

**REQUIREMENTS MANAGEMENT – QUALITY MANAGEMENT –
SAFETY MANAGEMENT – LEARNING MANAGEMENT
SYSTEMS MANAGEMENT COMBINED TOOLSET**

Concept Whitepaper

for

Proposed Partners

with

PICS, LLC
Georgetown, KY

This document was prepared from the results of work accomplished to develop a model advancing the use of packaged platforms with built-in and customized toolsets on a Google and/or Microsoft based suite, to support achieving a certification-ready management system.

Purpose and Scope

The primary purpose of the pilot project is to serve as a proof-of-concept effort to develop and implement a system to enable role owners to employ both local and remotely placed resources using an across-the-board approach to linking quality, safety, and learning management systems based upon a foundation maintained in a requirements management system (RMS-QMS-SMS-LMS). This concept proposes using web-enabled, cloud-serviced software tools provided through Software as a Service (SaaS).

The scope of the RMS-QMS-SMS-LMS for activities supporting the Pilot Project will include the:

- Requirements of each system in a Functional Description as purposed to a common management system
- Selection and evaluation of software tools, including but not limited to:
 - RMS:
 - Polarion
 - DOORS/IBM Rational
 - QMS and SMS:
 - SharePoint Designer/InfoPath
 - AODocs
 - iAuditor
 - LMS:
 - Curriculum management for instructor-led and computer-based training
 - EdApp for micro-learning
 - Predictive Index (PI) for talent optimization

The features of these software would be combined through the development of the applications for workflows across a relational database management system.

- Trials of tools used for transactions, validation, evaluations, and tracking/reporting
- Demonstration/evaluation of implementation scenarios (e.g., workstation/server and SaaS).

Please refer to the diagram in Figure 1. The relationships are presented in a conceptual process format using the MS Visio diagramming software tools.

