BR 1.4

The system shall allow for routing functionality within the application.

FR 6.1.1

The system will contain new workflow, menu and security group configuration.

BR 4.10

The system will have ability to assign multiple pieces of equipment to a work order.

FR 6.1.2

The system will ensure that the equipment location on PM schedules will stay current with the location on the equipment record.

BR 1.8

The system shall have the capability to configure field name labels, where appropriate, in order to comply with corporate nomenclature.

FR 6.1.4

All displayed dates should be of the format “DD-MMM-YYYY”.

BR 1.8

The system shall have the capability to configure field name labels, where appropriate, in order to comply with corporate nomenclature

FR 6.1.5

Whenever time is displayed or entered the 24-hr clock should be used.

BR 10.1

The system shall provide the ability to interface with active directory.

BR 10.1 Test Script: 143

BR 3.8

The system shall be able to route and track revisions to preventative maintenance plans.

FR 6.1.10

The system will have a revision approval process for PM Schedules, Job Plans, Material Lists, and Routes.

BR 3.10

The system shall be able to calculate due dates for preventive maintenance.

FR 6.1.11

The system will provide the ability to correctly calculate preventative maintenance due dates based on PM Schedule frequency, PM Schedule revisions, and PM Extensions.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

BR 8.1 Test Script: 65

FR 6.2.2

The system will provide the ability to separate data by organization (site), allowing some users access only to their local data, while allowing authorized users to view all data within the database. This viewing will be permitted through validated system screens and reports only.

BR 1.12

Ability for users to personalize home page with KPI’s and Inboxes

FR 6.2.4

Individual system users will be able to customize their home page with relevant inbox and key performance indicators (KPI) information.

BR 1.13

Ability to search for users by User Group.

FR 6.1.12

The system will allow users to search for other users in the system by using a lookup grid containing these fields: User Code, Employee ID, User Description, Role, Org, Default Org, and Out of Service.

BR 1.14

The system shall control and store the list of equipment validated for use in manufacturing a specific product (BOE)

FR 6.1.13

The system enables authorized users to generate Bill of Equipment records detailing lists of Equipment validated for use in manufacturing a specific product and the status of the Equipment; as well as to associate the Equipment on the BOE with the attribute settings required by the BOE.

BR 1.15

The system shall control and store product-specific manufacturing parameters (attribute settings).

FR 6.1.14

A settings tab on the BOE will detail existing Equipment attribute settings relevant to manufacture of the corresponding product.

BR 1.16

The system shall allow the user to select the equipment to be used for a manufacturing campaign from the BOE. (IEL)

FR 6.1.15

A button will be available on Equipment Change Request (ECR) records to populate the Incoming Equipment List (IEL) from the corresponding BOE.

BR 1.17

The system shall assert SME Review of all BOE and attribute changes.

FR 6.1.16

BOE will be revision controlled and support an SME review status prior to approval.

BR 1.18

The system shall assert QA Review of all BOE with settings listed in PCD.

FR 6.1.17

BOE will be revision controlled and applicable BOE will support a QA review status prior to approval, independent of the Type values assigned to Settings on the BOE.

BR 1.6

Users shall be able to define and save viewing properties (Dataspy).

FR 6.2.5

The system will allow users to alter the viewing structure of screens, such as equipment, job plans (task instructions), preventive maintenance (PM) routines and work orders. The system must also allow users to save the altered layout for future use.

BR 1.6

Users shall be able to define and save viewing properties (Dataspy).

FR 6.2.6

Individual system users will be able to define and save screen filters and data sorts.

BR 1.7

The system shall be able to store and attach electronic documents throughout the application.

FR 6.2.7

The system will allow for the storage and attachment of documents, images, and drawings to records such as equipment, work orders, PMs, parts, requisitions, and vendors.

BR 1.8

The system shall have the capability to configure field name labels, where appropriate, in order to comply with corporate nomenclature.

FR 6.2.8

The system will allow for the configuration of field name labels as appropriate to comply with corporate nomenclature.

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.

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.

FR 6.3.2

The system will be able to maintain equipment records with ID/Equipment numbers up to 20 characters long.

BR 3.5

The system shall be able to store equipment numbers and corresponding detailed information

FR 6.3.4

The system will allow read-only viewing of equipment move transactions into or out of a location.

BR 3.5

The system shall be able to store equipment numbers and corresponding detailed information

FR 6.3.5

The system will be able to identify equipment as GMP or non-GMP, direct or indirect, and critical or non-critical.

BR 3.3

The system shall have the ability to create and maintain a parent – child hierarchy.

FR 6.3.6

The system will allow the creation and/or viewing of equipment hierarchies.

BR 3.4

The system shall have the ability to create and maintain a spare parts list for each equipment item.

FR 6.3.7

The system will be able to create and maintain a spare parts list for each equipment item.

BR 3.2

The system shall have the ability to differentiate between Equipment classifications

FR 6.3.8

The system will be able to store equipment numbers and corresponding information such as description, type, make, model, serial number, classification, location, system number, vendor, old equipment number, operating status, process and instrumentation diagram (P&ID) tag numbers, P&ID drawing numbers, assigned cost center, and a history of maintenance costs.

BR 3.6

The system shall be able to store closing codes to construct accurate histories of the failures that affect equipment and operating locations

FR 6.3.9

The system will be able to store failure code to assist in the diagnosis of failures that affect equipment and operating locations.

BR 3.6

The system shall be able to store closing codes to construct accurate histories of the failures that affect equipment and operating locations

FR 6.3.10

The system will allow the association of failure codes to work orders so that failure trends can be captured and analyzed.

BR 3.7

The system shall provide the capability to maintain preventive maintenance records, and associate them with equipment and locations

FR 6.4.1

System PM Schedule records will allow for the addition, modification, and deletion of such information as, description, classification, schedule/due dates, equipment and trade requirements.

BR 3.9

The user shall be able to associate a job plan (task instruction) with each PM record.

FR 6.4.2

The system will have the ability to create, revise, and view job plan instructions.

BR 3.7

The system shall provide the capability to maintain preventive maintenance records, and associate them with equipment and locations

FR 6.4.3

The system will allow a PM frequency to be specified in days, weeks, months, or years.

BR 3.8

The system shall be able to route and track revisions to preventative maintenance plans.

FR 6.4.4

The system will be able to track revisions for PM entities..

BR 3.7

The system shall provide the capability to maintain preventive maintenance records, and associate them with equipment and locations

FR 6.4.5

The system will be able to associate PM schedules with job plan instructions, material lists, attached documents, estimated labor, and tools.

BR 3.9

The user shall be able to associate a job plan (task instruction) with each PM record.

FR 6.4.6

The system will allow the viewing, addition, modification, and deactivation of job plan records.

BR 4.3

The system shall allow the authorized user to plan, create, reject, review, modify, approve, and cancel work orders against equipment, as well as locations.

FR 6.4.7

The system will have the ability to calculate scheduled due dates from defined preventive maintenance intervals based on prior scheduled due date or prior work order completion date.

BR 4.1

The system shall allow the Company A corporate intranet authorized user community to create work requests in the system.

FR 6.4.8

The system will allow authorized users to create work requests via the Company A intranet.

BR 4.2

The system shall allow the Company A corporate intranet authorized user community to check the status of any work request.

FR 6.4.9

The system will allow authorized Company A corporate intranet users to check the status of the work requests that they have submitted.

BR 4.3

The system shall allow the authorized user to plan, create, reject, review, modify, approve, and cancel work orders against equipment, as well as locations.

FR 6.4.10

The system will allow authorized users to plan, create, review, reject, modify, approve, and cancel work orders and work requests for equipment and/or locations.

BR 4.8

The system shall be configurable to incorporate multiple work flows for various types of work and their associated processes

FR 6.4.11

The system will allow processing of work orders to route, complete, review, approve, and close, in compliance with the business processes.

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.

FR 6.4.12

The system will be able to store work order numbers

BR 3.9

The user shall be able to associate a job plan (task instruction) with each PM record.

