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Data Governance –

Keeping Control through a Well-Defined Change Request Process

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Introduction

The effective management of Change Requests is a keystone in the delivery of standards within an organisation. Without a well-defined process that supports tracks and informs standards managers of the status of updates, it will be difficult to maintain control of global standards.

This presentation will draw from real life experience and focus on the Data Governance processes required to deliver updates to standards from cross-functional teams (data managers, statisticians, programmers and standards managers).

The governance processes include development, maintenance, escalation and appeal. From initial request to an Impact Analysis assessment of a requested change (including understanding the potential impact on linked Library Objects), through to planning and tracking till completion, an efficient Data Governance Change Request (CR) process enables controlled changes to a global standards repository platform (aka Metadata Repository (MDR)) whilst keeping the change process nimble and open, with the goal that data standards defined in the repository are quickly adapted to reflect the changing needs of its users.

Effective Data Standards Governance

Although the configuration of standards management will differ from company to company, all organisations involved in the creation and use of Data Standards will have a governance mechanism in place. The elements included within an MDR may differ in other organisations, but there will be common elements to perform the controlled management of standards. The roles, functions and descriptions in this paper reflect the experience of working with a global pharma company and the development of BDLS's commercial platform, CDmation®.

The vision for the global standards repository was not limited to CDISC Standards (CDASH, SDTM, ADaM), but was to deliver End-to-End (E2E) metadata definition and management, including: Data Collection Modules (DCMs); Endpoints; Assessments; Statistical Methods; Protocol elements; Statistical Analysis Plan (SAP) elements; Tables, Figures and Listings (TFLs); and Analysis Results Metadata (ARM).

The successful development of a governance process flow combines multiple threads: Change Request Roles definition; Change Request Cluster categorization; Change Request Evaluation Criteria; Change Request Impact Analysis; and Assignment of Library Objects to Change Request Work Packages.

Data Standards Governance Change Request - Roles

In working with our client, a core principal of the platform was the need for it to be responsive to the business needs. The platform would be accessed across wide functional user-community - data management, biostatistics, programming, clinical scientists and standards management. Whilst most users would be read-only, consumers of standards, there would also be a number of subject matter experts drawn

from the different functions to act as key resources in the creation, update and maintenance of metadata within the framework of the Data Governance process, with this overseen by the Standards Office.

Figure 1 - Change Request Roles

Standards Consumer: Able to browse and consume the data standards stored within the global standards repository, but not able to make any updates (read-only access). In consuming the data standards, it is important that the users be engage with the standards, and be able to initiate requests for updates and additions to the standards.

Project Manager: Responsible supporting, overseeing and coordinating the Change Request activities, including Change Request Ownership; Validation of the CR; tracking of planning and implementation of CR after approval.

Standards Manager: Responsible for Standards Governance and maintenance of the global standards repository, including oversight of the process and final promotion of Library Objects from test into production.

Standards Administrator: Responsible for the user access management and definition, configuration and management of system level elements, e.g. Change Request Status; Role types; User Role assignment; Cluster assignment, through system level code lists. This enables the system to be adaptable to changes in business processes and requirements.

Standards Librarian: Imposes additional organization structures by applying tagging to Library Objects, e.g. Standards Version, TA, etc., with write access only to Library Objects for which they have responsibilities.

Standards Steward: Subject Matter Expert (SME) responsible for the development and maintenance of the standards within the Global Standards Repository, with Read/Write access to Library Objects for which they are a Subject Matter Expert.

