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| **Software Requirements Specification**  **E-Log Modules (Engineering)**  [Project Id: BCIL\_MUM\_202223\_P001-V1R1]  **For**  **Cipla Limited**  **Template Reference: BCIL-FRM-020-Software Requirements Specification**  **Date of Release of Template: 05-August-2016**  **Document Reference: Cipla\_E-Log\_SRS\_Aug'2022\_V1.0**   |  |  |  | | --- | --- | --- | | Prepared / Modified By | Role | Date of Preparation / Modification | | Prepared By | **Role** | **Date of Preparation** | | Leena Patil | Technical Writer | 24.08.2022 | | Reviewed By | **Role** | **Date of Review** | | Chandrakant Shindkar | Deputy Manager - Software |  | | Approved By | **Role** | **Date of Approval** | | Ritu Kapoor | Head of Engineering |  | | Circulation List | | **Release / Version** | |  | | V1.R1 | |

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**REVISION HISTORY**

This document is subject to the version management. Each change has to be entered into following table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section Changed** | **Release/Amendment summary** | **Release / Version** | **Release Date** | **Approved By** | **Signature** |
| All | Initial release | 1.0 |  |  |  |



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1. **INTRODUCTION**
   1. **Purpose**

The purpose of this document is to explain the system architecture of E-Track modules throughout the life cycle of the project. This document communicates the justification of software process & application module specification in detailed manner to understand the brief of it. BCI is pleased to submit this document to understand the application solution on customer requirement.

* 1. **Document Conventions**

|  |  |
| --- | --- |
| **Acronym, Abbreviation or Convention** | **Description** |
| **SRS** | Software Requirements Specification |
| **BCI** | Bar Code India |
| **HHT** | Handheld Terminal or Mobile Device. |

* 1. **Intended audience & Reading suggestions**

This document targets primarily the developers, projects managers and document writers. Secondary audience would if possibly include testers who have previous knowledge of software design or databases, but they are mostly recommended to just read the introduction and features specified in this document. The rest of this document contains information on the overall description of the application product, the system features and any other requirements needed that do not fall into these categories.

**The screen prototypes have been used while designing samples screens in this document may vary in actual development.**

* 1. **Product Scope**

The E-Log modules implement the persistent data requirement for logging & monitoring activities capturing equipment maintenance transactions. E-log modules will be deployed as enhancements in the existing barcode system. The solution is designed to satisfy the business rules while maintaining data integrity, consistency & performance. All the modules of E-Log are described in following section; information is presented with detailed descriptions to understand & support operational needs.

The entire solution consists of followings:

|  |  |  |  |
| --- | --- | --- | --- |
| **SR** | **Application** | **Technology** | **Usage** |
| 1 | Web Based Native App for HHT & TAB | Angular, .NET, MS SQL | For maintaining masters & configuration, For creating e-logs along with its review, approval, Report generation & audit log process. |

1. **OVERALL DESCRIPTION**
   1. **Operating Environment**
      1. **Software Prerequisites**

Following are the software pre-requisites will be installed on server system.

* Dot net Framework 4.7.2
* IIS (Internet Information Services)
  + 1. **Hardware Requirement**

Following are the hardware’s will be used in this system

* PC with Local Network Connectivity with Browser [Chrome/IE11].
* TAB
  + 1. **Database Requirement**

Following database will be installed on the server.

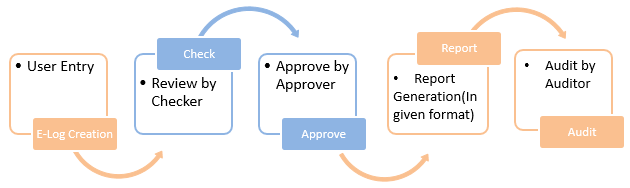
* MS SQL Server [*Existing central server to be used.]*
  1. **Design and Implementation Constrains**

The application is developed using Microsoft.net development technology, no other external program has been used & it is having ability to run on the basic computer environment.

1. **SYSTEM** **ARCHITECTURE**

Existing E-Track application architecture of load balancing will be followed as this e-log will be part of E-Track application.