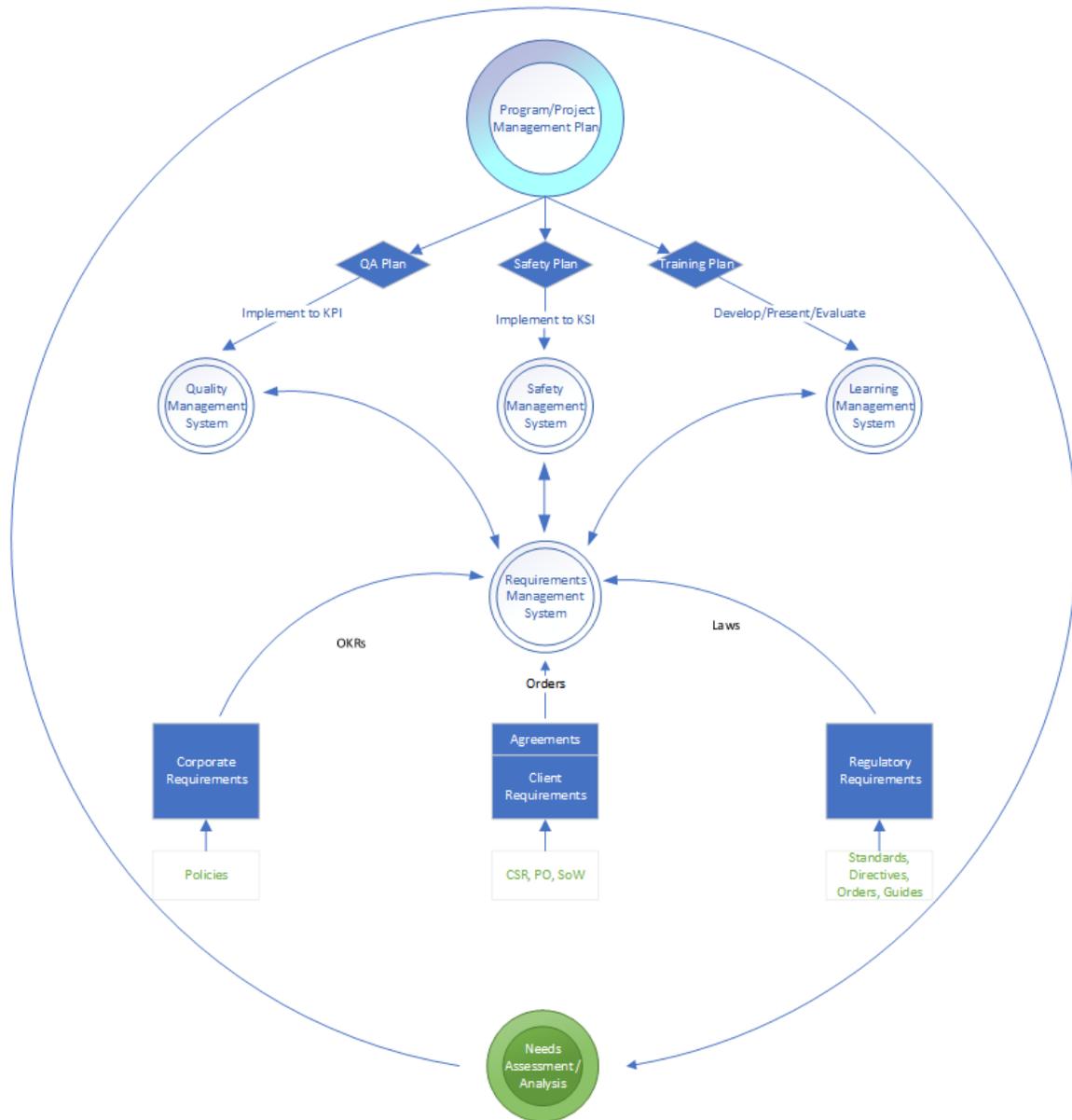


Figure 1: Conceptual model showing relationships across management systems along with the inputs

The primary goal of the program/project is to develop this model toolset and test it in an actual management system certification effort scenario. The trial will use all the demonstration set of information management systems and components.

The needs assessment/analysis is typically conducted in follow up to a gap assessment, to help identify the need for any tailoring of existing system(s). The scope is identified, sensitive to any Corporate and Regulatory stakeholders, and then the requirements are perfected through the client requirements. All are managed by the features of a Requirements Management System, or RMS, satisfying configuration management and change management expectations. The RMS must be highly responsive to change inputs and capable of functioning within a Continuous Integration and Continuous Deployment (CI/CD) environment.

The Quality Management System, or QMS, scope of the program will include workflows for document control and records retention, inspection and audit, and corrective/preventive action management. The inspection/audit workflow tool will be used in audits or surveillances during the pilot test to demonstrate administrative control and to promote continuous improvement. The implementation of the QMS will be defined, along with key performance indicators and a milestone schedule in a Quality Assurance Plan.

The Safety Management System, or SMS, scope of the program will include workflows for safety case management, incident response and reporting, facility/habitability management, and safety engineering assessment. The implementation of the SMS will be defined, along with key safety performance indicators and a milestone schedule in a Safety Management Plan.

The Learning Management System, or LMS, scope of the program will include workflows for registration/enrollment, student records management, curriculum management, and micro-learning. The implementation of the LMS will be defined, along with key safety performance indicators and a milestone schedule in a Training Plan.

The deliverables schedule and any risks will be shared with the stakeholders (e.g., process owners, SMEs, approving authorities) real-time as the Pilot Test progresses. Periodic reporting will be used to confirm the integration of all the systems to support the development of a management system to meet or exceed certification requirements.

The secondary goal of the program/project is to implement standardized tools and processes for use in training and qualifying role owners of the program. Two roles need to be accommodated to manage the program/project during the pilot test:

- an administrator responsible for the management system toolsets maintenance
- the registrar for management system certification (third party)

Premise

The niche market for the product is to fill the gap resulting from the growing need of streamlined “Agile” systems across the industry, and the risk of entities maintaining their certifications current in a changing regulatory environment (e.g., history of waterfall methodology for a Software Development Life Cycle now having to be conformed to the ASPICE, SAFe performance assessment model, or some hybrid).

Performance will be recorded during the trials. The expectation is the program will remain compliant throughout the project to the satisfaction of the requirements.

Note 1: Configuration Management of software will be approached separately, and as deemed applicable to the operation of the trainee-related and interfacing systems. A proposed Configuration Management Overview will be submitted for review by the stakeholders.

Note 2: Cyber Security is not within the scope of this project. The secure development and operating environment (SDOE) will be described in any generated plan and implementing procedure during the pilot. The RMS-QMS-SMS-LMS Pilot Test will initially comply with, and conform to the project implementing authority’s security plan, thereafter, offering programs to service each client or vertical market.

Introduction

In the interest of economy and efficiency, while at the same time establishing controls across a distributed workforce, a uniform management system maintenance toolset is needed for the existing and prospective PICS, LLC clientele. The end user workstations/mobile devices will be employing only the browser for interfacing with the RMS-QMS-SMS-LMS software tools. Initially, a representative combination of the software and workstation configurations will be evaluated. All workflows will be inspected to determine and measure their effect on all levels of user privacy and security.

Background:

A summary of a gap assessment of the ISO 9001 requirements to the existing documented information was shared by the author in September 2020 in response to a challenge posed by the client in August 2019. It included a proposal to design a model toolset to employ a Quality Management System – Cross-Functional Process Improvement Team (QMS-CFPIT) to build a “meta model”. A potential determination of the opportunity, as well as the impact of any identified weaknesses in existing programs and issues concerning the scalability were exchanged with the client through meetings and discussions held during the tenure of the sponsor. After a demonstration of a model relational database management system in early 2021, and the retirement of the sponsor that year, the client deemed it necessary to confirm the present status and applications of any software tools in use in the present environment and continue to explore the venture without gaining management system or product certification.