FR 6.4.13

The system will be able to maintain job plan descriptions.

BR 4.41

The system shall provide a means to generate work orders based on meter reading.

FR 6.4.14

The system will be able to release PM work orders from meter readings or inspection results.

BR 4.11

The system shall allow authorized users to generate work orders and requisitions.

FR 6.4.15

The system will have the ability to generate work orders to track preventive and corrective maintenance for systems, equipment, and/or locations.

BR 4.4

The system shall allow authorized users to generate work orders from a preventive maintenance schedule.

FR 6.4.16

The system will be able to generate preventive maintenance work orders from the PM schedule.

BR 3.3

The system shall have the ability to create and maintain a parent – child hierarchy.

FR 6.4.17

The system will be able to create and maintain parent-child work order hierarchies.

BR 4.6

The system shall be able to associate various work order types and priorities to specific tasks or work requests.

FR 6.4.19

The system will allow for the specification of the following work order types:

BR - Breakdown Maintenance

PM - Preventive Maintenance

CM - Corrective Maintenance

RM - Routine Maintenance

BR - Breakdown Maintenance

PM - Preventive Maintenance

CM - Corrective Maintenance.

RM - Routine Maintenance

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.

FR 6.4.20

The system will be able to identify if a piece of equipment or location on a PM or work order is GMP if QA Oversight is triggered by FLEX and checked.

BR 4.8

The system shall be configurable to incorporate multiple work flows for various types of work and their associated processes

FR 6.4.21

The system will be configurable to incorporate multiple work order flows for various types of work and their associated processes such as PM, work order requests, GMP, non-GMP, safety issues, and critical work orders.

BR 4.9

The system shall be capable of scheduling work by individual and/or trade.

FR 6.4.22

The system will be able to schedule work and assign labor trade requirements.

BR 1.7

The system shall be able to store and attach electronic documents throughout the application.

FR 6.4.23

The system will allow creation and viewing of attached documents.

BR 1.4

The system shall allow for routing functionality within the application.

FR 6.4.25

The system will give authorized users the ability to notify personnel associated with work on a piece of equipment for which there may be impending safety concerns.

BR 1.4

The system shall allow for routing functionality within the application.

FR 6.4.26

The system will notify members of the EHS (Environmental Health & Safety) group when work requests with safety implications are created.

BR 5.9

The system shall be able to reserve material requirements to scheduled or unscheduled work orders and provide visibility to the reservation.

FR 6.5.2

The system will allow authorized users to check the status of any CMMS generated parts request.

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.

FR 6.5.4

System item records will include the incorporation of such information as item/part number, description, manufacturer, manufacturer item number, vendor, vendor part number, general ledger, reorder point, lead time, unit of issue, unit of purchase, and cost. Functionality will be turned on at a future date if required

BR 5.3

The system shall be able to maintain inventory items that are stocked in one or more storerooms.

FR 6.5.6

The system will be capable of controlling inventory items by lot number and/or expiration date. Functionality will be turned on at a future date if required

BR 5.16

The system shall have the capability to track parts as Equipment/repairable spares

FR 6.5.7

The system will be able to monitor inventory items by serial number. Functionality will be turned on at a future date if required

BR 5.3

The system shall be able to maintain inventory items that are stocked in one or more storerooms.

FR 6.5.8

The system will allow items to be stored in multiple bins.

BR 5.18

Bin information will show current stock level and last physical count date. Functionality will be turned on at a future date if required.

FR 6.5.9

Bin information will show current stock level and last physical count date

BR 5.19

The system shall allow authorized users to override the automatic population of “Preferred Supplier” information on the “Stores” tab of Part records.

FR 6.5.22

Administrator User Groups will be allowed to override the automatic population of “Preferred Supplier” field on the “Stores” tab of Part records through manual editing of the field’s contents.

BR 5.3

The system shall be able to maintain inventory items that are stocked in one or more storerooms.

FR 6.5.10

The system will be able to maintain inventory information for multiple storerooms.

BR 5.4

The system shall be able to create and maintain main and satellite storerooms, and their associations.

BR 5.5

The system shall be able to track multiple vendor and manufacturer information for each inventory item.

FR 6.5.12

The system will be able to maintain multiple vendor and manufacturer listings for each inventory item record.

BR 5.6

The system shall be able to create and maintain rotating (repairable) equipment.

FR 6.5.13

The system will be able to create and maintain rotating (repairable) equipment.

BR 5.7

The system shall be able to issue/return inventory parts to Work Orders and Equipment

FR 6.5.14

The system will allow the issuance, receipt, and return of parts to/from a work order, equipment.

BR 5.8

The system shall be able to associate parts to equipment, to a building, or to a defined area.

FR 6.5.15

The system will be able to associate parts to equipment, system, or location.

BR 5.9

The system shall be able to reserve material requirements to scheduled or unscheduled work orders and provide visibility to the reservation.

FR 6.5.16

The system will be able to reserve materials requirements to scheduled or unscheduled work orders and provide visibility to the reservation.

BR 5.10

The system shall be able to provide inventory availability based on quantity in hand, quantity reserved, quantity awaiting repair, or quantity on order.

FR 6.5.17

The system will be able to provide inventory availability based on quantity on hand, quantity reserved, and quantity on order.

BR 5.11

The system shall provide authorized users the ability to run real-time part availability checks.

FR 6.5.18

The system will provide the ability to run real-time material availability checks.

BR 5.12

The system shall allow authorized users to view the transaction history of items.

FR 6.5.19

The system will allow the tracking of all inventory transactions, such as store-to-store and/or bin-to-bin transfers, and receipt of stocked, non-stocked, and special order items.

BR 5.13

The system shall have the capability to do inventory cycle count.

FR 6.5.20

The system will have the ability to perform a cycle count or physical inventory.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure

FR 6.6.1

The system will be able to indicate a purchase unit of measure, which can be different from the consumption unit of measure.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure

FR 6.6.2

The system will be able to indicate the conversion used between purchase unit of measure and consumption unit of measure.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

FR 6.6.3

The system will allow the viewing of vendor records containing relevant information such as vendor code, description, and other specific data.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

FR 6.6.4

The system will be able to prioritize vendors that are assigned to parts.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

FR 6.6.5

The system will be able to associate multiple vendors to each part, with the ability to indicate a default vendor.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

FR 6.6.6

The system will be able to associate multiple shipping address information to each vendor record.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.1

The system will have multi-level security to limit user access.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.2

The system will allow read-only access and be able to disallow access to tables and modules that are not part of the user functional job description.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.3

Configuration of security access levels will include the ability to define security filters associated with users, roles, and workflows.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.4

CMMS system administrators will be able to add/inactivate users, change user security settings, and add/inactivate reports within the system.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.6

The system will allow the definition and configuration of user groups to differentiate security access levels.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.7

The system will allow configuration of security access at the record/table level in regards to record inserts, updates, and deletes.

BR 8.1

The system shall provide security to allow or disallow functionality on the system level, site level, and user level.

FR 6.7.9

The system will allow configuration of a field to provide the last date and time a user has accessed the system.

BR 1.5

The system shall allow for user profiles

FR 6.8.1

The employee record in CMMS will include employee name, organization/location, and phone number.

BR 9.2

The system will create requestor user accounts by integrating into active directory

FR 6.8.3

The system will be capable of integrating with the authoritative source of employee and contractor data (i.e., Workday or Fieldglass) for access to corporate employee record information.

BR 9.1

The system shall be able to track employees by trades

FR 6.8.4

The system will be able to track labor by multiple occupation types/burden rates.

BR 10.1

The system shall provide the ability to interface with active directory

FR 6.9.1

The system will provide the ability to perform batch updates to CMMS employee data and cost center information from the authoritative source of employee and contractor data (i.e., Workday or Fieldglass).

BR 10.1

The system shall provide the ability to interface with active directory

ITPD-38444

GFR-004

BR 10.1

The system shall provide the ability to interface with active directory

ITPD-38444 GFR-005

The interface processes scheduled transmissions of Employee Data and delivers the packets to Infor

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.