**PROCESS FLOW CHART**



*\*The processes mentioned in the blue color are not necessary for all the e-logs.*

1. **APPLICATION ACCESS**

|  |  |
| --- | --- |
| Module | Application access |
| Description | This is defined for login into the application and accesses the e-log modules. |

***Exiting “E-Track” application login will be used for login into the application.***

***User access permissions will be created in the existing user rights master.***

***User can login and access the e-log modules from the main menu of the application.***

1. **E-LOG MODULES**
   1. **Disinfectant Preparation, Filtration and Storage Record for Nasal Spray Area**

***Business Process Identification***

|  |  |
| --- | --- |
| Module | Record for Disinfectant Preparation, Filtration and Storage Record for Nasal Spray Area. |
| Description | This module will be used for records of Disinfectant Preparation, Filtration and Storage Record for Nasal Spray Area. |

***Output Format / Report***

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
|  | Below is the e-log format will be generated / printed from this module. |

***Master Modules***

|  |  |
| --- | --- |
| Module | Below are the master modules associated to this module. |
| Description | * User Master * Equipment Master * Product Master * Department Master * Area/Room Master   *\*Detailed explanation of masters is covered in first log i.e. Record for lux level measurement of illumination (light source)* |

***Proposed Process:***

1. **Create:**

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **1.** | **Proposed Process Explanation** |
|  | Below is the snapshot of the module which will be used for the logs.    To operate this module user can follow the below steps.   1. Select Area from dropdown. 2. Enter name of disinfectant, batch no.   *\*User can use maximum 2 disinfectant.*   1. Enter Filter Serial No/Type if any.   *\*Enter NA if not applicable.*   1. Enter Lot No if any.   *\*Enter NA if not applicable.*   1. **Cleaning of Equipment and Accessories:** 2. Enter Code No. 3. Equipment/Accessories name will be displayed from Code No. 4. Click on Add button if user want to add multiple Code Numbers   *\*Respective Equipment/Accessories name will be displayed on the screen.*   1. Click on Cleaning Time Start button.   *\*System will save the cleaning start time.*   1. Click on Cleaning Time Stop button after cleaning completion.   *\*System will save the cleaning completion time.*   1. User details will be captured by the system. 2. **Pre-integrity testing of filter**     *\* Maximum two inputs will be taken for this section.*   1. Filter Serial No/Type will be displayed. 2. Select Filter integrity status as OK/NOT OK from dropdown.   *\* Enter NA in text fields if not applicable.*   1. **Autoclaving of Cartridge/Capsule Filter** 2. Select the Equipment/Accessory from dropdown. 3. User will click on Sterilization Start button to start the process of Autoclaving of Cartridge. 4. User will click on Stop button to stop the process after its completion.   *\* Enter NA in text fields if not applicable.*   1. **Preparation of disinfectant solution**      1. Batch No, Disinfectant Name and concentration, Quantity (ml) will be displayed on the screen as filled in section 1. 2. Click on Start button to start and the process of Addition. 3. Click on Stop button to stop and the process of Addition. 4. Enter Volume Made to (L) 5. Click on Start button to start mixing process. 6. Click on Stop button to stop mixing process 7. System will captured the user details.   *\* Enter NA in text fields if not applicable.*   1. **Filtration of 70% IPA disinfection solution** 2. Select Equipment/Accessories parameters from the dropdown. 3. Enter Observation. 4. Click on Start button to start the process. 5. Click on Stop button after completion of process. 6. System will captured the user details   *\* Enter NA in text fields if not applicable.*   1. **Post-integrity testing of filter**   *\* Maximum two inputs will be taken for this section.*   1. Filter Serial No/Type will be displayed. 2. Select Filter integrity status as OK/NOT OK.   *\* Enter NA in text fields if not applicable.*   1. **Description of excess solution** 2. Batch No, Disinfectant Name and concentration, Quaintly prepared details will appear on the screen 3. Enter Quantity used, Quantity Discarded in text fields. 4. System will capture the user details.   *\* Enter NA in text fields if not applicable.* |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| 2. | **Validations** |
|  | 1. If the filter is used then only Pre-integrity testing, Autoclaving of Cartridge/Capsule Filter, Post-integrity testing of filter is applicable. 2. After saving record it will have checked by (Review) process. 3. After clicking on **Start** button, this log will be non-editable. In case of any correction required, user can reject the log entry and can create new one. 4. **Stop** button will not work unless user will not enter Start button to start the inspection. 5. After clicking on plus symbol user can add text field to fill the data. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **3.** | **Risk & Assumptions** |
|  | 1. All master data like should be maintained in the respective master module. |

