

Standards Compliance

Corrective Action and Preventive Action

(CAPA)

Report for Services

**NC CY1602 AON & Promo Batch**

Monika Augustyniak

28-Jul-2016

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| --- | --- | --- | --- |
| **Project Assessment History** | | | |
| **Review #** | **Date** | | **Review Name** |
| 1 | 20-May-2016 | | Compliance Summary Report 1 – peer review |
| 2 | 25-May-2016 | | Compliance Summary Report 1 |
| 3 | 16-Jun-2016 | | Compliance Summary Report 2 – peer review |
| 4 | 21-Jun-2016 | | Compliance Summary Report 2 |
| 5 | 19-Jul-2016 | | Draft CAPA – peer review |
| 6 | 20-Jul-2016 | | Draft CAPA |
| 7 | 25-Jul-2016 | | Draft CAPA – Management Response |
| 8 | 28-Jul-2016 | | THE FINAL CAPA Report |
| **Project Information** | | | |
| Customer Name | | North Carolina | |
| SAP ID | | NC23629 | |
| Location | | Austin | |
| Go Live Date | | 01-Jul-2016 | |
| **Project Stakeholders** | | | |
| Regional Lead | | John Quigley | |
| Program Manager | | Patty Rogers | |
| Project Manager | | Emma Howsden | |
| Compliance Manager | | Karen Robertson | |
| Standards Compliance Lead | | Monika Augustyniak | |

**Note:**

\*\*\* Failure to submit and complete a resolution will result in an assignment of an “NI” to the project’s Process and Product Quality Assurance (PPQA) obligation and will be escalated to the Compliance Manager and responsible Regional Lead. All resolutions must be completed no later than a week prior to Project Close-out.

\*\*\* The conformity assessment involves a sample of processes and products that show your project meets the requirements of the CMMI, NASPL, and organizational requirements. It is not expected that findings will provide a detailed listing of the implementation status of every model practice, goal achievement, or specific practice implementation.

**Project Risk Rating**

|  |  |
| --- | --- |
| **Overall Project Risk Rating** | **# 3** |

**Assessment Summary**

This section is intended to provide the team a high level understanding of the Findings, Observations, and Opportunities For Improvement (OFI).

|  |  |
| --- | --- |
| **Process Area** | **Findings, Observations, Opportunity For Improvement Summary** |
| Project Planning | Project did not follow planning process; missed some planning document approvals |
| Integrated Project Management | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |
| Project Monitoring and Control | Project did not follow Project Monitoring process; missed milestone review |
| Risk Management | Observation: Project did not follow Risk Management process; no risk logged for the project at all. |
| Requirements Management | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |
| Requirements Development | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |
| Technical Solution | Project did not follow Project Software Design process and Technical Solutions Development process; missed design and release notes documents, missed some design document approval |
| Product Integration | Project did not follow Product Integration Process; missed Integration Testing Results; missed Releases to CAT and Production; missed Installation project documentation |
| Verification | Project did not follow Peer Review Process; missed some Peer Reviews and QA report approval |
| Validation | Project did not have CAT readiness criteria satisfied; missed CAT testing documents and Customer approval |
| Measurement and Analysis | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |
| Configuration Management | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |
| Process and Product Quality Assurance | Project satisfied the CMMI, NASPL and organizational requirements. No weaknesses |

**Note**: Organizational findings not depicted in the Summary above.

**Scope:**

The purpose of the CAPA report is to provide management with appropriate visibility into the processes being used by the software

project (s) and of the products being built. This report will provide insight into any process improvements, trend analysis or other

project issues that come up.  A Correction, Corrective Action, and/or Preventative Action will be assigned given based on the project management responses and the severity of the finding (s).

**Risk Rating Characterization**

The method used in the determination and the assignment of characterizations related to process area goals is detailed in table 1.0 Characterization of Process Areas. Each process area in the assessment scope will be given a Red, Yellow, Green, Blue or Grey characterization based on affirmations, direct-artifacts and indirect-artifacts, project progress, or waivers.

