### Compliance Findings (GAMP5 & CSA Standards)  
  
#### Finding 1  
- \*\*Issue:\*\* The document does not clearly define the risk assessment process for the changes being implemented, which is essential for determining the validation approach.  
- \*\*Section:\*\* Scope  
- \*\*Regulatory Reference:\*\* GAMP5 Principle 1: "A risk-based approach should be applied to the validation of computerized systems."  
- \*\*Correction:\*\* Include a detailed risk assessment section that outlines how risks associated with the changes will be identified, evaluated, and managed, in accordance with GAMP5 guidelines .  
  
#### Finding 2  
- \*\*Issue:\*\* The document lacks a clear description of the intended use of the software changes, which is necessary for compliance with validation requirements.  
- \*\*Section:\*\* Purpose  
- \*\*Regulatory Reference:\*\* CSA Guidance: "The regulation requires manufacturers to validate software that is used as part of production or the quality system for its intended use (see 21 CFR 820.70(i))."  
- \*\*Correction:\*\* Clearly define the intended use of each software change and how it supports production or quality system processes【4:6†source】.  
  
#### Finding 3  
- \*\*Issue:\*\* There is insufficient documentation of assurance activities related to the changes, particularly regarding testing and validation.  
- \*\*Section:\*\* Testing Overview  
- \*\*Regulatory Reference:\*\* CSA Guidance: "The record should include the intended use, risk determination, documentation of the assurance activities conducted, and the conclusion statement declaring acceptability of the results."  
- \*\*Correction:\*\* Enhance the documentation to include detailed records of testing activities, results, and any issues found, along with their resolutions【4:10†source】.  
  
#### Finding 4  
- \*\*Issue:\*\* The document does not specify how the validation activities will ensure that the software maintains a validated state throughout its lifecycle.  
- \*\*Section:\*\* Validation Approach  
- \*\*Regulatory Reference:\*\* GAMP5 Principle 5: "The validation process should ensure that the system remains in a validated state throughout its lifecycle."  
- \*\*Correction:\*\* Include a lifecycle management plan that describes how the system will be monitored and maintained in a validated state post-implementation .  
  
#### Finding 5  
- \*\*Issue:\*\* The document does not adequately address the need for periodic reviews of the system to ensure ongoing compliance and effectiveness of controls.  
- \*\*Section:\*\* Risks and Assumptions  
- \*\*Regulatory Reference:\*\* GAMP5 Principle 4: "The organization should periodically review the system to ensure that controls are still effective."  
- \*\*Correction:\*\* Establish a schedule for periodic reviews of the system and its controls, including criteria for evaluating their effectiveness .  
  
These findings highlight critical areas where the document can be improved to align with GAMP5 and CSA standards, ensuring compliance and effective risk management throughout the validation process.  
  
Based on the comparison between the provided document ("CMMS 2024 Bucket Change 1") and the Test Plan Template, here are the structural and consistency findings:  
  
### Structural & Consistency Findings  
  
1. \*\*Issue\*\*: Missing "Purpose" Section  
 - \*\*Location\*\*: The document lacks a clearly defined "Purpose" section that outlines the objectives of the Test/Validation Plan.  
 - \*\*Correction\*\*: Add a "Purpose" section at the beginning of the document, similar to the Test Plan Template, which should define the objectives and scope of the testing.  
  
2. \*\*Issue\*\*: Misalignment in "Definitions, Acronyms, and Abbreviations"  
 - \*\*Location\*\*: The document includes a "Definitions, Acronyms, and Abbreviations" section, but it is not clearly structured or labeled as such.  
 - \*\*Correction\*\*: Ensure this section is clearly labeled and formatted according to the Test Plan Template, including a list in alphabetical order.  
  
3. \*\*Issue\*\*: Incorrect Section Ordering  
 - \*\*Location\*\*: The "Roles" section appears before the "Testing Overview" section, which is inconsistent with the Test Plan Template.  
 - \*\*Correction\*\*: Move the "Roles" section to follow the "Testing Overview" section to align with the Test Plan Template structure.  
  
4. \*\*Issue\*\*: Missing "Out of Scope" Section  
 - \*\*Location\*\*: The document includes an "Out of Scope" section but does not clearly mark it as such.  
 - \*\*Correction\*\*: Clearly label the "Out of Scope" section and ensure it follows the format of the Test Plan Template.  
  
5. \*\*Issue\*\*: Incomplete "Test Strategy" Section  
 - \*\*Location\*\*: The "Test Strategy" section is present but lacks detailed subsections for "Vendor Testing," "Integration Testing," and "Regression Testing."  
 - \*\*Correction\*\*: Expand the "Test Strategy" section to include these subsections, even if marked as N/A, to match the Test Plan Template.  
  
