Enterprise Resource Planning(ERP)

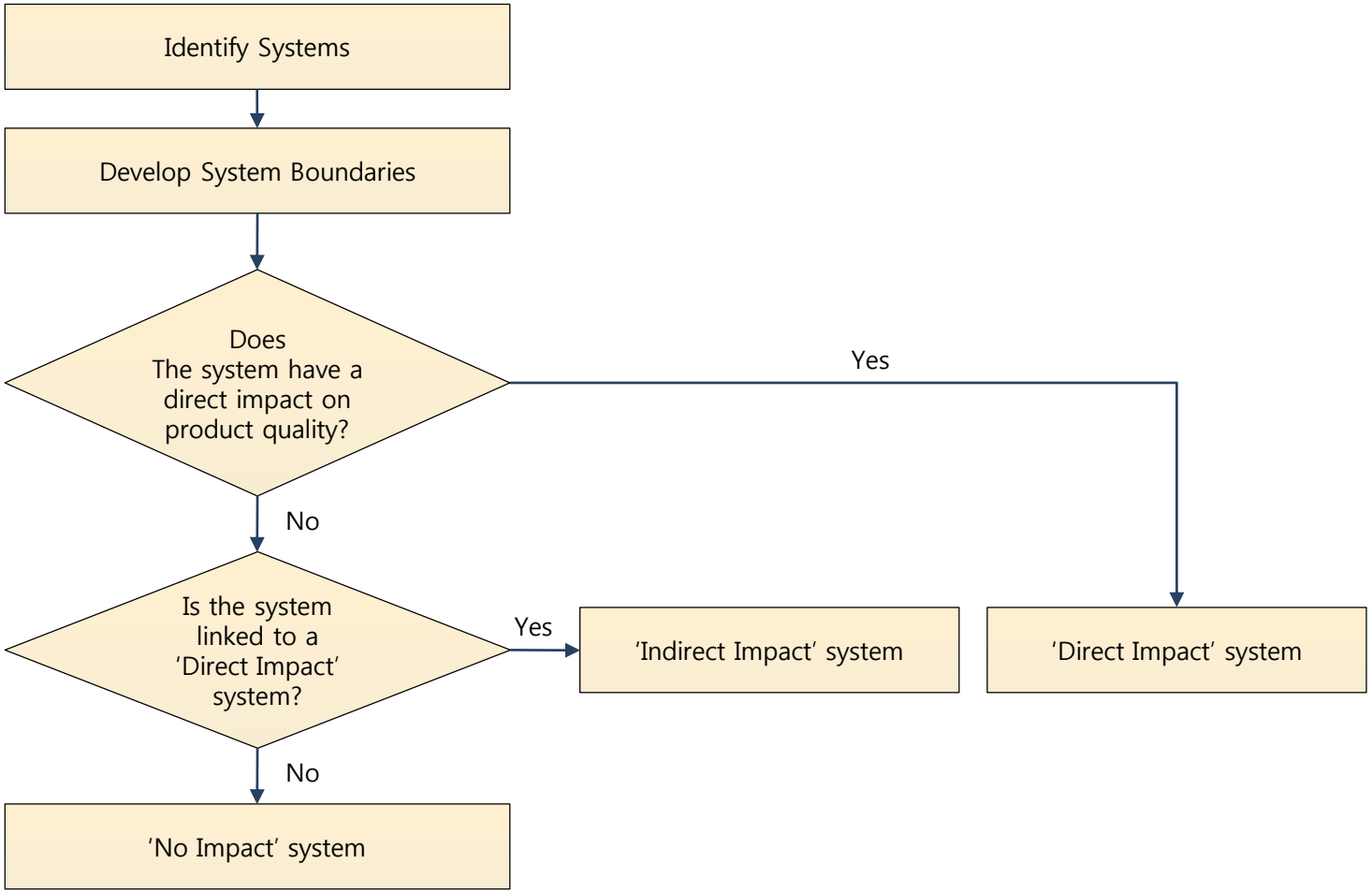
System 밸리데이션 전략

Computerized System Validation Strategy

User Requirements

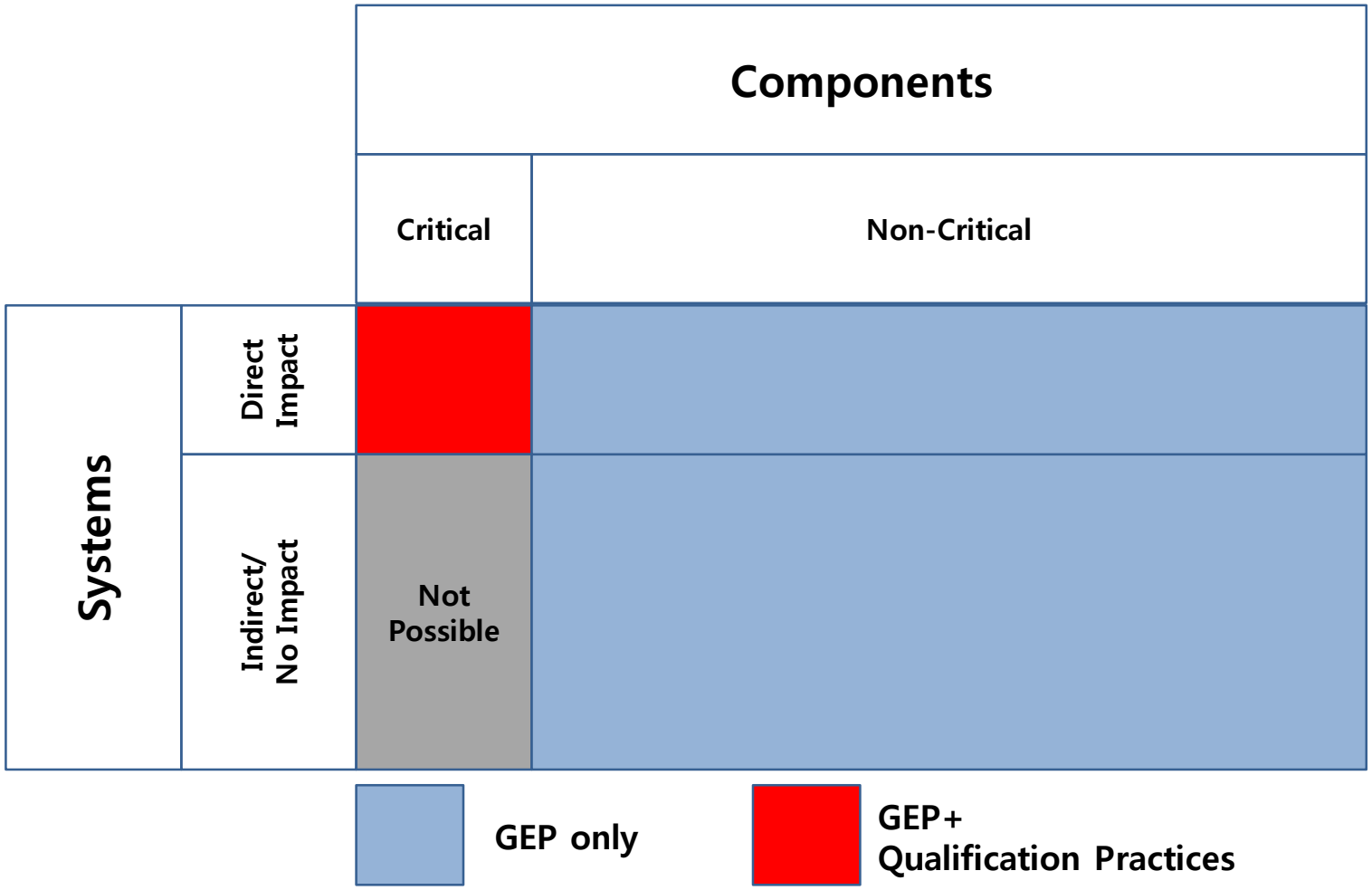
- Regulation or Guidelines
  - 새GMP해설서 제5개정
  - 21 CFR Part 211
  - 21 CFR Part 11
- Process-To be process(Online or Off-line/ GMP or Non-GMP)
- Equipment (if necessary)
- Management System (Hardware/ Software)
  - Network
  - Application
  - Database
- Interface
- Access and Security Requirements
- Constraints to be observed
- Life Cycle Requirements

GxP Determination



- Modules or Sun-modules to be included in GxP determination activities are based on a defined 'To be process' of the user requirements specification