FR 6.9.4

The requestor will be able to retrieve equipment and location information from the CMMS system.

BR 9.2

The system will create requestor user accounts by integrating into active directory

FR 6.9.5

All Company A personnel (employees, temps, contractors, interns, etc.) will be able to submit a work request from any Company A workstation in CMMS without having to request an application user account.

BR 1.4

The system shall allow for routing functionality within the application.

FR 6.9.6

The system shall be designed such that work requests can be input into one queue based on user login and then automatically routed to the appropriate site for review and approval.

BR 4.2

The system shall allow the Company A corporate intranet authorized user community to check the status of any work request.

FR 6.9.7

The system shall be designed such that users can search work requests.

BR 4.1

The system shall allow the Company A corporate intranet authorized user community to create work requests in the system.

FR 6.9.8

The Requestor module shall consist of sections containing the following types of information:

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure

FR 6.10.1

The system will be able to indicate a purchase unit of measure, which can be different from the consumption unit of measure.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

FR 6.10.6

The system will be able to associate multiple addresses for each vendor record.

BR 6.5

The system shall have the capability to generate and track purchase orders approved from requisitions.

ITPD-38444 GFR-001

BR 6.5

The system shall have the capability to generate and track purchase orders approved from requisitions.

ITPD-38444 GFR-002

The interface processes Purchase Order transmissions and delivers the packets to INFOR.

BR 6.6

The system shall have the capability to perform receipt transactions

ITPD-38444 GFR-003

The interface processes Parts and Service Receipts transmissions and delivers the packets to Oracle EBS.

BR 6.7

The system shall have the capability to track invoice information and reconcile expenditures against purchase orders/receipts.

ITPD-38444 GFR-003

The interface processes Parts and Service Receipts transmissions and delivers the packets to Oracle EBS.

BR 5.15

The system shall have the capability to reorder parts based on stocking parameters

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 REQ-001

Each Requisition is processed as a unique data set.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 REQ-002

The Requisition either passes all Fusion/Oracle validation and then is passed to EBS or it is returned to INFOR, via email, as an exception.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

ITPD-38444 REQ-003

The Requisition can be for parts and/or Service.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 PO-001

Each PO Line is transmitted in a separate file that is part of a unique data set.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 REC-001

Each Receipt is a unique data set.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 REC-002

The Receipt either passes all Fusion/Oracle validation and then is passed to EBS or it is returned to INFOR, via email, as an exception.

BR 6.1

The system shall be capable of integrating with Oracle Purchasing application for the generation of vendor records, and purchase orders, as well as the receipt of materials, and viewing of purchase order balances.

ITPD-38444 REC-003

The Receipt can be for Parts or Service.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 CCD-001

Cost Code Data is transmitted from EBS as a unique data set.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 CCD-002

Cost Code Data transmissions contain add and change transaction types.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 ED-001

Employee Data is transmitted from Oracle HR as a unique data set.

BR 6.2

The system shall have the capability to exchange pertinent procurement data with Oracle iProcure.

ITPD-38444 ED-002

Employee Data transmissions contain add and change transaction types.

BR 7.3

The system shall provide authorized users with the ability to extract/export data from the system in an acceptable format such as Microsoft Excel.

BR 4.7

The system shall be able to modify/control equipment information based on user permissions.

BR 3.12

The system shall be able to identify equipment records as instruments requiring calibration.

FR 6.3.11

The system provides a checkbox identifying the record as an instrument on all equipment screens.

BR 3.13

The system shall be able to capture the status of an instrument.

FR 6.3.12

The system provides a definable status field on the Equipment record.

BR 3.14

The system shall be able to identify the classification of an instrument.

FR 6.3.13

The system provides a class field on the Equipment Record View tab for classification purposes.

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).

FR 6.3.14

The system provides for creating and storing calibration data by instrument or instrument category including calibration limits, ranges, units of measure, tolerances, test points, comments, and standards.

BR 3.16

The system shall be able to designate differing units of measure for inputs vs. outputs in calibration testing.

FR 6.3.15

The system provides separate units of measure for a test point and test point output.

BR 3.17

The system shall be able to designate differing units of measure for individual test points within a set of test points on an instrument.

FR 6.3.16

The system provides a specific unit of measure for each test point on the instrument.

BR 3.18

The system shall provide a mechanism for storing calibration information as a template for like instruments.

FR 6.3.17

The system provides a Category code with calibration and test point data that can then be assigned to like instruments.

BR 3.19

The system shall be able to update calibration information as a batch for like instruments.

FR 6.3.18

The system provides an Update Equipment function in the Categories program to update all equipment assigned to that category.

BR 3.20

The system shall provide a mechanism for updating an instrument to a Measurement Device.

FR 6.3.19

The system provides a field to update equipment as a Measurement Device on the Equipment screen.

BR 3.21

The system shall be able to track the location of an instrument and shall maintain a history of all location changes.

FR 6.3.20

The system provides for a location in the Equipment structure that creates a history record in the Events tab each time the equipment location is changed.

BR 3.22

The system shall be able to track the parent system of an instrument and shall maintain a history of all equipment hierarchy changes.

FR 6.3.21

The system provides an equipment hierarchy on the Equipment Structure tab and captures hierarchy changes on the Events tab.

BR 3.23

The system shall provide a method of tracking calibration standards as serialized equipment and as standardized inventory items.

FR 6.3.22

The system provides for tracking of serialized equipment marked as calibration standards through the Part screen in the Record View tab.

BR 3.24

The system shall have the ability to identify all calibration work performed with a given standard within a given time frame. (Reverse Traceability)

FR 6.3.23

The system provides for reverse traceability for a defined date range using a defined standard.

BR 3.25

The system shall provide a mechanism for performing a criticality risk assessment on an instrument and capturing the results.

FR 6.3.24

The system provides a method of performing a criticality assessment on an instrument based on a predefined set of questions.

BR 3.26

The system shall provide a mechanism for identifying the criticality of an instrument.

FR 6.3.25

The system provides a Classification field with business rule capability to define the criticality of an instrument.

BR 3.27

The system shall provide a mechanism for attaching scanned documentation to an instrument record.

FR 6.3.26

The system provides for scanned document attachment capability on Equipment records on the Documents tab.

BR 3.28

The system shall provide a mechanism for communicating test point level instructions/comments and transferring this information to calibration work orders.

FR 6.3.27

The system provides a comments field on each calibration test point that can be used for instructions/comments and will transfer to the calibration work order.

BR 3.29

The system shall have a mechanism for tracking the approval flow of the CRA Process outside of the instrument record (CRA Request)

FR 6.3.28

The Instrument CRA screen is used to track the approval of an instrument update.

BR 3.30

The CRA Request mechanism shall include designation of Criticality Risk Assessment, Interval of calibration, range and tolerance information.

FR 6.3.29

A CRA request process is provided to document the criticality classification, the interval of calibration, the range, and the tolerance of the instrument. A check box on the instrument will indicate the CRA has been completed.

BR 3.31

The system shall provide automatic updates of the Category field and updating the CRA assessment results into the appropriate equipment Category field.

FR 6.3.30

The system provides capabilities through FLEX SQL configuration to update information on the equipment form based on the CRA assessment.

BR 3.32

The system shall allow for the association of instruments to parts records.

FR 6.3.31

The system provides for the direct association of instruments to part records on the Equipment Record View tab in the Part Information section.

BR 3.33

The system shall provide a mechanism for identifying an instrument as missing.

FR 6.3.32

The system provides a means to mark an instrument as 'missing' by creating and using a defined supplemental status on the Record View tab.

BR 4.12

The system shall allow authorized users to generate calibration work orders from a preventive maintenance schedule.

FR 6.4.27

The system provides authorized users a Generate WO program to generate PM work orders by work order type - 'PMCAL - Calibration' work orders.

BR 4.13

The system shall be able to associate multiple PM schedules to an individual instrument.

FR 6.4.28

The system allows multiple PM schedules to be associated to one instrument on the PM Schedules tab.

