Access must be limited to authorized individuals. • Must be able to perform system checks, authority checks, device checks.
Audit Trail and Record Traceability	• Secure, time stamped audit trails must be used to record the date and time of operator actions/entries. • Persons who maintain, or use electronic systems must be properly trained. • Written policies must be developed to hold individuals accountable for actions performed under their electronic signatures.
Copies of Records & Record Retention	• Must be able to generate copies of records in both human readable and electronic format suitable for inspection, review, and copying by the FDA.
Electronic Signatures	• Electronic signature must be unique to each individual. • Persons using electronic signatures must certify that their electronic signature is a legally binding equivalent to their handwritten signature. • Identification codes and passwords must be periodically checked to ensure authenticity.
Validation	• **Systems must be validated to ensure accuracy, reliability, and the ability to discern invalid or altered records.**

Background

Paper vs. Paperless Chart Recorders





Perceptions around Paperless Chart Recorders

- Potential to loose critical thermal processing related records
- Records can potentially be tampered and can’t be attributed to a single operator or reviewer
- Advanced computing skills are needed
- Lack of interest in embracing the technology (i.e., Cultural aspect)
- Part 11 Validation is quite expensive and rigorous
- Lack of regulatory or industry guidance (How vs. What)

Transition from Paper to Paperless Recording System

- **Option 1:** Electronic chart recorders may be used as a backup recorder to paper chart recorders
- **Option 2:** Electronic chart recorders may also be installed in place of paper chart recorders with the ability to print, review, and sign-off on the printed records in compliance with applicable regulations
- **Option 3:** The third option is a fully integrated electronic chart recording and data storage system that is 21 CFR Part 11 compliant

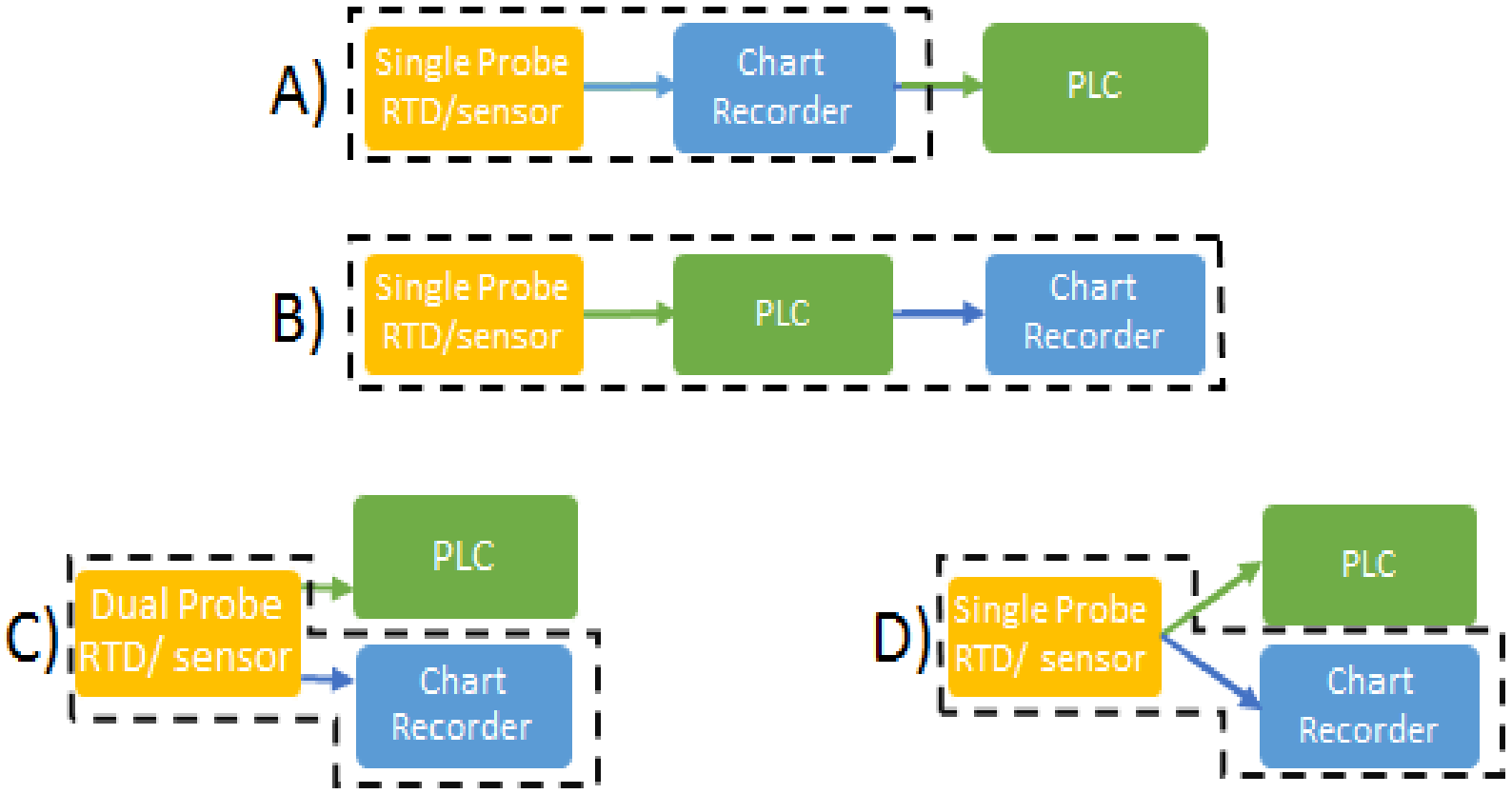
Paperless “Electronic” Chart Recorder Selection