GxP Determination



- In the ERP, each module will be considered a system of the diagram above, and components will be defined in accordance with what level users declare as the terminal components

Validation Plan 1

- Scope Definition
- Risk Assessment
- Design Review
- Test Strategy
- Training (System & Validation)
- GAMP Categorization
  - Hardware
  - Software
- Acceptance Criteria
- Roles and Responsibilities
- Deviation
- SOPs
- Change Control

Validation Plan 2

- Category 1 – Infrastructure Software
  : OS, Database managers, programming languages, middleware, ladder logic interpreters, etc
- Category 3 – Non-Configured Products (except for Run-time parameters)
  : COTS (Commercial Off the Shelf), Laboratory Instruments
- Category 4 – Configured Products
  : LIMS, SCADA, ERP, DCS, EDMS, etc
- Category 5 – Custom Applications
  : Custom ladder logic, Developed IT applications, Spreadsheets (macro), etc

Note: Judgement based on Risk, Impact and Complexity should determine whether systems used with default configuration only are treated as a Category 3 or Category 4.

Validation Plan 3

- Test Approach for Category 4
  - Life cycle approach
  - Risk-based approach to supplier assessment
  - Demonstrate supplier has adequate QMS
  - Some life cycle documentation retained only by supplier (e.g., Design Specification)
  - Record version number, verify correct installation
  - Risk-based testing to demonstrate application works as designed in a test environment
  - Risk-based testing to demonstrate application works as designed within the business processed
  - Procedures in place for maintaining compliance and fitness for intend use
  - Procedures in place for managing data

Validation Plan 4

- Test Approach for Category 5

  Same as for configurable, plus:

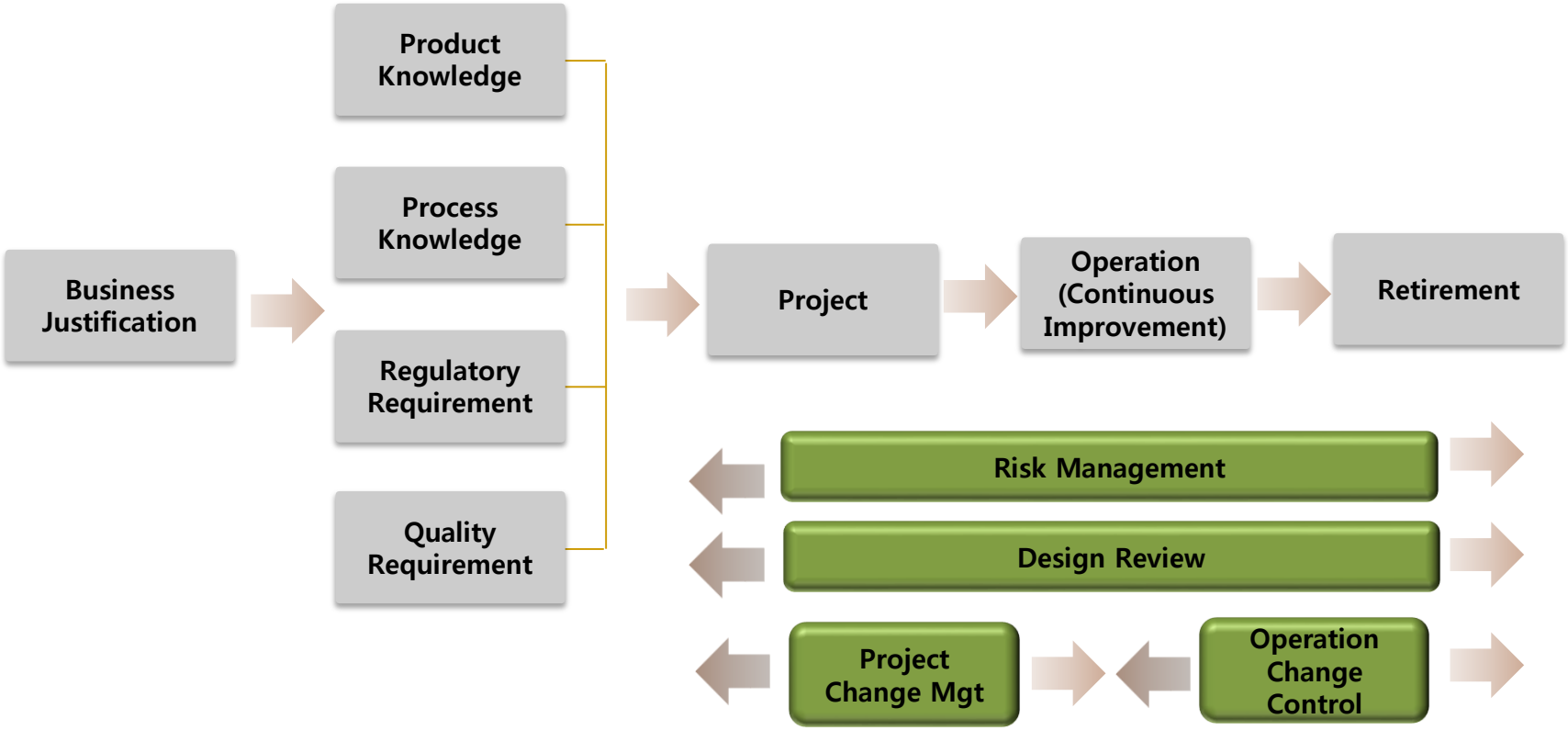
  - More rigorous supplier assessment, with possible supplier audit
  - Possession of full life cycle documentation (FS, DS, structural testing, etc.)
  - Design and source code review