BR 4.14

The system shall allow authorized users to generate calibration work orders for unscheduled or on-demand calibrations.

FR 6.4.29

The system allows for the creation of unscheduled calibration work orders in the Work Order program.

BR 4.15

The system shall provide a method of differentiating Calibration Work orders from general maintenance work orders.

FR 6.4.30

The system provides a way to categorize work orders by using a UDF checkbox labeled as 'Calibration WO' on the Work Order Record View tab.

BR 4.16

The system shall provide a method of differentiating calibration work orders performed by Company A technicians vs. performed by vendor calibration technicians.

FR 6.4.31

The system provides a 'Supplier' field on the Record View of the work order that can house the calibration vendor code.

BR 4.17

The system shall provide a mechanism for capturing the name of the vendor performing the calibration.

FR 6.4.32

The system provides a Supplier field on the work order that can indicate the calibration vendor.

BR 4.18

The system shall be able to identify which instruments have been sent off-site to external vendors.

FR 6.4.33

The system provides a work order status field that will designate that the calibration work order has been sent to a vendor. (Status = "With Vendor")

BR 4.19

The system shall provide a mechanism for vendor performed calibrations allowing users to attach scanned certificates.

FR 6.4.34

The system provides Document Attachment capability so that vendor certificates may be attached to a calibration record.

BR 4.20

The system shall be able to capture calibration data and status per test point for As-Found conditions and As-Left conditions including failures and adjustments during the calibration process.

FR 6.4.35

The system provides the ability to capture calibration data and status per test point for As-Found conditions and As-Left conditions including failures and adjustments during the calibration process.

BR 4.21

The system shall be able to capture the overall calibration status of an instrument As-Found at the time of the calibration and As-Left after all test points have been completed including failures and adjustments.

FR 6.4.36

The system provides the ability to capture the overall calibration status of an instrument As-Found at the time of the calibration and As-Left after all test points have been completed including failures and adjustments.

BR 4.22

The calibration technician must be able to see whether the entered calibration result is within or outside of the Calibration tolerance and the Adjustment tolerance.

FR 6.4.37

The system provides the means for the calibration technician to view whether the entered calibration results are within or outside of the Calibration tolerance on the calibration work order.

BR 4.23

The system shall provide a mechanism for capturing all standards used during the calibration of an instrument.

FR 6.4.38

The system provides the ability to capture the Standard used on a calibration work order.

BR 4.24

The system shall provide a method of verifying a standard is not past its expiration date before being used for calibration.

FR 6.4.39

The system provides business rules to identify standards past their expiration dates.

BR 4.25

The system must provide a work order status flow for the calibration work order.

FR 6.4.40

The system provides a work order status flow for the calibration work order.

BR 4.26

The calibration status shall exist independently of the work order status for the calibration work order.

FR 6.4.41

The system provides a calibration status that is independent of the work order status.

BR 4.27

The system shall provide a mechanism for documenting adjustments made during the performance of the calibration.

FR 6.4.42

The system provides As-Left information, test point comments and work order comments for calibration notes.

BR 4.28

The system shall provide a method for documenting out of tolerance "RAR" reference record from supporting systems for failed calibrations on critical equipment for calibrations requiring an RAR. This field will require population for work orders requiring an RAR.

FR 6.4.43

The system shall provide a field on the work order for capturing RAR Information (Trackwise #). Population of this field will be required via FLEX configuration for work orders requiring an RAR.

BR 4.29

The system shall be able to capture the employee performing a calibration work order.

FR 6.4.44

The system captures the e-Signature of the employee completing the work order.

BR 4.30

The system shall be able to capture the time required to perform a calibration work order.

FR 6.4.45

The system provides an "Hours Worked" field on the work order which captures the time worked by employee.

BR 4.31

The system shall provide a searchable database of unscheduled or scheduled calibration work order records.

FR 6.4.46

The system provides a searchable database of work orders. Calibration work orders will have a checkbox to identify calibration work orders whether they are scheduled or unscheduled.

BR 4.32

The system shall provide a method of associating a calibration work order to a repair work order resulting from the performance of calibration activities.

FR 6.4.47

The system provides a Parent/Child relationship with regard to Work Orders which can associate repair work orders to calibration work orders.

BR 4.33

The system shall allow for a grace period for the performance of a calibration work order after the work order is generated. This grace period is determined procedurally based on criticality and frequency of calibration.

FR 6.4.48

The system provides a PM Due Date and PM Interval that defines the 'grace period' for each Calibration PM schedule.

BR 4.34

The system shall provide the capability of tracking schedule extensions for calibration work orders.

FR 6.4.49

The system provides a work order status field that will designate that the calibration is working its way through the extension process.

BR 4.35

The system shall provide a method of identifying instruments having 3 or more sequential calibrations found out of tolerance.

FR 6.4.50

The system provides reporting to identify instruments that have 3 or more consecutive failures.

BR 4.36

The system shall provide a method of displaying work instructions on a calibration work order.

FR 6.4.51

The system provides comments text blocks for work instructions.

BR 4.37

The system shall provide a method of indicating whether an instrument passed or failed calibration at the calibration work order level.

FR 6.4.52

The system provides a calibration status to indicate whether the instrument passed or failed calibration.

BR 4.38

The system shall provide a method of identifying a corrective work order as a calibration work order.

FR 6.4.53

The system provides a checkbox indicating the work order includes calibration information.

BR 4.39

The system shall provide a mechanism for identifying different sets of test points for a particular category/instrument.

FR 6.4.54

The system provides 'sets' at the test point level to separate groups of test points on scheduled calibrations.

BR 4.40

The system provides automated e-mail notification of equipment owner for out of tolerance calibration results upon completion of supervisor review of the order. If the equipment owner is not populated, no notification will be sent.

FR 6.4.55

The system provides an email notification tool that can be configured to send email notifications for out of tolerance calibrations.

BR 5.17

The system shall provide a mechanism for identifying a part as a Calibration Standard.

FR 6.5.21

The system provides a checkbox on the Part record that is linked to the Equipment which identifies the part as a Calibration Standard.

BR 7.6

The system shall provide access to historical calibration event records in a searchable format within the framework of the application.

FR 6.11.6

The system provides a historical calibration event for each equipment record on the Events tab of Equipment.

BR 7.7

The system shall provide access to historical calibration related records maintaining the relationship to the equipment/instrument record for migrated equipment.

FR 6.11.7

The system will provide an additional tab linked to equipment records to show historical calibration data that occurred outside of CMMS.

BR 7.12

The system shall provide a method of displaying all active or open calibration work orders.

FR 6.11.12

The system will provide a list of all active calibration work orders based on the work order type, Calibration WO checkbox, and Status.

BR 7.15

The system shall provide a method of displaying all historical calibrations performed on an instrument.

FR 6.11.15

The system provides event history of all calibrations performed on an instrument.

BR 11.4

The System shall provide a method of storing and accessing legacy system transactional data that will not be migrated into the base application.

FR 6.12.4

The system will provide access to legacy system transactional data searchable by instrument through a customized data grid.

BR 11.5

Legacy information shall be accessible for migrated instruments and equipment as well as obsolete, non-migrated instruments and equipment.

FR 6.12.5

This should be: The system will provide access to legacy system information via an equipment tab custom data grid for currently installed equipment and a custom transactional data grid for equipment that may or may not be in Infor 10.

BR 11.6

Legacy information shall be sortable, searchable, filterable, and exportable.

FR 6.12.6

Legacy transactional data will be located in a custom data grid which will be sortable, searchable, filterable and exportable to Excel.

BR 3.34

The system shall provide a means to store meter readings for equipment/instrument.

FR 6.3.33

The system provides a meter tab to record PI meter readings both automatically and manually. The tab will provide options to update and track meter readings for each specific equipment/instrument.

BR 4.41

The system shall provide a means to generate work orders based on meter reading.

FR 6.4.56

The system provides a Meter-based PM schedule to generate PM work orders based on meter readings from the PI system.

BR 4.42

The system shall provide a means to pull specific readings from the PI System.