- Select Part 11 compliant e-recorder (both Hardware & Software)
- E-recorder is compliant with predicate rule requirements
- Obtain “Statement of compliance letter” from the supplier

Validation Plan

- Validation Scope
- Cross-functional team roles and responsibilities
- Risk Assessment
- Validation Activities & Timelines

Validation Scope



Signal Distribution (Note: area within dotted line represents Part 11 validation scope).

Team Roles & Responsibilities

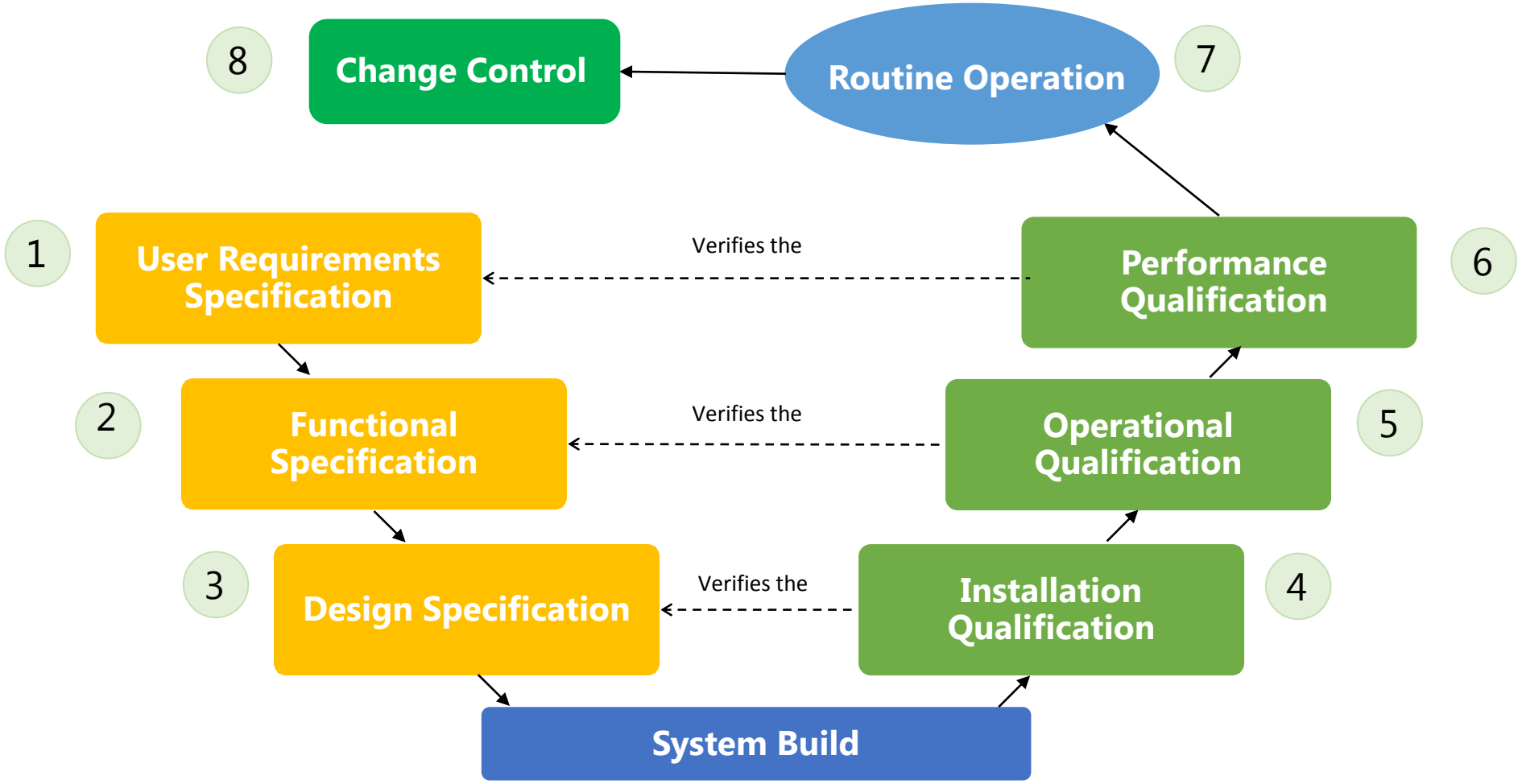
Risk Assessment

- Factors that may affect data reliability, accuracy, storage and security should be considered
- User Required Specification (URS) should be developed based on Risk Assessment

Validation Activities & Timelines

Activity	Target Date	Responsibility
User Requirements Specifications		
Functional Specification		
Design Specifications		
Installation Qualification		
Operational Qualification		
Performance Qualification		
Validation Report		

Validation Life Cycle



1) User Requirements Specification (URS)

- Developed by End User, defines system requirements **upfront**
- Describes requirements or “needs” (from user/regulatory perspective, risk assessment) vs. good-to-haves or “wants”
- Using the information gathered in the URS, an electronic system may be selected and purchased

2) Functional Specification (FS)

- Provided by System Supplier
- Describes all major components and functions of the electronic chart recording system (i.e., System Display, Operational Overview, Set-up, Instrumentation, Hardware & Software, Networking, Data Security & Storage, and Data Recording, Monitoring, Reporting).
- All of the functional requirements (“Needs” and “Wants”) from the URS should be addressed by the FS

3) Design Specification (DS)

- Provided by System Supplier
- How is the system configured and programmed in order to perform the functions identified in the Functional Specification?

4) Installation Qualification (IQ)

- Verifies that system hardware and software have been built, installed and connected properly

  Verifies hardware and software connections, calibration verification and I/O checks for the electronic chart recording system

5) Operational Qualification (OQ)

- Verifies that system operates as intended during normal and abnormal operating conditions

  Conduct Functionality Challenge Tests

  Implementation of SOP's – System Operation; Logical Security; Record Review & Recordkeeping