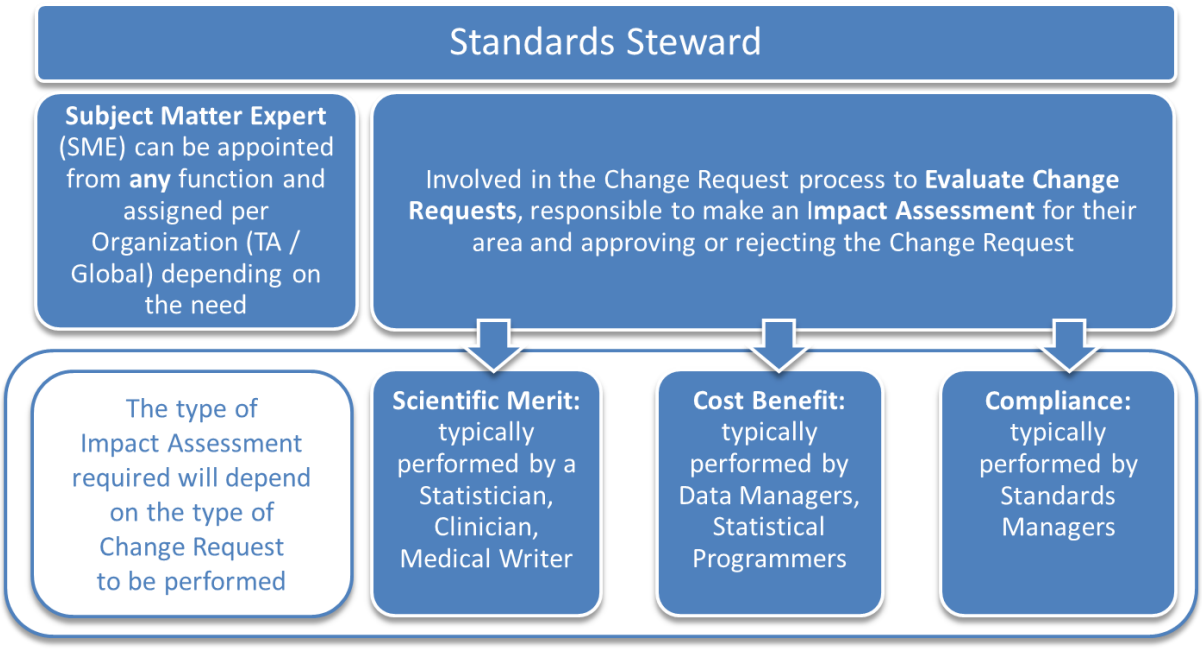


Figure 2 - Standards Steward role

Data Standards Governance Change Request – Cluster Categorization

Early on the development of the Change Request process it was recognized that the type of change request being submitted would influence the evaluation to be performed, which in turn would influence who needed to be involved in the Change Request Evaluation step. To support this, Change Requests were grouped into three distinct clusters:-

Cluster 1: Major standard development initiatives

- Requests for major standard development initiative, for example:
  - A new Disease Area
  - A new Global Standard
  - An upgrade to a new CDISC standard (e.g. upgrade to new SDTM or ADaM IG)

Cluster 2: Changes or additions related to Implementation of the standards

- Requests for changes or additions to the implementation of standards, for example:
  - A new or updated library implementation object - amendment or correction of a Library Object, but not the creation of new content, such as an Endpoint.
  - A data collection / data analysis implementation object error
  - A compliance issue

Cluster 3: Changes or additions related to Content of the standards

- Requests for changes or additions related to content of the standards, for example:
  - A new or updated library content object: this refers to the creation of new Library Object, such as an Endpoint.
  - A data collection / data analysis content object error
  - A new or updated standard from Transcelerate

Data Standards Governance Change Request – Evaluation Criteria

As part of the Evaluation process, three dimensions are applied to assess whether a Change Request is justified and should be supported. Depending on the Cluster assigned, traffic lighting is applied to the Change Request, and one or more Evaluation Criteria may be applied and require a 'green light' for it to progress to approved status.

Evaluation Criteria 1: Scientific Merit

Scientific Merit looks at whether or not a change request represents good science. For any Change Request to have scientific merit, it may contain the following components: address the importance to the disease area to be changed; utilize established scientific principles; demonstrate the scientific knowledge to support the Change Request.

Evaluation Criteria 2: Cost Benefit

The cost/benefit criteria will be used to evaluate whether the cost to implement the Change Request is supported by the rationale and reasoning for the change to be implemented. When the Change Request is a Content-related Change Request, e.g. change to the statistical requirements, the scientific merit of the change is the supporting rationale for the change request.

Evaluation Criteria 3: Compliance

Compliance is the conformance to a specification, convention, policy or standard or law, with a set of compliance rules supporting the implementation of compliance. Examples of such conventions, policies and specifications are SDTM and ADaM Implementation Guides. The evaluation for compliance of a Change Request will be positive if the compliance rules are met, and negative if there's an issue with one or more compliance rules, resulting in the request for Change being supported in term of Compliance Evaluation Criteria.

