Data Migration and Verification – Validation Strategies when Transferring Data from Legacy System

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Data Migration Strategies
  Migration: What and How?
  Documenting Migration Strategy
Preparing for Migration
  “Data Scrubbing”
Data Migration Verification
  Verification Strategies
  Sampling Methodologies
Case Studies
You are Moving!
Why?

- Obsolescence of Legacy System
- New Hardware Requirements
- Moving to a New Solution
- Consolidating of Legacy Systems
- Moving to a Cloud Solution
- Lack of support with Current System
- Etc...
Migration increases project:
- Complexity
- Risk
- Timeline
  - Not by hrs.... by weeks... or months
- Cost

Migration can NOT be an afterthought.
Key Question for Migration

- What?
- Where?
- How?
What are you “Moving”/Migrating?

Define your “data”
- Database
- Application/Solution/Software and Database
- Raw Data/Metadata
Where are you Migrating?

**Source**
- One Source
- Multiple Sources
- Type of System
- Type of data
- Metadata
- Export Capabilities

**Target**
- System Capabilities to accept data from one source or different sources
- Compatibility of Data

Change?
**Data archiving** is the process of moving **data** that is no longer actively used to a separate storage location for long-term retention.
Considerations Archiving vs Migrating

- How often you access the data
- Criticality of the data
- High amount of data manipulation to move to new solution
- Project budget constraints
- Unable to transfer to new solution

What do you need to migrate vs what you want to migrate?
Additional Considerations: Archiving

Consider

- Regulatory Impact
- Data must be saved with **all** its Metadata
- Data must be Retrievable
- Data must be Accessible during its entire retention period
Consider alternatives: Keep Legacy System “Read Only”

Considerations:

- Legacy System is still Active
  - Part of your Review Process (with exceptions)
- Must add additional controls
  - Limit Access to the system (few users/licenses)
  - No changing data - configuration updates
- Still incur in costs
How are you migrating?

- Define the PROCESS at a high level then ENSURE that the Technical Team can make it a reality
- Obtain agreement on the migration strategy
- Critical information to define testing strategy
- Planning takes TIME
- Must include all responsible parties
  - Business
  - Technical SME (IT/Automation)
  - Including Quality!
Data Migration Plan

Documents Migration Strategy for a project/solution
Can be its own document or combined with the Validation Plan
  - Depending on risk level and complexity
Defines Project Scope
Included High Level Migration Strategy
Assessment of Data Criticality
Defines Testing Strategy
Data Migration Plan

Defines Roles and Responsibilities

- Agreed by the team
- Includes all vendor responsibilities

Must be an Approved deliverable
Data Migration Plan – Document Sections

- **Scope**
- **Roles and Responsibilities**
- **Source and target systems**
- **What data will be moved/ exclusions if any**
- **Tools to be used/ if any**
- **Sampling justification/if any**
- **Acceptance criteria**
- **Error/Deviation strategy**
High Level Migration Strategy

Should identify three main strategies:

- Pre-Migration
- During Migration
- Post Migration
Data Migration Protocol

- Executable document
- Can be a stand alone document or combined with any other deliverable (dependent on risk level and/or complexity)
  - Data Migration Plan (If not in Validation Plan)
  - A section in either OQ or PQ
- Contains Executable Data Verification Tests
Data Migration Summary Report

- Can be a stand alone document or combined with any other report deliverable.
- Summarizes all Results
- Identifies Errors/Deviations, Resolutions and Exception Justifications
“Planning is the number one success factor for any migration project, independent of complexity. Not only does upfront planning help shorten the duration of the migration process... it reduces business impact and risk...”

Anonymous Industry Expert
Plan for “failure”

- Identify risk scenarios for failure points pre, during and post-migration.
- Provide mitigation strategies
- Make team aware of risks and mitigations – Limit the surprises
“Scrubbing”

Data is “Scrubbed” or “Cleaned” when it needs to change prior to import to Target System.

Data changes either by manual or automated tools.

Examples:
- Addition of Metadata
- Alignment of Metadata
- Addition of Fields not in Legacy System
- Removal of field not mapped to Target System
Document what you are doing to the data.

- If automated:
  - Must confirm functionality of the tool used.

- If Manual:
  - Provide clear guidance of mapping requirements
  - Ensure control of data files
  - Provide List of Values for fields
  - Keep eye for extra spaces, special characters, character limitations
Data should be verified by SMEs once updates are complete
Verification should include legacy data and updated data
Sampling may be used, depending on risk and criticality of data
Ensure data integrity is maintained through the process
Verification Strategies

Verification/Qualification of data migration encompasses
- Pre-Migration
- During Migration
- Post-Migration

Post Migration should NOT be the only time data should be verified.
Automated Extraction and Importing Tools need to be tested.