Risk Assessment 1

- FMEA (Failure Mode and Effect Analysis)
  - System Components
  - Process
  - System Functions

- Possible Issues
  ① Poor Design
  ② Lack of Safety
  ③ Poor Quality Finishes
  ④ Lack of Cleaning
  ⑤ Lack of Maintenance
  ⑥ No Usage Log or Record

Risk Assessment 2



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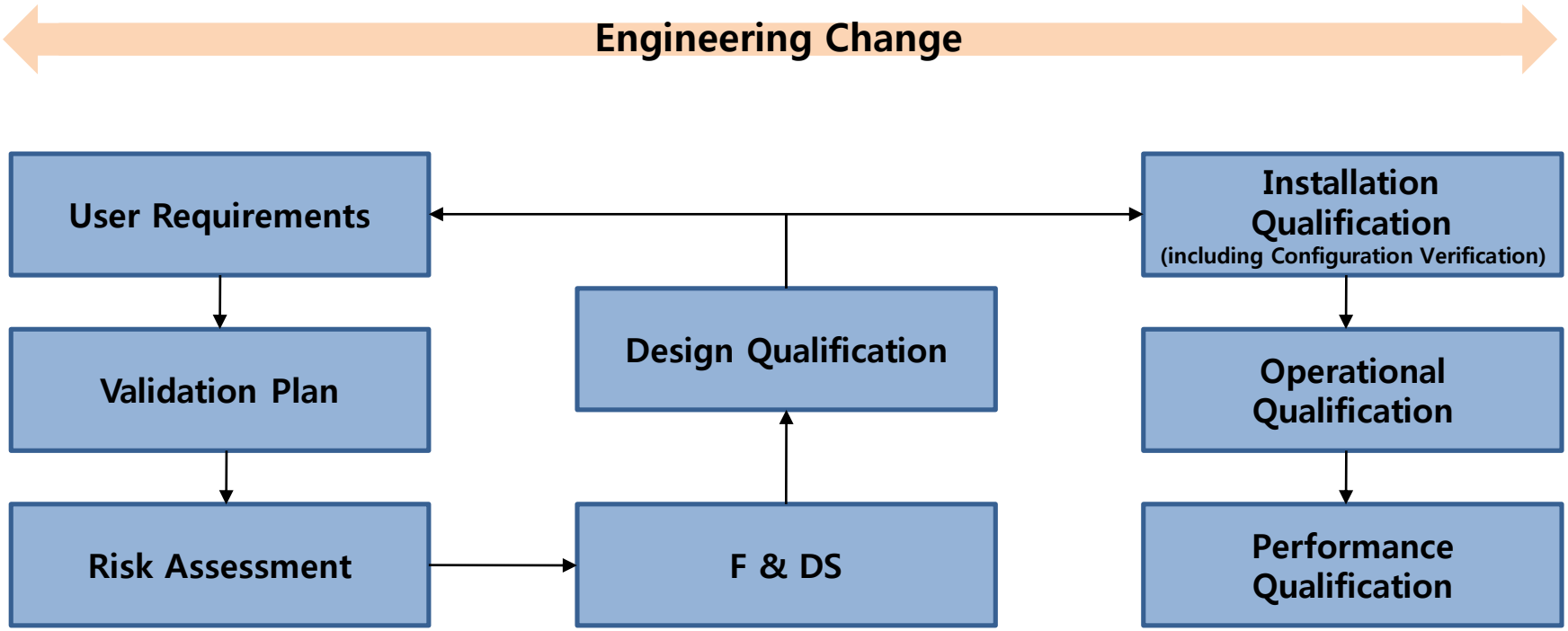
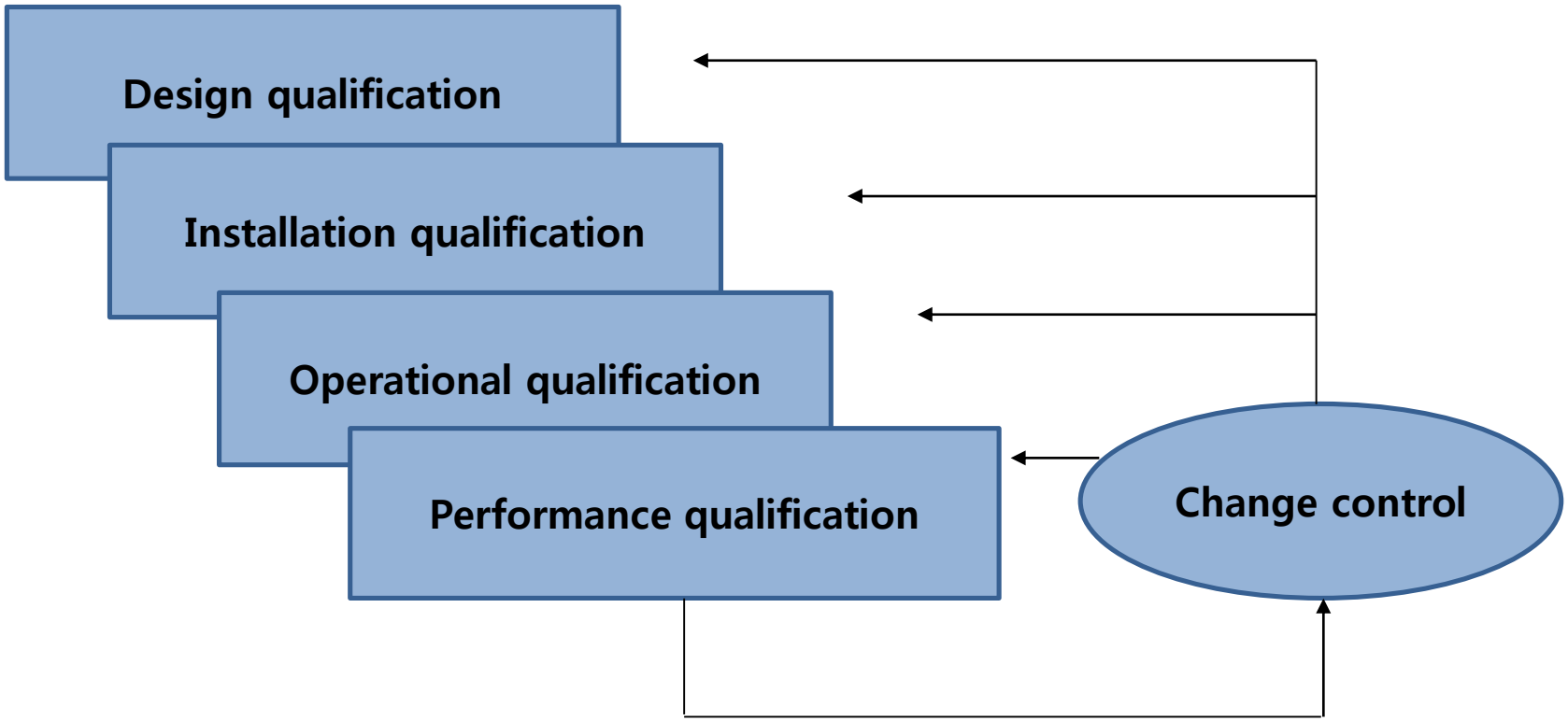
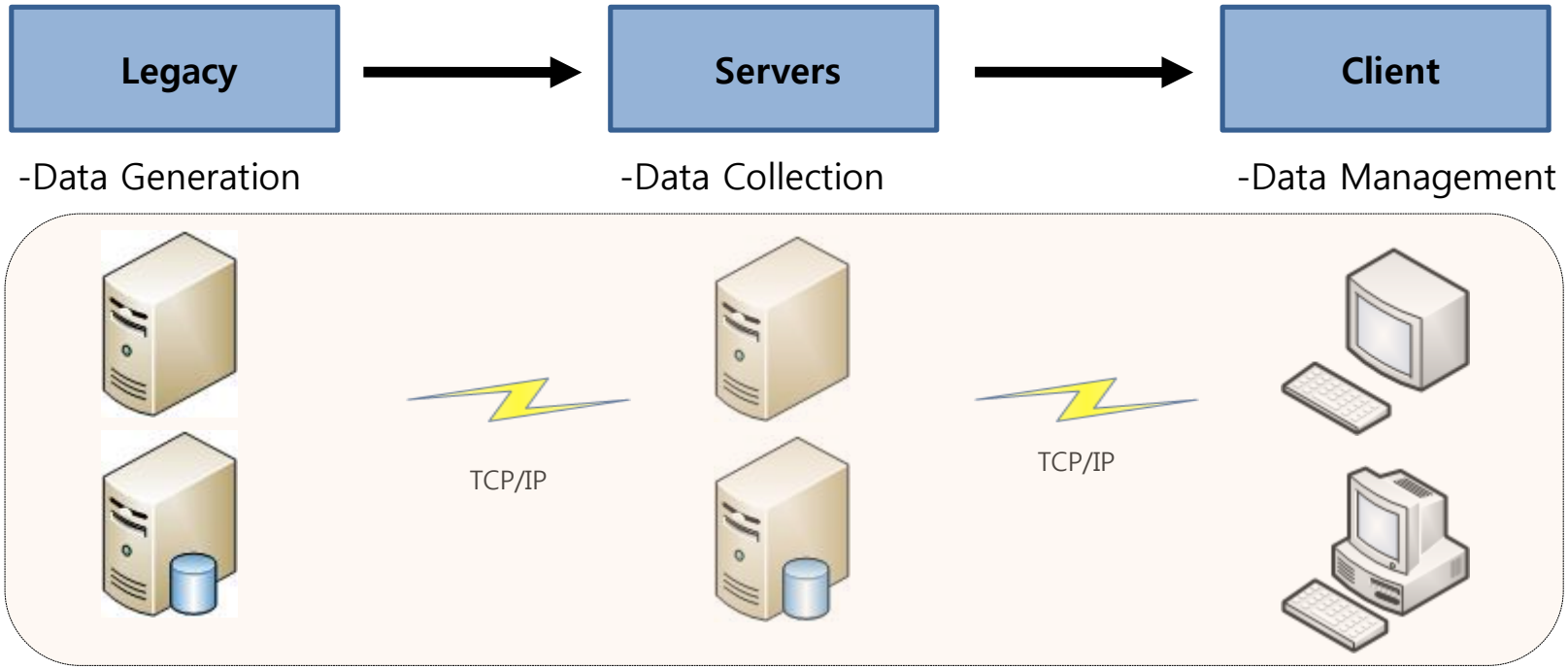
Change Control 1