FR 6.4.57

The system provides a “Meter” tab on equipment and a “PI Alert Data” screen to extract reading points from the PI System.

BR 4.43

The system shall provide a means to store alert critical and extreme limits for equipment/instrument.

FR 6.4.58

The system provides the “Aspects” tab on the Monitored Equipment screen to setup min/max values for alert critical and extreme limits for non-metered equipment/instrument. For metered equipment, the limits are set on the record view of the equipment screen.

BR 4.44

The system shall provide means to generate automated e-mail notification based on equipment alert criticals and extremes.

FR 6.4.59

The system provides a place to setup automated e-mail notification when equipment alert critical/extremes are met or surpassed. Automated email notification is handled through the existing “Alert Management” menu, using the “E-mail Alerts” tab.

BR 4.45

The system shall provide means to generate work orders based on equipment alert extremes.

FR 6.4.60

The system provides a mechanism to generate work orders if extremes are met or surpassed. Work order generation is handled through the existing “Alert Management” menu, using the “Work Order Alerts” tab.

BR 10.2

The system shall provide the ability to interface with the PI System.

FR 6.9.9

The system provides the “PI Meter Equipment” grid, Equipment “Meter” tab and “PI Alert Data” grid displaying instruments associated with PI tags and the related data.

BR 3.35

The system shall provide a mechanism for performing a system impact assessment (SIA) on equipment and capturing the results.

FR 6.3.34

The system provides a method of performing an SIA on equipment based on a predefined set of questions.

BR 3.36

The system shall provide a mechanism for identifying the latest SIA performed on equipment.

FR 6.3.35

The system provides a field on the equipment record that shows the latest CRA/SIA request.

BR 3.38

The system shall provide a method to update multiple equipment on one CRA/SIA request.

FR 6.3.37

The system provides an extra tab on the latest CRA/SIA Request screen to allow input of additional equipment on one request.

BR 3.39

The system shall provide a method to roll-down updates to the children of an equipment using the CRA/SIA Request screen.

BR 3.39

The system shall provide a method to roll-down updates to the children of an equipment using the CRA/SIA Request screen.

FR 6.3.52

The system has the ability to determine the ‘Direct Impact or Child of Direct Impact’ status on a piece of equipment and roll-down to their children (if any), on the Equipment CRA/SIA Request screen.

BR 3.39

The system shall provide a method to roll-down updates to the children of an equipment using the CRA/SIA Request screen.

FR 6.3.53

The system provides SIA request types on the Equipment CRA/SIA Request screen that will determine the SIA on a piece of equipment and roll-down to their children (if any) that are functional systems.

BR 6.8

The system shall allow users to manually change the status of purchase orders within CMMS.

FR 6.10.7

The system will allow authorized user groups to update the status of a purchase order manually.

BR 6.9

The system shall allow all sites to order parts and in multiple currencies.

FR 6.10.8

Authorized users from all sites have the ability to create a purchase requisition and set the currency that is not specific to the organization.

BR 6.10

The system should allow for proper pricing to be transferred to the purchase order for all units of measures.

FR 6.10.9

The part record on a purchase order shall maintain the same quantity, price, and unit of measure as the purchase requisition it was generated from.

BR 10.3

The system shall maintain updated active supplier information for suppliers that accept orders from Oracle EBS.

FR 6.9.10

The system will provide the ability to perform batch updates to the Supplier screen with active supplier data from Oracle EBS.

BR 3.11

The system shall provide a means to assess equipment for its criticality to business operations through the Reliability Ranking module.

FR 6.3.39

The system will provide a means to assess the Reliability Ranking of the equipment to determine the critical nature of the equipment in terms of business operations.

BR 3.40

The system shall be able to identify reviewers for revisions to preventive maintenance entities.

FR 6.3.40

The system will provide reviewer fields on PM Entity screens for users to select the primary approvers for revisions.

BR 3.41

The system shall be able to identify the reasoning for revisions to preventative maintenance entities.

FR 6.3.41

The system will provide a free text field on PM Entity screens to enter the reason for revisions.

BR 3.42

The system shall be able to put restrictions on initiators being approvers for GMP PM entity revisions with the exclusion of administrative changes.

FR 6.3.42

The system will provide a means to restrict initiators from approving GMP PM Entity revisions that are not administrative changes.

BR 3.43

The system shall be able to put the enforcement of QA Review for GMP PM Entity revisions with the exclusion of administrative changes.

FR 6.3.43

The system will provide a means to enforce QA Review on GMP PM Entity revisions that are not administrative changes.

BR 3.44

The system shall be able to consolidate multiple processes for equipment onboarding.

FR 6.3.44

The system will provide the Equipment Onboarding screen that incorporates equipment creation, CRA/SIA, Reliability Ranking, PM assessment, Alarm Classification, and optional upload.

BR 3.45

The system shall provide a process to install or retire equipment

FR 6.3.45

The system will provide the Equipment Install/Retire Request screen to install or retire equipment.

BR 3.46

The system shall be able to by-pass QA Review on non-GMP Equipment CRA/SIA Requests for equipment in the TD, RESEARCH, and CAM GEF departments.

FR 6.3.46

The system will provide a means to by-pass QA review for certain equipment on Equipment CRA/SIA Request

BR 3.47

The system shall be able to by-pass review on calibration work orders that does not contain critical in the classification.

FR 6.3.47

The system will provide a means to by-pass review and go straight to close status on scheduled and unscheduled calibration work orders.

BR 4.46

The system shall be able to by-pass planning when creating an unscheduled work order.

FR 6.4.61

The system will provide a means to by-pass PLNSCH review (Planning) and go straight to Released status when creating unscheduled work orders.

BR 3.48

The system shall provide a means to automatically update equipment information on PM Schedules when the equipment is being updated.

FR 6.3.48

The system will provide a flex that will update fields on the Equipment tab of the PM Schedules screen after updating fields on the Equipment screen.

BR 4.47

The system shall be able to enforce a requirement to populate a value in the Supervisor field for DEN and SOL work orders.

FR 6.4.62

The system will provide a flex that will make the Supervisor field a mandatory requirement for DEN and SOL work orders when the WO is saved to the Released, Review, and Closed Statuses.

BR 3.49

The system shall be able to hide the “Assigned To” field on PM Schedules and Equipment screens.

FR 6.3.49

The system will be able to hide the “Assigned To” field in the PM Schedule and Equipment screen.

BR 3.50

The system shall be able to detect if a PM Entity is GMP or Non-GMP, based on the status of the related equipment.

FR 6.3.50

The system shall be able to detect if a PM Entity is GMP or Non-GMP from the status of the related equipment which determines the selection of approvals lists for PM Entity revisions.

BR 7.17

The system shall provide a means to lookup open revisions on PM Entities.

FR 6.11.17

The system will provide a grid showing all active open revisions on PM Schedules, Job Plans. Material Lists, and Routes.

BR 4.49

The system shall allow authorized users to use checklists to track work performed on work orders.

FR 6.4.64

The system will be able to display the correct completion status of the checklist on a work order, when any type of checklist is used.

BR 3.51

The system shall provide a mechanism to assess the classification of alarm records and create alarm records.

FR 6.3.54

The system provides an “Alarm Classification” screen which can be used to create alarm records and perform an alarm classification assessment.

BR 3.52

The system shall provide a means to show alarm records with alarm classification values.

FR 6.3.55

The system provides an “Alarms” screen which displays alarm records with alarm classification values.

BR 3.53

The system shall provide a means to upload Alarm Classification requests.

FR 6.3.56

The system provides a means to upload Alarm Classification data for the respective request/multiple requests at a time.

BR 10.4

The system shall maintain an outbound Equipment publication service.

FR 6.9.2

The system will publish records indicating changes to Equipment master attributes for select Equipment to a database staging table, for external systems to read.

BR 10.4

The system shall maintain an outbound Equipment publication service.

FR 6.9.3

The system will query for PM or PMCAL Work Orders that are Overdue each day at midnight Organization time. The system will then publish an Overdue status for select Equipment that are impacted to a database staging table, for external systems to read. Overdue status is defined as an open Work Order not equal to 3RVW, 3QA, 3UPD, and Due Date less than the date at the location of the Equipment on the Work Order.