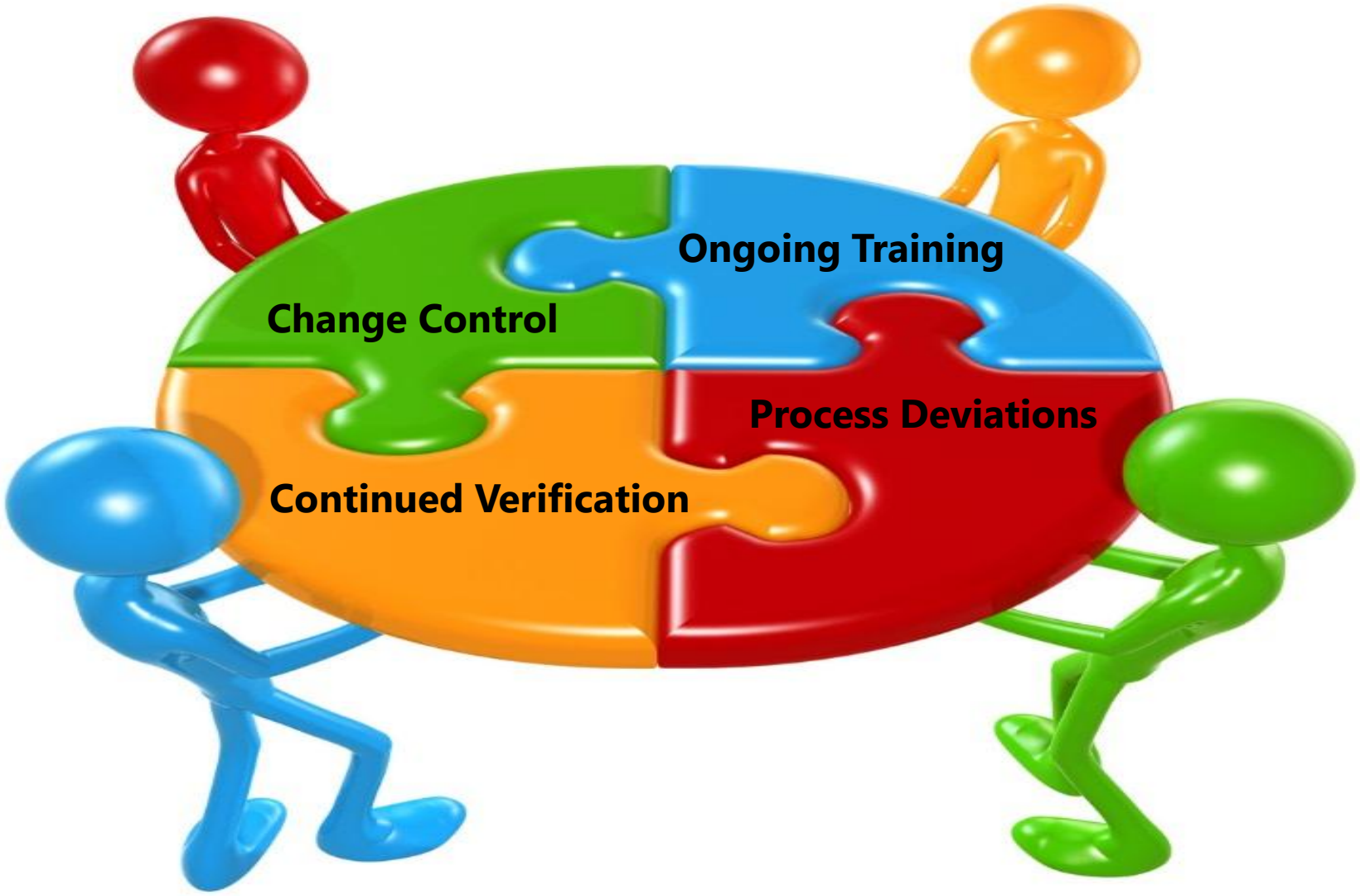
6) Performance Qualification (PQ)

- Verifies that the system is working properly under normal operating conditions and system meets all regulatory requirements (i.e. URS) prior to beginning regular use in production