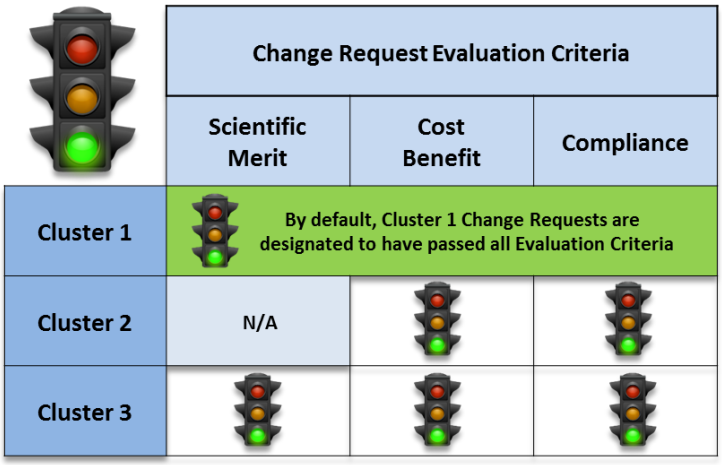


Figure 3 - Change Request Evaluation Criteria / Cluster Categorization

Data Standards Governance Change Request – Impact Analysis

As Library Objects are by definition related to other Library Objects, understanding the relationships that exist is a critical piece in defining the scope of a Work Request – simply put, a change to one Library Object may have a ripple effect and impact other objects. Consequently, a Change Request may impact across different functional areas, e.g. addition of a new ADaM variable or Value Level metadata parameter may touch Data Management, Stats, Programming, etc.

A key feature of the Impact Analysis requirements for the Change Request tool was the ability to represent the relationship between Library Objects in a both a graphical and a tabular format.