1. **Review:**

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **1.** | **Proposed Process Explanation** |
|  | Below is the snapshot of the module which will be used for the review of logs.    Application will show the list of logs pending for review in this module in the first view.  User will click on **View [ ]** button showed in first column to see the log entry details for the review.  Reviewer can view each section by clicking on arrow [ ]. Following screen will get displayed:    To operate this module user can follow the below steps:   1. Authorized user will check the details entered in the log. 2. Click on **Review** button if entered log is ok. 3. User will click on **Reject** button in case of there is any change in the log.   *\*Application will ask user to enter the remark if it is going to be rejected.*   1. Corresponding details get saved in the database. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **2.** | **Validations** |
|  | 1. Only authorized users can review the logs. 2. The log should be non-editable for reviewer. 3. While rejecting the record during checked by stage user will have rejection comment entry option. 4. User can click on **Search** button to filter the records in list of records. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **3.** | **Risk & Assumptions** |
|  | 1. Log should be created with proper data. |

1. **Approve:**

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **1.** | **Proposed Process Explanation** |
|  | Below is the snapshot of the module which will be used for the verification of logs.    Application will show the list of logs pending for verification in this module in the first view.  User will click on **View** button showed in first column to see the log entry details for the verification. Approver can view each section by clicking on arrow [ ]. Following screen will get displayed:    To operate this module user can follow the below steps.   1. Authorized user will check the details entered in the log. 2. Click on **Approve** button if entered log is ok. 3. User will click on **Reject** button in case of there is any change in the log.   *\*Application will ask user to enter the remark if it is going to be rejected.*   1. Corresponding details get saved in the database. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **2.** | **Validations** |
|  | 1. Only authorized users can verify the logs. 2. While rejecting the record during checked by or approved by stage user will have rejection comment entry option. 3. The log should be non-editable for verifier. 4. User can click on **Search** button to filter the records in list of records. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **3.** | **Risk & Assumptions** |
|  | 1. Log review should be completed. |

1. **Audit Log:**

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **1.** | **Proposed Process Explanation** |
|  | Below is the snapshot of the module which will be used for the audit of logs:    These logs will monitor the activities of user who accessed the application, made changes to File/ Document and the time stamp of these activities. |

1. **REPORT**
   1. **Report Generation**

***Business Process Identification***

|  |  |
| --- | --- |
| Module | Report Generation |
| Description | Below module will be used for generating the report of the log. |

***Proposed Process***

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| **1.** | **Proposed Process Explanation** |
|  | Below is the snap shot of the module which will be used for generating the report of the logs.    Below is the list of activities needed to be followed for generating the report.   1. User will select the report name from dropdown. All the list of log name will be shown in the selection field. 2. After selecting the log name its report generating filters will populate for selection on the basis of selected report, in the above screen filters are shown for log i.e., “Disinfectant Preparation, Filtration and Storage Record for Nasal Spray Area”. 3. User will select the filters. 4. User need to click on **Generate** button. 5. Application will generate the log report in the associated format. |

|  |  |
| --- | --- |
| **Sr. No** | **Topics** |
| 2. | **Validations** |
|  | 1. Log format is mentioned in each log module section. 2. Report generation filters should be populated based on the report name selection. Shown in the image is just an example. 3. User can download the populated report in the PDF/Excel format. |

**ACCEPTANCE**

***Before Sign Off***

Any changes in SRS need to be informed by **Cipla Limited** then it will be incorporated / confirmed only after doing detailed feasibility study by BCI.

***After Sign Off***

Any changes in proposed solution after approval of this document by **Cipla Limited** are subject to confirmation from BCI, taking feasibility constraints into account. These changes will be incorporated (if any) into the solution only after delivering proposed solution & may be charged as extra.

BCI reserves the rights to change Details of Application before & after Sign Off i.e., Fields on Screen, Reports, Database, etc. without changing the functionality or outputs assured for the project.

Agreed and Accepted by **Cipla Limited.**

**Steering Committee**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr** | **Name** | **Dept.** | **Signature** |
| 1 |  |  |  |
| 2 |  |  |  |

**Project Manager**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr** | **Name** | **Dept.** | **Signature** |
| 1 |  |  |  |

**Team Members**

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr** | **Name** | **Dept.** | **Signature** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |
| 4 |  |  |  |
| 5 |  |  |  |