Change Control 2

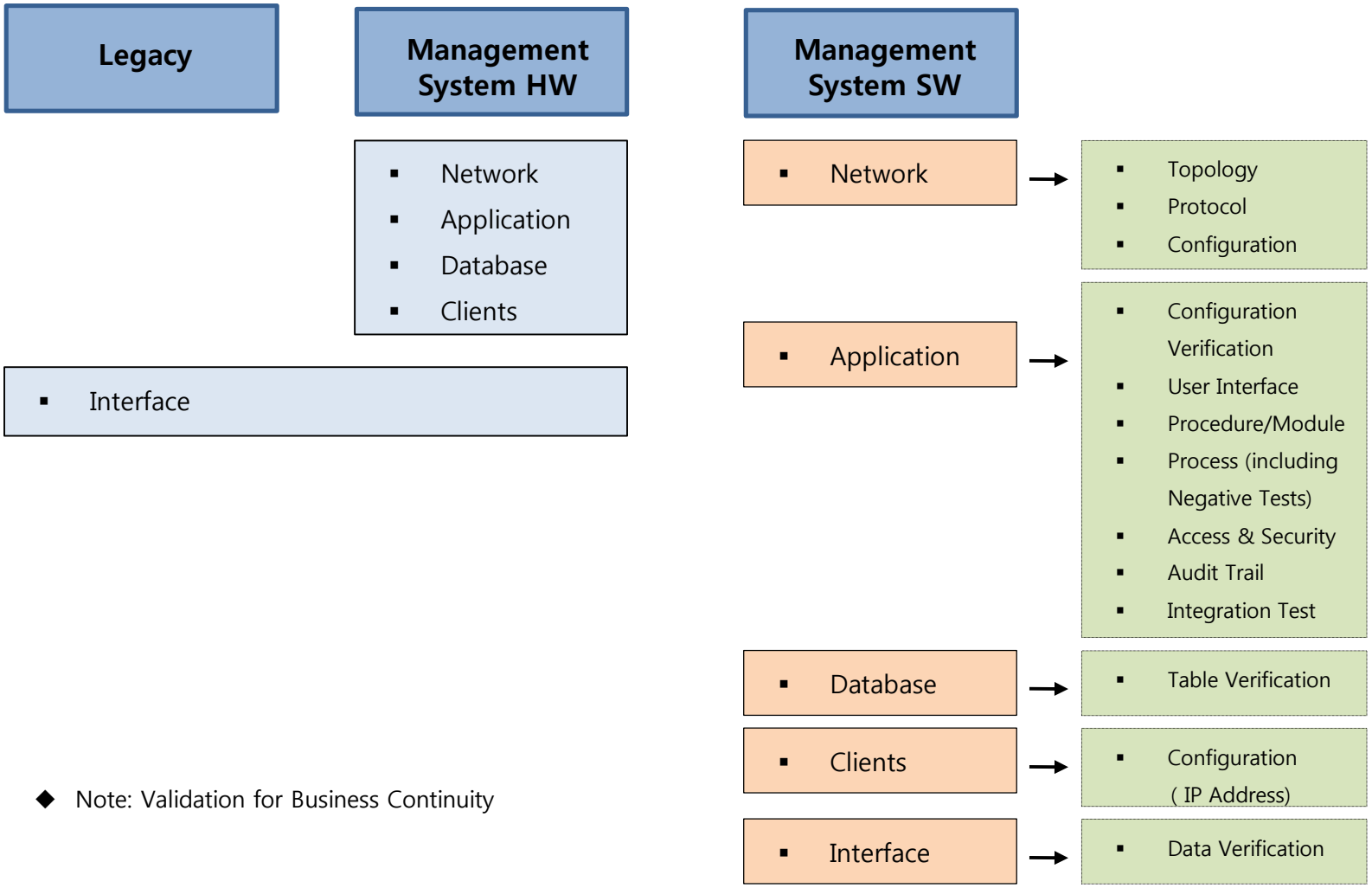


Data Flow of Management System



◆ Components to be validated
① Network
② Application
③ Database
④ Clients
⑤ Interface

Tests Applicable for Management System



◆ Note: Validation for Business Continuity

Design Qualification

- Documentation verification of Functional Detailed Design Specification (F&DS) against User Requirements Specification (URS)

- Management System
  - Architecture
  - Network
  - Application (Based on a defined 'To be process')
  - Database
  - Configuration

Installation Qualification

- Management System
  - Network
  - Infrastructure
  - Application Installation
  - Database
    - ✓ Clustering Service
  - Clients
  - Configuration Verification (Documentation for the Implementation Guide Settings)

Operational Qualification

- Management System
  - User Interface
  - Procedures/ Modules/ Sub-modules
  - Process
  - Access & Security
  - Backup & Recovery
  - Audit Trail
  - Data (Table Verification)
  - Reports
  - Interface
  - Integration Tests

◆ Negative Case should be considered when a protocol written

On-going SOPs

- Operation
  - Procedures
  - Critical Parameters
  - Preventative Maintenance
  - Cleaning
  - Calibration
- Backup & Recovery (Data & Application)
- Access & Security
- Business Continuity Plan
- User Training

- GAMP 5 A risk-based approach to compliant GxP computerized system
- GAMP Good Practice Guide: Validation of Process Control Systems