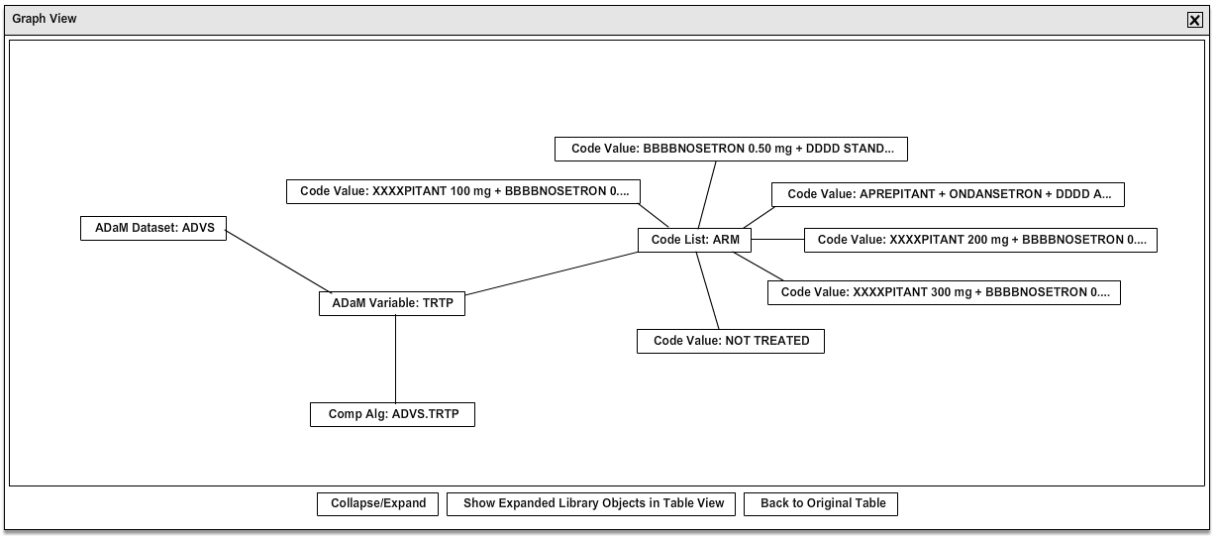


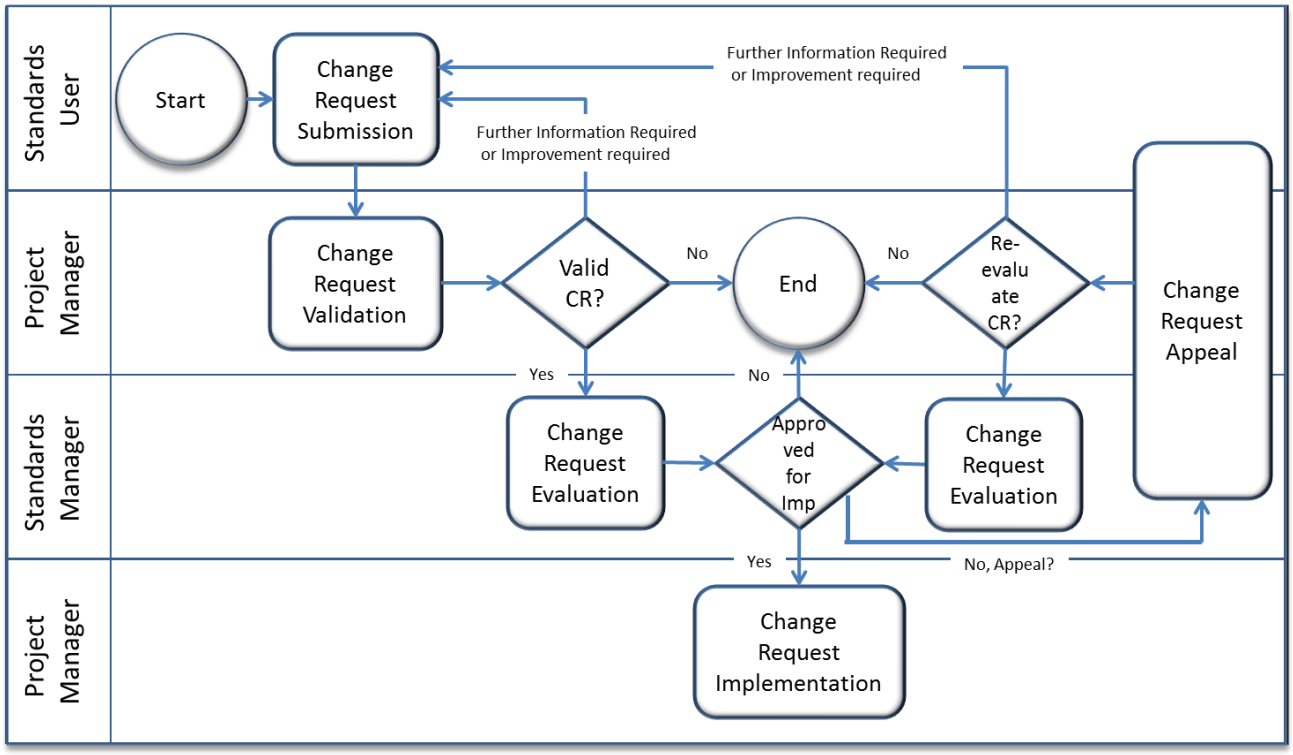
Figure 4 - Graphical View of Change Request Impact Analysis

Data Standards Governance Change Request – Work Package

As part of the impact analysis, the Library Objects impacted by the Change Request are assigned a Change Request Work Package category. In the design of the system, six Change Request Work Packages were identified: *DCM; eDC library Data Management (DM) Metadata; Statistical Requirements; Statistical Metadata; Programming*. By doing so, it eased assignment of Ownership of the changes to a Library Object, tracking of completed CR Work Packages, and ultimately completion of the Change Request overall.

Data Standards Governance Change Request Process Flow - Overview

In developing the Change Request Process, a swim lane approach was adopted to better understand the triggers, responsibilities and relationships in the Submission, Validation, Evaluation, Appeal, and Implementation stages of a Change Request to the standards.



*Imp = Implementation

Figure 5 - High Level Overview of the Change Request Process

From this, a more detailed description of the Change Request process Life Cycle was developed.

Data Standards Governance Change Request Process – Life Cycle

Expanding on the overview Change Request process, ten steps were identified that describe the life cycle of a Change Request from Initiation through to Completion - Implementation (if Accepted), or Closed (if Rejected) is tracked through a Change Request portal, which closely integrates with the Global Standards Repository. Changes to the Library Objects within the Global Standards Repository are performed outside of the Change Request portal.

Note: depending on the nature of the Change Request (Cluster assignment) and the decisions made during the Validation and/or Evaluation, some steps may or may not be applicable.