6. \*\*Issue\*\*: Missing "Acceptance Criteria" for each Test Type  
 - \*\*Location\*\*: The document does not specify acceptance criteria for each test type (IQ, OQ, UAT).  
 - \*\*Correction\*\*: Include a subsection for "Acceptance Criteria" under each test type, as outlined in the Test Plan Template.  
  
7. \*\*Issue\*\*: Lack of References Section  
 - \*\*Location\*\*: The document does not include a "References" section.  
 - \*\*Correction\*\*: Add a "References" section at the end of the document to cite relevant documents and standards, as per the Test Plan Template.  
  
### Summary  
These findings highlight areas where the document can be improved to align with the Test Plan Template. Addressing these issues will enhance clarity, consistency, and compliance with regulatory standards.  
  
### System Name Consistency Check  
  
\*\*Official System Name:\*\* Computerized Maintenance Management System (CMMS)  
  
#### Inconsistent References Found:  
  
1. \*\*Incorrect Name Used:\*\* CMMS 2024 Bucket Change 1  
 - \*\*Sentence:\*\* "For the Computerized Maintenance Management System (CMMS) 2024 Bucket Change 1 (CHGXXXXX), this combined Test & Validation Plan describes the implementation strategy..."  
 - \*\*Correction:\*\* Replace with "For the Computerized Maintenance Management System (CMMS), this combined Test & Validation Plan describes the implementation strategy..."  
  
2. \*\*Incorrect Name Used:\*\* CMMS  
 - \*\*Sentence:\*\* "The primary users of the CMMS are Facilities, Engineering, Manufacturing, Metrology, and Quality Assurance."  
 - \*\*Correction:\*\* Replace with "The primary users of the Computerized Maintenance Management System (CMMS) are Facilities, Engineering, Manufacturing, Metrology, and Quality Assurance."  
  
3. \*\*Incorrect Name Used:\*\* CHGXXXXX  
 - \*\*Sentence:\*\* "This change (CHGXXXXX) plan outlines the validation process and deliverables required to execute the updates required per change control CHGXXXXX."  
 - \*\*Correction:\*\* Replace with "This change (CHGXXXXX) plan outlines the validation process and deliverables required to execute the updates required per change control CHGXXXXX for the Computerized Maintenance Management System (CMMS)."  
  
### Summary of Corrections  
- Ensure that all references to the system consistently use the full name "Computerized Maintenance Management System (CMMS)" throughout the document.  
- The abbreviation "CMMS" can be used after the full name has been introduced.  
  
This consistency check is crucial for maintaining clarity and compliance in documentation related to the system.  
  
Change Description: Prevent New Users from Taking Active License. New users are assigned 'Requestor' by default and must submit a separate request to gain active status. Ensures user access control and compliance with role-based security policies.   
Chosen Requirement: BR 9.2 (FR 6.8.3) (Low)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 85  
- BR 1.4 — The system shall allow for routing functionality within the application. - Certainty Score: 80  
- BR 1.12 — Ability for users to personalize home page with KPI’s and Inboxes - Certainty Score: 75  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 70  
- BR 3.1 — The system shall allow for the creation /modify of equipment, systems, and locations, as well as associated detailed information for each equipment record. - Certainty Score: 65  
  
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Change Description: Calibration Standards Tab Update. Enhancing the Calibration Standards tab by displaying Lot locations for calibration records in the Standards Used section of Work Orders, ensuring compliance with calibration data storage requirements, including instrument categories, calibration limits, and standard tracking.   
Chosen Requirement: BR 4.3 (FR 6.4.10) (Low)   
AI Chosen Impacted Requirements:  
- BR 3.15 — The system shall be able to store calibration data including calibration limits, ranges, units of measure, tolerances, test points, comments and standards used at an instrument level (Calibration Information). - Certainty Score: 90  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 85  
- BR 4.52 — The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings. - Certainty Score: 80  
- BR 4.53 — The system shall generate work orders to change any current process settings to N/A in cases where those attributes are not specified for the incoming campaign. - Certainty Score: 75  
- BR 4.54 — The system shall not generate work orders in cases where the current equipment process setting matches that of the incoming campaign. - Certainty Score: 70  
  