BR 10.4

The system shall maintain an outbound Equipment publication service.

FR 6.9.13

The system will determine if no other Overdue maintenance exists against an Equipment or its Child Equipment, once a PM or PMCAL Work Order completes for an Equipment deemed Overdue. If it finds none, the system will publish a Not Overdue status for select Equipment, as well as for any select Parent Equipment that have no other Child Equipment in an Overdue status, to a database staging table, for external systems to read. Completed status is defined as when the Work Order reaches a status of 3RVW, 3QA, 3UPD or a system status of C. Overdue status is defined as having an open PM or PMCAL Work Order against the Equipment not equal to 3RVW, 3QA, 3UPD, and Due Date less than the date at the location of the Equipment.

BR 10.4

The system shall maintain an outbound Equipment publication service.

FR 6.9.14

The system will determine if an Equipment structure change causes any Equipment to become Overdue or Not Overdue. Overdue status rolls up to all Parent Equipment. Not Overdue status rolls up to all Parent Equipment with no other Overdue Child Equipment. The system will publish an Overdue or Not Overdue status for select Equipment to a database staging table, for external systems to read. Overdue status is defined as having an open PM or PMCAL Work Order against the Equipment not equal to 3RVW, 3QA, 3UPD, and Due Date less than the date at the location of the Equipment.

BR 10.4

The system shall maintain an outbound Equipment publication service.

FR 6.9.15

A “Broadcast Changes” checkbox, editable by Administrator User Groups, will be available on the Equipment screen to select Equipment for which status and Equipment master attribute changes will be recorded onto a database staging table, for external systems to read.

BR 10.5

The system shall provide the ability to interface with the Advanced Scheduler application.

FR 6.9.16

Database Views will be installed to stage data for the Advanced Scheduler application to pull. The Views will display general Work Order data for select Work Orders, Trades associated with Activities on each Work Order, sum of Estimated Hours of each Trade per Work Order, and sum total of all Estimated Hours per Work Order.

BR 3.54

Protected “PM Due” and “PMCAL Due” indicators will be made available on the Equipment screen to indicate whether an Equipment is Overdue for Preventative Maintenance or Calibration, respectively.

FR 6.3.63

Protected “PM Due” and “PMCAL Due” checkboxes will be added to the Equipment screen as indicators of Preventative Maintenance or Calibration Overdue status of corresponding Equipment. Overdue status is defined as having an open PM or PMCAL Work Order against the Equipment not equal to 3RVW, 3QA, 3UPD, and Due Date less than the date at the location of the Equipment.

BR 3.55

The system shall allow change in to be completed for different areas or zones of manufacturing at different times.

FR 6.3.64

BOE will allow Equipment to be categorized by Zone and Area.

BR 3.56

The system shall be able to store process settings of the equipment.

FR 6.1.18

A settings tab on Equipment records will detail existing attribute settings relevant to the Equipment record.

BR 3.57

The system shall be able to route and track revisions to the BOE and attributes.

FR 6.1.19

BOE will be revision controlled and support a review status prior to approval.

BR 3.58

The system shall be able to record the reasoning for revisions to BOEs or equipment attributes.

FR 6.3.65

Revision Reason field will capture justification for revision.

BR 3.59

The system shall support the ability to perform bulk data uploads of Attributes, BOE Equipment and BOE Settings.

FR 6.3.66

The CMMS Import Utility application will support bulk data upload for BOE, attributes, and attribute settings.

BR 3.60

The system shall display whether each piece of equipment selected for a campaign is dormant or is currently due for PM.

FR 6.1.13

The system enables authorized users to generate Bill of Equipment records detailing lists of Equipment validated for use in manufacturing a specific product and the status of the Equipment; as well as to associate the Equipment on the BOE with the attribute settings required by the BOE.

BR 3.61

All current process settings for a piece of equipment shall be able to be viewed.

FR 6.1.14

A settings tab on Equipment records will detail existing attribute settings relevant to the Equipment record.

BR 3.62

A record of initial process settings shall be able to be viewed in the change request.

FR 6.3.67

IEL will include a tab detailing a comparison between initial (Equipment) settings and BOE settings.

BR 3.63

A record of date and time of implementation of new process settings shall be able to be viewed in the Equipment Change Summary report.

FR 6.3.68

The IEL will provide a timestamp for new process settings that have been implemented.

BR 3.64

The system shall allow a user to change process settings on a piece of equipment outside of campaign changeover.

FR 6.3.69

A settings tab on Equipment records will detail existing attribute settings relevant to the Equipment record.

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.

FR 6.4.68

A settings comparison tab is available on the Equipment Change Request screen.

BR 4.52

The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings.

FR 6.4.69

The system will generate a Work Order for each Zone under the Equipment Change Request. The system will also generate Routine Maintenace Work Orders against each Equipment on the IEL, as children to the respective Zone Work Orders. The Routine Maintenance Work Orders will include checklists to change any current process settings which differ from the incoming campaign’s process settings; and will be organized into Activities on the Work Order. corresponding to the Trade of the respective settings being changed.

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.

FR 6.4.70

If the Equipment Change Request does not specify the value for a process setting that exists on an Equipment included in the IEL, then the ECR will include work orders to change the value of those unspecified settings to N/A on the Equipment record.

BR 4.54

The system shall not generate work orders in cases where the current equipment process setting matches that of the incoming campaign.

FR 6.4.71

Equipment Change Requests will not generate Work Orders to change process settings when the value of the setting on the Equipment included in the IEL matches that setting value on the BOE.

BR 4.55

A single work order shall be generated for each piece of equipment for each trade and zone, with a checklist of attributes to be updated. The checklist notes shall be pre-populated with the new value and old value.

FR 6.4.72

Upon approval of the Equipment Change Request, a single work order shall be generated for each piece of equipment for each trade and zone, with a checklist of attributes to be updated per the associated BOE. The checklist notes shall be pre-populated with the new value and old values.

BR 4.56

System shall provide the ability to complete WO based on checked process setting status.

FR 6.4.73

The system automatically updates Equipment attributes when respective checklist items are marked as successfully completed. Otherwise the system does not update the Equipment.

BR 4.57

System shall provide the ability to complete WO based on unchecked process setting status.

FR 6.4.73

The system automatically updates Equipment attributes when respective checklist items are marked as successfully completed. Otherwise the system does not update the Equipment.

BR 4.58

The system will assign Work Orders to the trade that is assigned to the associated parameters (BOE Settings).

FR 6.4.74

BOE will support association of attribute settings with specific trades against which the Work Orders to update the attributes will be generated.

End of general requirements.

BR 7.2

The system shall provide standard reports, as well as the ability for a user to create and save searches.

FR 6.1.7

CMMS built-in Cognos reporting functionality will be used for reporting.

BR 7.5

The system shall allow for auto generated reports to be distributed via email

BR 7.8

The system shall provide a report to access historical calibration measurement data records.

FR 6.11.8

The system provides a Calibration History report which shows historical calibrations on each piece of equipment specified.

BR 7.9

The system shall provide a Calibration Work Order Report capturing a calibration event.

FR 6.11.9

The system will provide a custom Calibration Work Order report that reports all calibration data for the specified equipment/instrument.

BR 7.10

The system shall provide a Confirmation of Calibration report displaying the last calibration performed on an instrument.

FR 6.11.10

The system will provide a custom Confirmation of Calibration report that displays the last calibration performed on an instrument by Organization code.

BR 7.11

The system shall provide a method of displaying all parents and/or children records for an instrument. (Hierarchy Report)

FR 6.11.11

The system provides a report for equipment structure to show parent/child relationships.

BR 7.13

The system shall provide a report to forecast scheduled calibrations including calibration data.

FR 6.11.13

The system provides a method of forecasting scheduled calibrations including calibration data:

BR 7.14

The system shall provide a report displaying all devices calibrated using a specific standard over a specified period of time. (Reverse Traceability)

FR 6.11.14

The system provides a reverse traceability feature by tying a part record, marked as a standard, to an instrument.