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| --- | --- | --- |
| **Characterization** | **Rating** | **Description** |
| Not Implemented | 4 | One or more Process area(s) have been rated Not Implemented (NI)   * One or more key process (es)/practice was not implemented during the lifecycle of the project creating a significant risk to the project. * Insufficient artifact evidence was provided to satisfy one or more practice for the process area. |
| Partially  Implemented | 3 | One or more Process area(s) have been rated Partially Implemented (PI)   * One or more key process (es)/practice was partially implemented during the lifecycle of the project creating a risk to the project. * Inadequate artifact evidence to fully satisfy one or more practice for the process area. |
| Largely  Implemented | 2 | Majority of the Process area(s) have been rated Largely Implemented (LI)   * Most of the process areas are largely implemented during the lifecycle of the project, minor risks are identified. * Direct artifacts are present and judged to be sufficient with minor weaknesses are noted. |
| Fully Implemented | 1 | Majority of the Process area(s) have been rated Fully Implemented (FI)   * Process areas are Fully Implemented during the lifecycle of the project and no risks are identified. * Direct artifacts are present and judged to be adequate * No weaknesses are noted |
| Not Rated | NR | Process Area Not Rated (NR)   * Process Area has been waived in accordance with IGT Tailoring Guidelines |

Table 1.0 Characterization of Process Areas.

**Summary of Findings/Observations**

|  |  |
| --- | --- |
| **PP** | **Finding**   * Late ADM, RL and Customer approval for PSS. REMOVE !!! |
| **Management Response**   |  | | --- | | I have the signature page that includes ADM, PgM, and customer. The project is now closed (as of 7/16) so I will be unable to check this document in. | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  *This will be completed by STC once management responses are completed* |
| **IPM** | **Finding**   * No weaknesses |
| **PMC** | **Finding**   * Late Customer approval to go to CAT. REMOVE !!! |
| **Management Response:**   |  | | --- | | We do not have a formal meeting with the lottery on the approval to go to CAT. We keep the customer updated the last week of QA via email and other status meetings for the project. We notify the lottery of all remaining TIRs that are open at the time of CAT start, but we always stick to the scheduled CAT start date. | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  *This will be completed by STC once management responses are completed* |
| **RSKM** | **Finding**   * No weaknesses |
| **REQM** | **Finding**   * No weaknesses |
| **RD** | **Finding**   * No weaknesses |
| **TS** | **Finding**   * No evidence of SDDs GWARE Host and GWARE PC. REMOVE !!! * Unable to verify SDD ETL approval. Late SDD ETL approval. REMOVE !!! * No Release Notes (RNs) GWARE Host and GWARE PC. REMOVE !!! |
| **Management Response:**   |  | | --- | | GWARE host/PC – There was an assumption at the beginning of the project that GWARE host and PC would be needed but after some evaluation of the host changes, we found that no changes were necessary for those disciplines. Since there was no design – therefore there were no release notes or releases for GWARE host or PC.  SDD ETL – We struggled finding engineers to review this document and had to escalate to the regional lead for BI. Once we finally got the review, I believe the approval was late as well – but was still approved. Actual documentation of the approval was not checked in. | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  *This will be completed by STC once management responses are completed* |
| **PI** | **Finding**   * Integration Log is incomplete. The Log tab regarding Build and Deployment is not filled out. No Test Case Execution Results completed. * Unable to verify CAT and Production Product Release Requests. * No evidence of Installation Procedure. REMOVE !!! |
| **Management Response:**   |  | | --- | | Install Plan – A formal install plan review took place on 5/10 @ 10am, along with several desk check versions. We were very prepared the week before go-live with the installation procedure. Documentation was missed in clarity. | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  *This will be completed by STC once management responses are completed* |
| **VER** | **Finding**   * No evidence of the Test Summary approved by PM. REMOVE !!! * No evidence of peer reviews for the following work products:   + SDDs ETL, GWARE Host and GWARE PC peer review REMOVE !!!   + RNs GWARE Host and GWARE PC peer review REMOVE !!!   + Late Peer Review Work Product documented. - Install Peer Review REMOVE !!! |
| **Management Response:**   |  | | --- | | -Test summary was checked in – was not aware that I (PM) was required to approve this document. I was very aware of the progress of testing that was taking place during site test as well as CAT test.  - Peer Reviews: ETL SDD, we struggled getting a reviewer for weeks. Escalation took place.  No GWARE host or PC peer review needed, as there were no changes for these disciplines.  Install Plan – A formal install plan re view took place on 5/10 @ 10am. Documentation was missed in clarity. | |  | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  Peer review must be submitted to the PRMS tool. This finding will be included in the subsequent batches preventive action report. |
| **VAL** | **Finding**   * No evidence of the final Summary Site Test and CAT Report. REMOVE !!! |
| **Management Response:**   |  | | --- | | I had requested this from the site QA resource, but this document was never provided. I was fully aware of all testing and open issues which I reviewed on a daily basis. Weekly lottery meeting reviews with QA and CAT team took place as well. | |
| **Correction, Corrective Action (CA), and /or Preventive Action (PA)**  *This will be completed by STC once management responses are completed* |
| **MA** | **Finding**   * No weaknesses |
| **CM** | **Finding**   * No weaknesses |
| **PPQA** | **Finding**   * No weaknesses |
| **DAR** | **Finding**   * Not rated |
| **SAM** | **Finding**   * Not rated |