Validation Report

- Documented evidence that the validation was completed with successful results
- Validation documents and report should include applicable team member sign-offs
- Validation documents and final validation report shall be considered as permanent records and kept on file at the plant and/or at the corporate level

Post Validation Activities



Summary

- The validation guideline is a compilation of industry best practices that aims to serve as a practical guide for implementation and execution of 21 CFR Part 11 validation in our industry

Authorship and Acknowledgements

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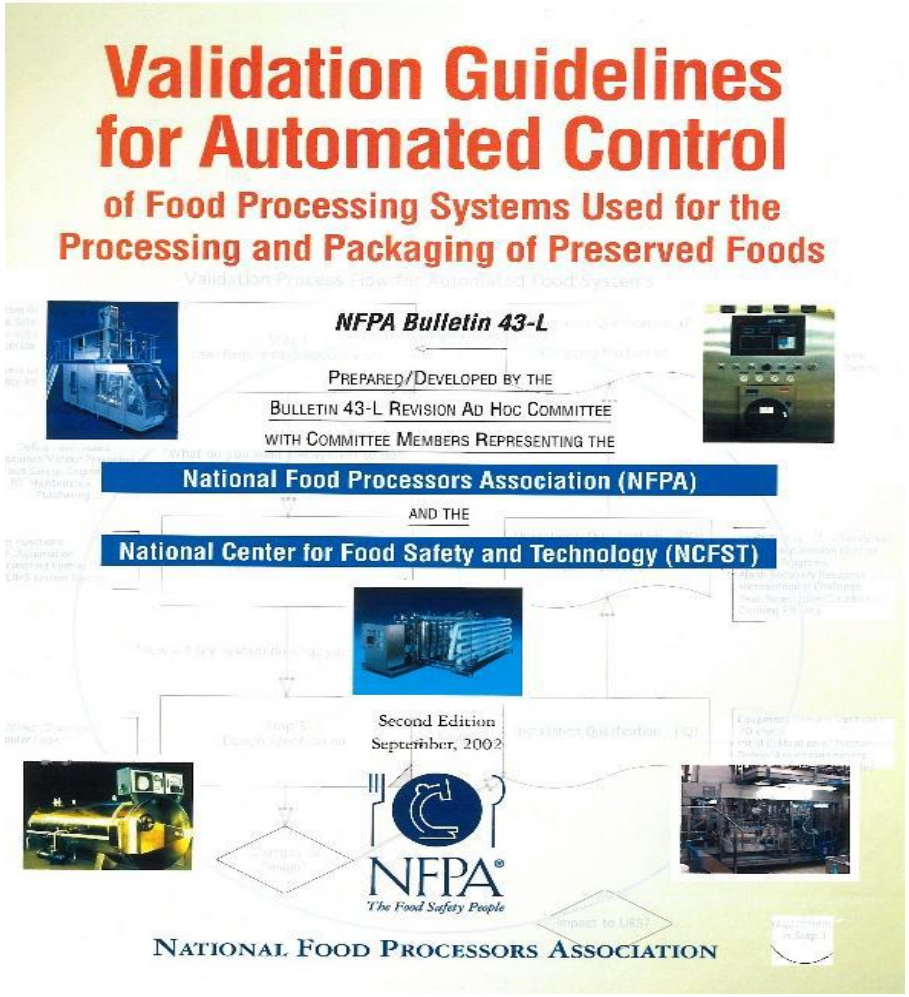
References



FDA

21 CFR Part 11

Next Steps

- General Membership review and comments
- Deadline for receiving membership comments: Mid May 2017
- Target publication date: June 1st 2017
- Your feedback is needed!

“Feedback is the breakfast of champions.”– Dr. Ken Blanchard

Thank You

thank you
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рахмат
謝謝
ngiyabonga
teşekkür ederim
Баярлалаа
спасибо
faafetai lava
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dank je
misaotra
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blagodaram
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