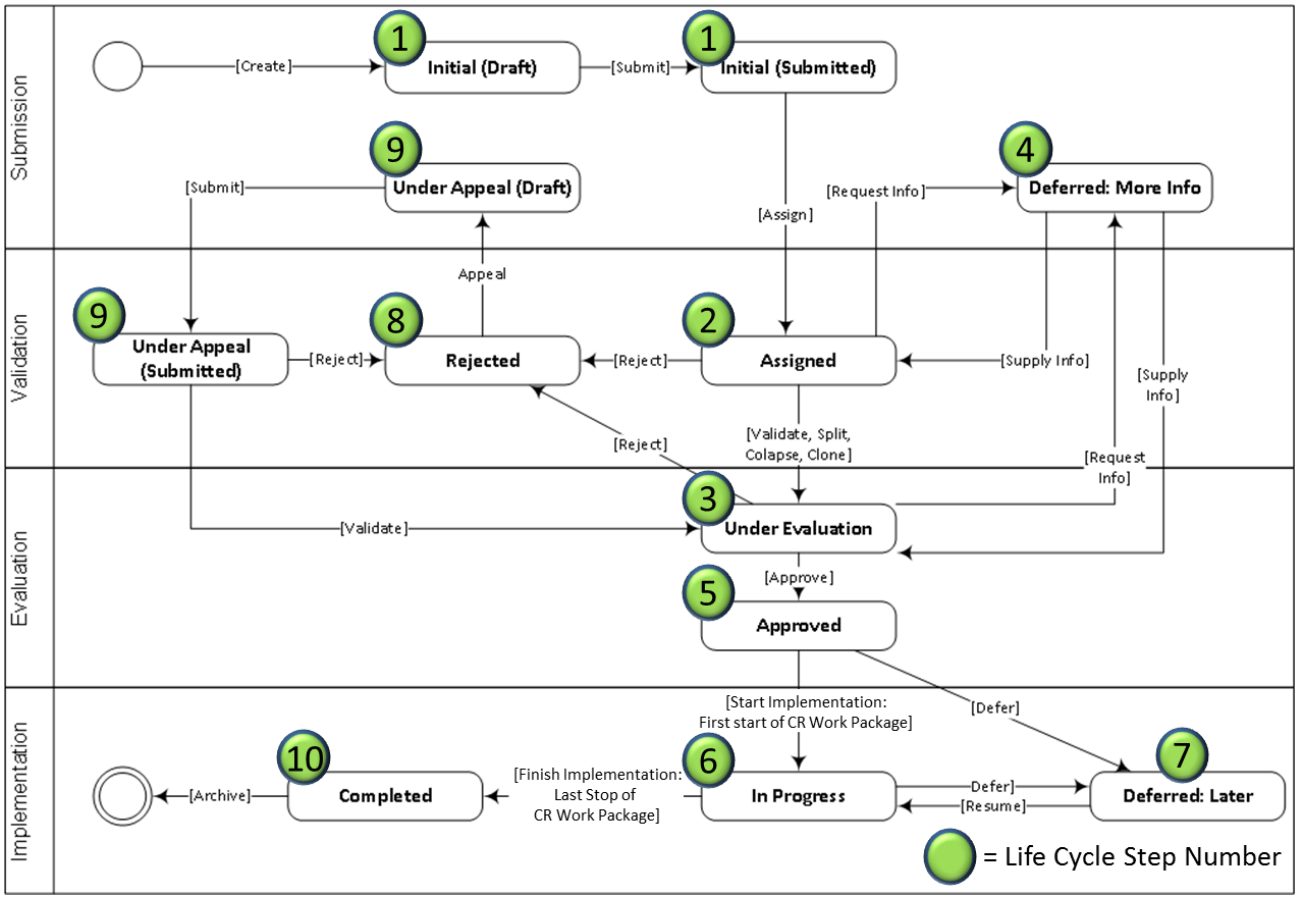


Figure 6 - Change Request Process Life Cycle

Change Request Process Life Cycle Steps

1 *Initiation and submission – Initial(Draft) / Initial (Submitted)*

- Step Description: Change Request discussed by a team (any Standards Consumer is permitted to raise a Change Request, but in practice, it is likely that a change Request would be discussed within a team, and possibly with a Standards Steward prior to submission.
- Step Status: **Initial (Draft)** / **Initial (Submitted)*** - status after saving = Initial (Draft), allows for further edit before formal submission; Status after formally submitting = Initial (Submitted).
- Applicable To: Cluster 1, 2 and 3 Change Requests