**Detail of Findings:**

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| --- | --- | --- | --- | --- |
| **CAPA Report** | | | | |
| **Process Area** | **Goal** | **Practice** | **Description** | **Rating** |
| PP | SG1 | 1.1 | Late work product documented. - PSS approved by ADM, RL and Customer. | LI |
| PMC | SG1 | 1.7 | Late work product documented. - Customer approval to go to CAT. | LI |
| RSKM | SG1 | 1.1 | No risks logged for the project at all. | OBV |
| TS | SG1 | 2.1 | No evidence of SDDs GWARE Host and GWARE PC. - It 's not an issue. GWARE Host and GWARE PC not needed as no changes were necessary for those disciplines |  |
| TS | SG1 | 2.1 | Late work product documented. - Unable to verify SDD ETL approval. | LI |
| TS | SG1 | 2.1 | No RNs GWARE Host and GWARE PC. - It 's not an issue. GWARE Host and GWARE PC not needed as no changes were necessary for those disciplines |  |
| PI | SG1 | 1.1 | Integration Log is incomplete. The Log tab regarding Build and Deployment is not filled out. No Test Case Execution Results completed. | PI |
| PI | SG1 | 1.1 | Unable to verify CAT and Production Product Release Requests. (CM 3.1) | NI |
| PI | SG1 | 3.4 | Late work product documented. - No evidence of Installation Procedure. | NI |
| VER | SG1 | 2.1 | Late work product documented. - No evidence of the Test Summary approved by PM. (VAL 2.1) | LI |
| VER | SG1 | 2.2 | No evidence of peer reviews for the following work products: - SDDs ETL peer review - SDDs GWARE Host and GWARE PC peer review - It 's not an issue. GWARE Host and GWARE PC not needed as no changes were necessary for those disciplines - RNs GWARE Host and GWARE PC peer review - Late Peer Review Work Product documented. - Install Peer Review | LI |
| VAL | SG1 | 2.1 | Late work product documented. - No evidence of Summary Site Test and CAT Report. | LI |

**Appendix**

**CMMI Process Areas and Definitions**

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| --- | --- |
| **Process Area** | **Definition** |
| Requirements Development | Elicit, analyze, and establish customer, product, and component requirements |
| Requirements Management | Management of product requirements and align requirements with project plans and work products |
| Project Planning | Establish and maintain plans that define project activities |
| Project Monitoring and Control | Provide management an understanding of the project’s progress and provide corrective actions for deviations |
| Risk Management | Identify potential problems, define a strategy to prevent its occurrence, and monitor its behavior |
| Configuration Management | Establish/maintain integrity of product using identification, control, status accounting, and auditing practices |
| Process and Product Quality Assurance | Provide objective insight into compliance and effectiveness of processes and work products |
| Measurement and Analysis | Develop and sustain measurements used to support management reporting and defined objectives |
| Decision Analysis and Resolution | To analyze decisions using a formal process with an established criteria to evaluate alternatives |
| Technical Solution | Select, design, and implement solutions to requirements |
| Product Integration | To assemble the components, ensure as integrated works as intended, and deliver the product |
| Verification | Verify products meet specified requirements, identify defects, and remove defects prior to execution of task |
| Validation | Demonstrate that a product or components satisfy it intended use |
| Integrated Project Management | Establish/manage the project, relevant stakeholders according to an integrated, defined and tailored process |
| Organizational Process Definition | Establish/maintain a usable set of process assets, standards, and rules and guidelines for teams |
| Organizational Process Focus | Plan, implement and deploy organizational process improvement based on process weaknesses and strengths |
| Organizational Training | Develop skills and knowledge of people so they can perform their roles effectively and efficiently |
| Supplier Agreement Management | Manage the acquisition of products and services from suppliers. |