Confirm functionality – “proof of concept”
- Utilize small data set
- If available, take advantage of Development/Test Environment
- Document proof of concept
Automated Verification Tools

Verifications tools should be independent from Extraction/Import Tools

Can be used at any time of verification
- Pre-Migration
- During Migration
- Post-Migration

Must be qualified
- Challenge with smaller data set
- Must include Negative testing
Sampling Methodologies

Sampling vs 100% or more

There is not a “One Size Fits All” approach

Decision between sampling or full data verification must consider:

- Risk – Is the data high Risk Data or low?
- Migration Process – Understanding the technical process on how the data is moved from Source to Target
- Amount of human intervention
Traditionally Use of ANSI/AQL Tables

Determine a sample size according to Level and Severity

<table>
<thead>
<tr>
<th>Lot size</th>
<th>Special inspection levels</th>
<th>General inspection levels</th>
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<td></td>
<td>S-1</td>
<td>S-2</td>
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<tr>
<td>9 to 15</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>16 to 25</td>
<td>A</td>
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<td>91 to 150</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>151 to 280</td>
<td>B</td>
<td>C</td>
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<tr>
<td>281 to 500</td>
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<td>C</td>
</tr>
<tr>
<td>501 to 1200</td>
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<td>C</td>
</tr>
<tr>
<td>1 201 to 3 200</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>3 201 to 10 000</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>10 001 to 25 000</td>
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</tr>
<tr>
<td>35 001 to 150 000</td>
<td>D</td>
<td>E</td>
</tr>
<tr>
<td>150 001 to 500 000</td>
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<td>E</td>
</tr>
<tr>
<td>500 001 and over</td>
<td>D</td>
<td>E</td>
</tr>
</tbody>
</table>
Determine your Accept Reject Criteria by selecting AQL level

Table 2-A — Single sampling plans for normal inspection (Master table)
Sampling Methodology

Due to the regulatory impact of our data, accept/reject criteria tends to be 0-1.

Nonconforming data is not acceptable
Case Studies
Firm wants to migrate legacy documents to new electronic document management system. Legacy system contains multiple revisions of each document. Document types are not uniformed. It includes procedures, forms, engineering drawings, validation documentation, etc.
Challenges:

- Multiple Document types
- Multiple Document Formats
- Multiple Document Versions
- Document Numbers
- Prior Approvals (e-signatures/audit trails)
- Conflicting Metadata between Source and Target Systems
- Verification Plan
Case Study: eDMS

Migration Strategies:
- Confirm what metadata legacy system maintained
- Document ‘scrubbing’ requirements
  - Map each Legacy metadata field with Target system
- Document data migration for each document type
- Identified Data to migrate – not 100% of records
- Versions
  - Migrated previous versions in PDF only
Case Study: eDMS

Pre-Migration Strategies:

- Iterative Qualification of Export Tool
  - Confirmed each file type
  - Different Acceptance Criteria for each type file

- Criticality of Data Scrubbing
  - Training to Data Owners
  - Clear responsibility for each Data Type
Post-Migration Strategies:

- Specific Verification Criteria for each file type
  - Dependent on file criticality
- UATs to confirm functionality with migrated data
Firm needs to upgrade hardware for a continuous historian. Historian runs 24-7. Files are continuously updating with data. System monitors HVAC system for both regulated and not regulated areas.
Case Study: Continuous Historian

Pre- Migration Strategies:
- Stand up new target system parallel to legacy system
- Pre and Post comparison of each data type
- No data sampling (no data scrubbing)

During Migration Strategies:
- Utilized file size/date time stamps

Post-Migration
- Comparison of Data with Pre Migration
- UATs to confirm functionality
Case Study: Continuous Historian

Challenges

- Accepted “Loss” of Data during Migration
  - Documented that No activities occurred in Regulated Areas
- Communication Plan - Critical
Firm utilizes cloud solution A to review and approve its commercial art that will be used in packaging and medical brochures. Due to issues with solution A, firm is transitioning to new cloud solution B.
Case Study: Art Work Software System

Migration Strategies:
- Limited control on Extraction and Import tools
- All focus on data

Pre-Migration
- Define logistics for data transfer
- Determine mapping between data from source and target system
- Iterative proof of concept for target system data display
- Document strategy for each file type
- Defined Interim Data location after export
Case Study: Art Work Software System

During Migration
- Verification of data to interim location
- Full Migration to New Target Test System
- Execution of UATs for acceptance
- 100% verification of data
- Full Migration to Production System

Post-Migration
- Confirmation of migration
- Sampling of Data
Case Study: Art Work Software System

Challenges

- Vendors
  - Agreements/SLA
  - Communications
  - Timing
  - Support
Firm will be upgrading the hardware and infrastructure for their PCS system. In addition, the software will be upgraded. The system contains data for the control of all their manufacturing process and it’s tied directly to their batches. Manufacturing process runs 24-7. Approval has been granted for 7 days for the system to be down.
Case Study: Migrating PCS

Pre- Migration Strategies:
- Stand up new target system parallel to legacy system
- Upgrade of software
- Proof of concept – critical
- Pre and Post data comparisons
- Use of automatic tools for comparisons
  - Automatic Tools Qualified PRIOR to migration
- Phased approach for data migration
Case Study: Migrating PCS

Pre-Migration Strategies:
- No data loss – Merging Data
- MUST perform “dress rehearsals”

Generation of Playbook
- Step by step process
- Identifies Responsible Parties
- Identifies Strategies in case of failure
During Migration Strategies

- Communication and Planning – Critical
- Phased release of the system
- Comparison of Pre/ Post data
- Merged functional verification of system with data verification tests
- “War Room” – SMEs available for unpredicted error resolution
Post-Migration Strategies:

- Verification of functionality, per UATs
- 100% verification of merged data
  - Used Automatic tools
- Post – Migration support team
Plan... Plan... Plan...

Document your Strategy

  - Pre-Migration
  - During Migration
  - Post-Migration

Sampling – when appropriate

UAT – Functionally Challenge