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Change Description: View All Equip Update Requests Screen Updates. Adjusting visibility settings in the Equipment Update Requests module by restricting access to the QA Review field, enforcing data access controls per system permissions.   
Chosen Requirement: BR 3.1 (FR 6.3.1) (Low)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 90  
- BR 1.4 — The system shall allow for routing functionality within the application. - Certainty Score: 85  
- BR 1.12 — Ability for users to personalize home page with KPI’s and Inboxes - Certainty Score: 80  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 75  
- BR 3.1 — The system shall allow for the creation /modify of equipment, systems, and locations, as well as associated detailed information for each equipment record. - Certainty Score: 70  
  
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Change Description: Audit Trail Report:   
Chosen Requirement: BR 4.50 (FR 6.4.65) (Low)   
AI Chosen Impacted Requirements:  
- UR-REG-34 — The system audit trail must provide secure (not editable), date and time-stamped record of the action (obtained from a secure, reliable source, i.e. the server and not the client PC) and the identity of the operator any time an electronic record is created, modified, or deleted. - Certainty Score: 95  
- FS-REG-34 — System shall have the ability to generate a secure audit trail report of the actin from application server which must provide the time stamp information’s in non-editable format when an particular action is performed. - Certainty Score: 90  
- UR-REG-36 — The system must record the creation, change, and cancellation of access authorizations. - Certainty Score: 85  
- FS-REG-36 — System provides an audit trail on events within the system. - Certainty Score: 80  
- BR 4.50 — The system shall provide authorized users a method to generate and review audit trail reports of work orders. - Certainty Score: 75  
  
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Change Description: Work Order Report Location Update:   
Chosen Requirement: BR 7.2 (FR 6.1.7) (Low)   
AI Chosen Impacted Requirements:  
- BR 7.2 — The system shall provide standard reports, as well as the ability for a user to create and save searches. - Certainty Score: 90  
- FR 6.1.7 — CMMS built-in Cognos reporting functionality will be used for reporting. - Certainty Score: 85  
- BR 7.5 — The system shall allow for auto generated reports to be distributed via email. - Certainty Score: 80  
- BR 7.8 — The system shall provide a report to access historical calibration measurement data records. - Certainty Score: 75  
- BR 7.9 — The system shall provide a Calibration Work Order Report capturing a calibration event. - Certainty Score: 70  
  
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Change Description: Forgot Password Button:   
Chosen Requirement: BR 10.1 (FR 6.1.9) (Low)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 85  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 80  
- BR 1.4 — The system shall allow for routing functionality within the application. - Certainty Score: 75  
- BR 1.12 — Ability for users to personalize home page with KPI’s and Inboxes - Certainty Score: 70  
- BR 3.1 — The system shall allow for the creation /modify of equipment, systems, and locations, as well as associated detailed information for each equipment record. - Certainty Score: 65  
  
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Change Description: Functional testing (positive and negative, where applicable) will be performed to validate the following High risk functional requirements:   
Chosen Requirement: UR-REG-36 (FS-REG-36) (High)   
AI Chosen Impacted Requirements:  
- UR-REG-34 — The system audit trail must provide secure (not editable), date and time-stamped record of the action (obtained from a secure, reliable source, i.e. the server and not the client PC) and the identity of the operator any time an electronic record is created, modified, or deleted. - Certainty Score: 95  
- FS-REG-34 — System shall have the ability to generate a secure audit trail report of the actin from application server which must provide the time stamp information’s in non-editable format when an particular action is performed. - Certainty Score: 90  
- UR-REG-36 — The system must record the creation, change, and cancellation of access authorizations. - Certainty Score: 85  
- FS-REG-36 — System provides an audit trail on events within the system. - Certainty Score: 80  
- BR 4.50 — The system shall provide authorized users a method to generate and review audit trail reports of work orders. - Certainty Score: 75  
  
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Change Description: See Last Login of User:   
Chosen Requirement: BR 8.1 (FR 6.7.9) (High)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 90  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 85  
- BR 1.4 — The system shall allow for routing functionality within the application. - Certainty Score: 80  
- BR 1.12 — Ability for users to personalize home page with KPI’s and Inboxes - Certainty Score: 75  
- BR 3.1 — The system shall allow for the creation /modify of equipment, systems, and locations, as well as associated detailed information for each equipment record. - Certainty Score: 70  
  
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Change Description: ECDB Menu Modifications:   
Chosen Requirement: BR 8.1 (FR 6.7.2) (High)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 90  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 85  
- BR 1.4 — The system shall allow for routing functionality within the application. - Certainty Score: 80  
- BR 1.12 — Ability for users to personalize home page with KPI’s and Inboxes - Certainty Score: 75  
- BR 3.1 — The system shall allow for the creation /modify of equipment, systems, and locations, as well as associated detailed information for each equipment record. - Certainty Score: 70