2 *Validation – Assigned*

- Step Description: When a Change Request is submitted in the system, the Project Manager takes ownership, performing a Validation of the Change Request. If rejected, it will be sent back to the Requestor with rationale for rejection and potentially requesting further information. If accepted, it will be assigned to the appropriate Standards Steward(s).
- Step Status: **Assigned**
- Applicable To: Cluster 2 and 3 Change Requests

3 *Evaluation – Under Evaluation*

- Step Description: Evaluations are performed according to Change Request Evaluation Criteria, with the criteria of evaluation applied for a specific request based on the Change Request Cluster categorization. In addition, as Library Objects are related to other Library Objects, a critical step in the Evaluation is the performance of an Impact Analysis to understand the scope of the Change Request across the Data Standards Repository, and development of a Change Request Work Package.
- Step Status: **Under Evaluation**
- Applicable To: Cluster 2 and 3 Change Requests

4 *Evaluation – Deferred (More information)*

- Step Description: Triggered when a Change Request under evaluation requires more information to effectively evaluate it, and is routed back to the requestor. Should further information be received then the Change Request would revert to Step 3: *Evaluation – Under Evaluation*.
- Step Status: **Deferred (More information)**
- Applicable To: Cluster 2 and 3 Change Requests

5 *Evaluation – Approved*

- Step Description: Change Request approved by the appropriate Standards Steward(s). The Change Request progresses to the next step (Implementation) to be planned and executed.
- Step Status: **Approved**
- Applicable To: Cluster 1, 2 and 3 Change Requests

6 *Implementation – In Progress*

- Step Description: Change Request is set to 'In Progress' when the implementation of the Change Request is started and the standards related to the Change Requests are being developed. Note, it is not the purpose of the Change Request tool to perform the detailed Project Management often involved in the execution of a complex Change Request, but rather by tracking for each Change Request Work Package its key milestones (start / end date and status) to allow the status of the individual Work Package components of a Change Request to be assessed, and the overall status of the Change Request ascertained.
- Step Status: **In Progress**
- Applicable To: Cluster 1, 2 and 3 Change Requests

7 *Evaluation – Deferred (Later Date)*

- Step Description: A Change Request can have multiple related Work Packages, and it is quite possible for one or more of the planned Work Packages to be deferred to a later when all other work packages, if any, are completed. In these instances, Change Request status = "Deferred (Later Date)".
- Step Status: **Deferred (Later Date)**
- Applicable To: Cluster 1, 2 and 3 Change Requests

8 *Evaluation – Rejected*

- Step Description: Following assessment against the Evaluation Criteria, it is possible that a Change Request will not be approved for one or more particular reasons. Where Change Requests are rejected with rationale for rejection provided to the initiator of the Change Request.
- Step Status: **Rejected**
- Applicable To: Cluster 2 and 3 Change Requests

9 *Appeal – Under Appeal (Draft) / Under Appeal (Submitted)*

- Step Description: When a Change Request is rejected, the initiator of the Change Request can appeal the rejection and the Change Request. Should an initiator decide to appeal, they will usually be expected to supply additional information and rationale to appeal the rejection decision.
- Step Status: **Under Appeal (Draft)** / **Under Appeal (Submitted)** status after saving = Under Appeal (Draft)), allows for further edit before formal submission; Status after formally submitting = Under Appeal (Submitted).
- Applicable To: Cluster 2 and 3 Change Requests

10 *Implementation – Completed*

- Step Description: All Library Objects included in the Work Package(s) must be completed before it can be assigned as completed.
- Step Status: **Completed**
- Applicable To: Cluster 1, 2 and 3 Change Requests

Conclusion

Through reference to the roles involved, the types of changes to be performed, the criteria for evaluation, and impact of a change requests, a well-designed Data Governance Change Requests process can be developed.

This should be capable of leveraging the information within the Global Standards Repository to support the development, maintenance, evaluation (including Impact Analysis), escalation and appeal of Change Requests, whilst maintaining strong control features that allow the status of Change Request to be clearly identified and managed as it moves through the Change Request Life cycle.

CONTACT INFORMATION

Since submitting this paper, G. Winpenny has moved company. In the first instance, please contact BDLS (email address below) for queries related to the content of the paper.

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