BR 7.16

The system shall provide a method of printing calibration labels using the existing report functionality.

FR 6.11.16

The system provides a method to print calibration labels using the built in Cognos reporting functions. The report will be able to be generated automatically or manually.

BR 7.18

A summary change report shall be generated with Current equipment settings and BOE settings.

FR 6.11.19

An Equipment Change Summary report shall be generated with Current equipment settings and BOE settings.

BR 7.19

An BOE Summary Report that will show BOE header information, BOE equipment and BOE Settings.

FR 6.11.20

A BOE Summary Report will show BOE header information, BOE equipment and BOE Settings.

BR 7.20

An Revision Change Detail Report for BOEs will show changes between revisions from the record view, BOE equipment, and BOE equipment Settings

FR 6.11.21

An Revision Change Detail Report for BOEs will show changes between revisions from the record view, BOE equipment, and BOE equipment Settings

BR 7.21

An Equipment Change Summary Report that shows IEL record view information, incoming equipment list with calibration overdue status and dormancy information,settings comparison to the BOE, excecutable wokrorder info , inital process settings , and esigniture section.

FR 6.11.22

An Equipment Change Summary Report will show IEL record view information, incoming equipment list with calibration overdue status and dormancy information,settings comparison to the BOE, excecutable wokrorder info , inital process settings , and esigniture section.

BR 4.50

The system shall provide authorized users a method to generate and review audit trail reports of work orders.

FR 6.4.65

The system will be able to pass records of changes made to information on the screen of a work order of any type to an attached ‘Audit Trail Review’ tab. The system will then compile and display the records in an audit trail report in the ‘Audit Trail Review’ tab.

UR-REG-01

The system must have appropriate controls to (a) protect the system and records from inadvertent as well as deliberate destruction or alteration and (b) prevent, detect, and mitigate harmful effects of viruses, worms, and other harmful codes and ensure their accurate and ready retrieval throughout the records retention period. (§11.10c, Annex 11 7.1, MHRA Data Retention section; EU Vol 4 Chpt 4 4.1 and 4.10; EU Annex 11 7.1; PMDA MHLW Ord 169 Article 9 1; EMA Q10, PDA Data Integrity Code of Conduct 3.3.1.2)

FS-REG-01

ITCD-22525, *Information Security Policy* provides a control mechanism to protect Company A systems from inadvertent and deliberate destruction and harmful effects of harmful codes and programs. PRCD-94210, *Global Records Retention and Disposition Policy* outlines a methodology to protect and retain system data and ensure accurate retrieval of data throughout the retention period.

UR-REG-02

The system must be able to display or print accurate and complete copies of records suitable for inspection. Raw data must permit the full reconstruction of the activities resulting in the generation of the data.  (§11.10b, Annex 11 8.1, MHRA Raw Data section; PDA Data Integrity Code of Conduct 3.3.1.5)

FS-REG-02

The system shall display or print all documents suitable for use during an inspection.

The system provides a viewable audit trail which covers user interaction, system records at the workflow level.

The audit trail can be generated from the Audit Trail Review tab.

UR-REG-03

The system must produce reports of electronically stored data, including audit trails. (Annex 11 8.1, MHRA Raw Data section; PDA Data Integrity Code of Conduct 3.3.1.5)

FS-REG-03

System shall generate and store data in the form of reports including audit trails.  Reports can be generated from the report section.

UR-REG-04

Where required, the system must use operational checks to enforce permitted sequencing of Step(s) and events. (§11.10f)

FS-REG-04

The system provides the workflow functionality which will have a sequence of review, approve, release and complete statuses.  Workflow will promote to the next status only after the approval in a sequential manner.

UR-REG-05

The system must incorporate built-in checks where appropriate in order to determine the validity of source of data input or operational instruction. (§11.10h, Annex 11 5)

UR-REG-06

The system should employ additional checks for critical data entered manually to ensure the accuracy of the data.  This check may be done by a second operator step or by validated electronic means.  (§11.10 f, Annex 11 6, MHRA Raw Data section; PDA Code of Conduct 3.3.4)

FS-REG-06

Approver will view and make the decision whether to approver or reject. After all the approver signoff, workflow will be promoted to the next status.

UR-REG-07

The system must automatically log users off after a specified period of inactivity. (§11.10d, g, Annex 11 12.1, MHRA Computerized System User Access section)

FS-REG-07

Upon inactivity, the system shall automatically log users out after a configured period of inactivity.

UR-REG-08

Open systems must employ digital signatures and data encryption as necessary in order to maintain data authenticity, integrity, and confidentiality. (§11.30, Annex 11 7.1, 12.1, MHRA Data Section)

UR-REG-09

The system must provide human readable forms of signed electronic records (e.g., computer screen displays, printouts).  These should bear the printed name of the signer, the date and time of the signing, and the meaning of the signature (e.g., review, approval, responsibility, and authorship). (§11.50, Annex 11 14, MHRA Data Integrity)

FS-REG-09

The system shall capture the following information with all electronic signatures:

•  The unique username for the user.

•  The date and time that the signature was captured, stored and displayed with CMMS Application Server time.

•  The meaning of the signature is inherent in the record that the signature is stamped on.

UR-REG-10

The system must provide a permanent link between signatures (whether electronic or handwritten) executed to electronic records and their associated electronic records to ensure that signatures cannot be excised, copied, or transferred to falsify an electronic record by normal functionality and user authorization. (§11.70, Annex 11 14, MHRA Data Integrity)

FS-REG-10

Network ID’s are permanently linked to records in the Audit Trail.  Access is assigned according to PRCD-15979, *Company A Account Management Procedure*.

Access to the application will be granted based on the users Network ID and AD group membership.

The requirements are also supported through adherence to SOP PRCD-30916, *IT Controls: Security Management*.

In the event of an upgrade or migration, this data will remain in the Audit Trail linked to Company A Network ID.

UR-REG-11

The system must be backed up and all relevant data/records must be retained and retrievable.  Backups must be complete and accurate data/records.  (§11.10c, Annex 11 7.2, MHRA Data Retention and Backup sections; EMA Q10 )

FS-REG-11

This requirement is supported by ITPD-82011, Backup and Restore Requirements and Test Plan.

UR-REG-12

The system must use secure data retention storage locations to prevent data from being saved to unauthorized file storage locations including removable devices. (§11.10c, Annex 11 7.1, MHRA Data Retention section; PDA Data Integrity Code of Conduct 3.3.1.4)

FS-REG-12

CMMS data will be retained within the validated system databases.  Access to the system data is controlled according to CMMS Application Management PRCD-16000.

CMMS servers are within a secure data center on Company A network location which adheres to global data integrity requirements.

UR-REG-13

If the system is used for archiving data, the system must lock archived records such that they cannot be altered or deleted without detection and audit trail.  The archive arrangements must be designed to permit recovery and readability of the data and metadata.

UR-REG-14

The system must employ controls that maintain unique ID/password combinations such that no two individuals have the same combination of ID and Password. The system should not allow IDs to be reassigned or deleted once an ID is affixed to an electronic record.  The system should allow for the ID to be deactivated. (§11.10d, §11.100a, §11.300a, Annex 11 12.1, MHRA Data Section)

FS-REG-14

User accounts are controlled using Active Directory, which follows the company standard security controls as per PRCD-30916, *IT Controls: Security Management* and guidelines established in ITCD-36476, *Password Policy*.

If a user is deactivated from the network, the system will not allow the user to access the application.  The CMMS audit trail will retain the electronic records containing the user’s information and will not be deleted.

UR-REG-15

The system must incorporate periodic mandatory expiration of passwords or other access keys. (§11.300b, §11.10d, Annex 11 12.1)

FS-REG-15

User accounts are controlled using Active Directory, which follows the company standard password policy as per ITCD-36476, *Password Policy*.