During that project, the AODocs platform was launched on the Google Suite. The workflows designed and implemented satisfied the following QMS, SMS, and LMS processes:

- Document Control and Records Management
- Corrective and Preventive Action Management (except Corrective Action Planning and Tracking, which used the *iAuditor* platform)
- Auditor/Assessor Certification and Tracking
- Homologation Management System for Regulatory/Statutory requirements satisfaction
- Curriculum/Media control and maintenance for safety-related content

In addition, the *iAuditor* platform was launched as a browser-based platform serving mobile users (phones, tablets, laptops). The inspection templates designed and implemented included workflows that would collect evidence for use in measuring and managing the following QMS and SMS processes:

- Software Quality Assurance (SQA) Inspections
- Internal Process Audits
- Corrective action planning and tracking
- Project Trackers for development of documentation frameworks

The features of the SAP LITMOS and EdApp platforms were used to implement the five levels of QMS training and qualification. The SAP LITMOS managed the instructor-led method of presentations, along with computer-based training developed using the Articulate360 StoryLine toolset. The EdApp platform was used to implement microlearning on mobile devices.

The proposed model relational database management tools and recommended processes for maintenance of certification were shared with, and endorsed by the proposed partnership through a Pilot Test continuing through the first quarter 2022.

Diffusion Potential

Research on the approaches by other providers of platforms, by the industry groups, government agencies, association-sponsored programs (e.g., Automotive Industry Action Group or AIAG, Institute of Nuclear Power Operations or INPO) supplemental training programs and the operation of existing distance learning services facilities provided input on the processes and controls recommended in this conceptual model. Specifically, any certification-supporting products offered by the following marketers of quality, safety, and training products have been evaluated:

- For the RMS:
 - [IBM Rational](#) and [DOORS](#) combination for distributed control systems for reactor safety systems design, development, testing, and installation
 - [Polarion](#) for systems engineering, safety engineering, and supplier requirements management for autonomous vehicles design, development, fabrication, and testing

- For the QMS and SMS:
 - [Oracle Agile Product Lifecycle Maintenance \(PLM\)](#) with the Product Quality Management (PQM) module for distributed control systems (DCS)
 - [AODocs QMS](#) for CAPA, Auditing, and Document Control and Records Management (DCRM)
 - [iAuditor](#) for inspection and testing, auditing, corrective action planning and tracking
 - [PTC/Windchill Quality Solutions](#) for Failure Modes and Effects Analysis (FMEA)

- For the LMS:
 - Digital Chalk (see: <http://www.digitalchalk.com/train-staff-online>) which uses the Amazon Cloud, on a pay-as-you-go basis. The SCORM-Compliant features would serve well with the government offices. The video captures, chatting and a browser-based synchronized whiteboard would enable offering to serve one or a few, distributed trainees. This could grow in popularity rapidly, so the use of several brick-and-mortar production studios with interactive classrooms could make this very effective in meeting the demand internationally as well as within the Labs and other government facilities.
 - Polycom's CloudAXIS Suite, Active Touch, Smart Pairing (see: <http://www.polycom.com/products-services/products-for-microsoft/video-solutions-microsoft-lync.html>)
 - The [SAP LITMOS](#) learning management system module, exercised independent of the overall SAP platform, in a safety-related environment with a primary purpose of supporting the qualification of operators

The following Distance Learning – equipped centers were evaluated:

- Center for Rural Technology 2292 South Highway 27, Suite 300, Somerset, KY 42501 (see: <http://www.youtube.com/watch?v=w47MYn152w4>)
- Kentucky Educational Television's distance learning project (see: <http://i2.ky.gov/>)

Conclusion

The background of the author of this white paper includes the development of patent-awarded applications of expert systems software in the DOE Laboratories. Portions of the model have been implemented in NRC-regulated commercial nuclear facilities, USN Nuclear Propulsion Plant operations, manufacturing, and research & development. The dynamic of changing training arenas influenced the design of the inspection, cross-functional process improvement model recommended herein.

The proposed selection of the SharePoint and Office 365[®] or the AODocs[®] tools is based upon the customizable features of these platforms and the ease of rapidly gaining uniformity across the parties involved in the program/project. As a benefit to the stakeholders, an intellectual property opportunity may result from the implementation of

these tools in this project, with technology transfer to the other facilities and interests owned by the stakeholders through the eventual development of an application to centralize all of the activities depicted in the diagram in Figure 1.

The outcome is predicted to be of value in the form of tools accommodating processes and procedures for use in achieving and maintaining management system certification. A value-added result in the form of improved validation and registration tools for use by the registrar and other validation authority resources is expected.