UR-REG-16

For systems that use non-biometric electronic signature, it must employ at least two distinct identification components such as identification code and password. (§11.10a, Annex 11 12.1, MHRA Data Section)

FS-REG-16

The system will use active directory login credentials, and thus will be compliant with Company A password policy ITCD-36476, *Password Policy*.

UR-REG-17

The system must use technical means to administer non-biometric electronic signatures to ensure that improper attempted use by anyone other than the genuine owner requires collaboration of two or more individuals. (§11.200a, Annex 11 12.1, MHRA Computerized System User Access section)

FS-REG-17

System has the ability to differentiate the electronic signature between signing off at the approval step and restricts approval access based on user groups and does not permit a user to approve a stage of the workflow if the user group is not configured to approval privilege.

User accounts are controlled using Active Directory, which follows the company user management policy as per SOP PRCD-15979, *Company A Account Management Procedure* and PRCD-30916 “IT Controls: Security Management”.

UR-REG-18

The system must allow electronic signatures to be permanently linked to their respective record and include the time and date that there were applied and demonstrate the means to retain the link between the signature and the record, e.g., in situations when the data in a system is being migrated due to upgrade or retirement. (§11.70, Annex 11 14, MHRA Data section)

FS-REG-18

The system shall directly associate all signatures to the electronic record that the signature signs.

Signatures are applied to the entities assigned to (i.e; PM Revision, Work Order Status Change).

UR-REG-19

The system must require at least two individual-specific electronic signature components for the initial signing when signings are performed within a single, continuous period.  Subsequent signings must be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual. (§11.200a, MHRA Computer System Transactions Section)

FS-REG-19

System Access requirement is fulfilled through adherence to SOP PRCD-15979, *Company A Account Management Procedure* and PRCD-30916, *IT Controls: Security Management* for granting access.

UR-REG-20

The system must employ the same controls for electronic signatures as it does for electronic records and must include them as part of any human readable form of the electronic record (such as electronic display or printout). (§11.50b, Annex 11 8.1, MHRA Data section, MHRA Raw Data section; PDA Data Integrity Code of Conduct 3.3.1.5)

FS-REG-20

Signatures bear the user ID, printed name of the signer, the date and time of the signing, and the meaning of the signature.

The electronic signatures Are displayed when applicable on validated reports (i.e; work order report).

UR-REG-21

When a computerized system is used for recording certification and batch release, the system must allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batches. This should be performed using an electronic signature.  (Annex 11 15)

UR-REG-22

The system must have logical controls to restrict access and system functionality, and use to authorize individuals based on job responsibilities or roles. (§11.10d, g, Annex 11 12.1, MHRA Computerized System User Access section)

FS-REG-22

System will support restricting access to authorize individuals based on job responsibilities through creation of different Groups. Users will request access to AD groups through BAM and system will synchronize users in AD groups automatically.

The system shall allow access groups to be defined, which control the functionality in the system that associated users are permitted to use.

UR-REG-23

The system must limit access to authorized individuals by using unique user ID/password login, or equivalent biometric identifier. (§11.10d, 11.200a, 11.300a, Annex 11 12.1, MHRA Computerized System User Access section)

FS-REG-23

System will support restricting access to authorize individuals based on job responsibilities through creation of different AD Groups.

System Access requirement is fulfilled through adherence to SOP PRCD-15979, *Company A Account Management Procedure* for granting access.

The system is integrated with the Active Directory, which also follows the company security policy which includes unique user ID / password logins.

UR-REG-24

The system must support individual user accounts/access, including unique logins for system administrators, to allow actions in the audit trail(s) to be attributed to a specific individual. (§11.10d, 2.1, MHRA Computerized System User Access section)

FS-REG-24

System will incorporate audit trails with changes not obscuring previously recorded information.

UR-REG-25

The system must allow administrator to assign appropriate privileges to each user account. (§11.10d, Annex 11 12.1)

FS-REG-25

The application shall allow access groups to be defined, which control the functionality in the application that associated users are permitted to use.

The application shall allow Administrator users to associate a user account with a single access group, thereby defining the functionality that the user can execute.

UR-REG-26

The system must not allow write access for shared, groups, guests (or similar) accounts.  (§11.10d, MHRA Computerized System User Access section)

FS-REG-26

The application shall allow access groups to be defined which grants ‘read-only’ access only to specified functional areas of the application.

UR-REG-27

The system must demonstrate access levels granted to users and historical information regarding user access level and track any changes to system-specific accounts, privileges, and roles in the system. (§11.10d , Annex 11 12.1, MHRA Computerized System User Access section)

FS-REG-27

The system access is granted by assigning different users an AD Group.

The access management will be performed using BAM, which will record details of access requests and approvals.

Any changes to user or group access levels and historical information will be maintained in the Audit Trail.

UR-REG-28

The system must have the ability to configure system administrator rights (permitting activities such as data deletion, database amendment or systems configuration changes) to limit functionality.  Administrator rights to not be combined with roles/functionality that can be assigned to individuals with a direct interest in the data (data generation, data review or approval). (MHRA Computerized System User Access section)

FS-REG-28

System administrator (Admin) role will not be assigned to individuals with direct interest in the data.

The Administrator role (Company A System Admin) is specifically for those who will make changes to system.

UR-REG-29

The system must have documented transaction safeguards/monitoring alerts in place to immediately detect any attempts at unauthorized use of IDs and/or passwords and to report such attempts to the appropriate system security personnel or organization/site management. (§11.300d, Annex 11 12.1)

FS-REG-29

System will support LDAP integration on for login and hence this requirement is fulfilled through adherence to SOP ITCD-22525, *IT Information Security Policy* and PRCD-30916, *IT Controls: Security Management*.

Account lockout/notification upon incorrect entry of username and password are handled via active directory when the user attempts to access the system server.

Upon successive invalid login attempts, the user account is locked per company policy.

UR-REG-30

If the system utilizes devices such as tokens or cards that bear or generate ID or password information, the devices must function properly and prevent alteration in an unauthorized manner. (§11.300e, Annex 11 12.1)

UR-REG-31

For systems that incorporate the use of biometric signatures, mechanisms must be employed to ensure that biometric signatures cannot be used by anyone other than the individual whose biometric profile matches that on file. (§11.200b, Annex 11 12.1, MHRA Computerized System User Access section)

UR-REG-32

If the system is a data acquisition system, it must have secure access to prevent unauthorized changes to electronic data.  (MHRA Computerized System User Access section; PDA Code of Conduct 3.4.1)

UR-REG-33

The system must incorporate and maintain audit trails which record all relevant changes and deletions, with changes not obscuring previously recorded information, including changes executed by the system administrator.  The reason for the change or deletion must be documented.  The system must be able to generate printouts of the audit trail. (§11.10e, Annex 11 8.2, 9, MHRA Audit Trail section; EMA Q8, Q15, MHRA Raw Data Section)

FS-REG-33

System shall be able to incorporate and maintain the audit trail record related to changes and deletions made in the system with changes not obscuring previously recorded information, including changes executed by the system administrator.

System must have the electronic proof stating the reason for the deletion and system must be able to print the audit trail document.

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. (§11.10e, Annex 11 8.2, 9, 12.4, MHRA Audit Trail section; PDA Data Integrity Code of Conduct 3.3.1.3)

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. The report generated from the system is non-editable.

UR-REG-35

The system must not allow users to amend or switch off the audit trail. (§11.10e, Annex 11 9, MHRA Audit Trail Section)

FS-REG-35

System provides an audit trail on events within the system.

System will generate and store audit trails based on the time zone generated by the CMMS application server.

The Audit Trail is configured by the System Admin.  Any deactivation to Audit Trail fields are managed under IT Change Control.

UR-REG-36

The system must record the creation, change, and cancellation of access authorizations. (§11.300d, Annex 11 12.3, MHRA Data Section).

FS-REG-36

System provides an audit trail on events within the system.

System will generate and store audit trails based on the time zone generated by the CMMS application server.

The Audit Trail is configured by the System Admin.  Any deactivation to Audit Trail fields are managed under IT Change Control.

End of Regulatory requirements.