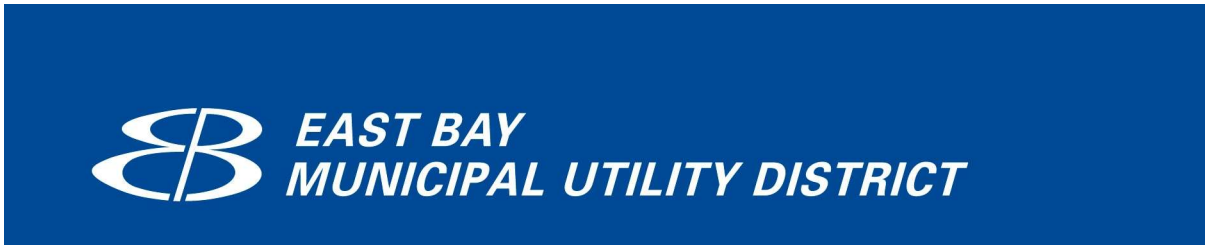


Laboratory Document Processing & Management Software System

Request for Proposal
Functional Requirements

Appendix - 1

Functional Requirements

1.0 Overview

Feature descriptions are organized by major functional module. Each module is comprised of one or more features. Each feature is defined by one or more requirement.

2.0 Definition of Acronyms

CAPA = Corrective and Preventive Action
C of A = Certificate of Analysis
CHO = Chemical Hygiene Officer
DPMSS = Document Processing and Management Software System
EPA = Environmental Protection Agency
KPI = Key Performance Indicator
LIMS = Laboratory Information Management System
NCCAR = Non-Conformance Corrective Action Report
QA = Quality Assurance
QAO = Quality Assurance Officer
PT = Proficiency Testing
RIFO = Refrigerator, Incubator, Freezer, Oven Temperature Documentation
SM = Standard Methods
SOP = Standard Operating Procedure
TNI = The NELAC Institute (The NELAC Institute (TNI) (nelac-institute.org))

3.0 General System Requirements

3.1.1	Established software as a document management system that can used for next 20 years
3.1.1.1	Compliant with ISO 17025 and NELAC (TNI 2016) standards
3.1.1.2	Implemented in > 5 comparable-sized environmental laboratories
3.1.1.3	Have undergone a 3rd party TNI audit or ISO audit
3.1.1.4	Compliant with Office 365
3.1.1.5	Browser based and compatible with Google Chrome and Microsoft Edge
3.1.1.6	Data backed up once a day with data recovery back on in 24 hours
3.1.1.7	Doesn't utilize subcontractors for maintenance of Document Processing & Management Software Systems (DPMSS)

3.1.1.8	Implementation of software will include training. This training will cover usage, maintenance, and implementation of the software
3.1.1.9	Implementation shall include training in upload, organizing and control of documents, and modifying/creating new workflows
3.1.1.10	Implementation and training completed 4 months after contract is awarded
3.1.1.11	Ability to support the lab during normal business hours M-F 8 AM- 5 PM PST. Ability to support the lab for emergency (i.e., system outage, documents not accessible) M-Sun 6 AM - 6 PM
3.1.1.12	Ability to have robust traceability, searchability, indexing, workflow, alerting
3.1.1.13	Ability to edit locally in word, excel, PDF, or any other format, and documents can be uploaded and stored in a structured and organized folder within the software
3.1.1.14	Ability to maintain and easily retrieve electronic back-ups
3.1.1.15	Ability to maintain electronic records securely and in confidence
3.1.1.16	Ability to retain both published and archived/obsolete documents
3.1.1.17	Ability to automatically label draft and archived documents, preferred watermarked in the document
3.1.1.18	Ability to retain obsolete documents for 12 years. These documents must be retained and accessible
3.1.1.19	Ability to have published document available while the new version is being edited/approved
3.1.1.20	Ability to restrict obsolete/archived documents based on user roles and privileges
3.1.1.21	Ability to replace the new version of the document without links changing
3.1.1.22	Ability to create hyperlinks to documents that can be used in other applications such as LIMS (Cloud System)
3.1.1.23	Ability to clearly distinguish a draft from a published document
3.1.1.24	Ability to clearly distinguish an obsolete from a published document
3.1.1.25	Ability to accept a bulk transfer of documents
3.1.1.26	Ability to accept bulk transfer on a nightly, weekly, monthly basis (for example, client reports generated in XLIMS can be sent to DPMSS) (Potential future enhancement)
3.1.1.27	Ability to automate the document management process (see workflows in appendix 3), including uploading documents to the appropriate folder by the type or other indexing keys, the date and time stamp, approval process and specific user(s), and other user defined actions
3.1.1.28	Ability to drag and drop files into folders and auto-assign indexing associated with the folder to the new file based on the folder type

3.1.1.29	Ability to securely “check-in” and “check-out” document
3.1.1.30	Contain an established document repository for “check-in” and “check-out”
3.1.1.31	Ability to export the selected or all documents in bulk
3.1.1.32	Ability to export documents in bulk in the format that can be uploaded to the District’s DOCs System (Potential future enhancement)
3.1.2	The system will consider interoperability with the following EBMUD systems/applications:
3.1.2.1	DOCs, in-house Document management system
3.1.2.2	XLIMS, Cloud Laboratory Information System

4.0 Dashboard

4.1.1	Ability to have a user configurable dashboard to show outstanding tasks across different projects
4.1.2	Ability to show un-completed tasks associated with workflows
4.1.3	Ability to display phases of a workflow
4.1.4	Ability to display alerts
4.1.5	Ability to favorite certain documents in the system for an individual user profile or for all users. These favorited documents would have an easy short-cut to access

5.0 Searchability

5.1.1	Ability to query document with legacy tracking number
5.1.2	Ability to search DMS off any word in the document in various document file types (i.e., pdf, word, PowerPoint etc.)
5.1.3	Ability to link related documents and documents with dependencies
5.1.4	Ability to index documents to support system search engine
5.1.5	Ability to OCR (optical character recognition/handwriting) uploaded documents for searchability
5.1.6	Ability to sort and filter search results
5.1.7	Ability to organize search results by document type and document identifier number
5.1.8	Ability to store documents in a hierarchal structure that may be established by the user

6.0 Traceability

6.1.1	Sophisticated version control features:

6.1.1.1	File Check-in and check-out file ability
6.1.1.2	Automatic version enumeration
6.1.2	Ability to track the location of a document, revision, last update, document number, date of approval and approver
6.1.3	Ability to track revision history for a document
6.1.4	Ability to display the all the document attributes, including document revision history, edits made, by who and when, in one location for 3rd party auditing
6.1.5	Ability to track each reviewer comment/edit with reviewer unique ID, by means of Microsoft Word "track Changes", Microsoft Word "comments" or some other comparable means which identifies individual making the changes
6.1.6	Ability to track who made changes to documents at the edit/review phase
6.1.7	Ability to link bench sheets to Corrective Action Requests
6.1.8	Ability to track when staff has read and understood new SOP, documentation
6.1.9	Ability to link related documents
6.1.10	Ability to track the review and approval of all documents (see table 2)
6.1.11	Ability to track periodic review (see table 2)
6.1.12	Ability to track acknowledgment/completion of non-analytical training and training tests by individual user
6.1.13	Ability to add electronic signatures or electronic ID (requires user to sign in with unique ID and encrypted password)
6.1.14	Ability to have staff take tests and track whether staff passes the test
6.1.15	Ability to correlate/assign the section of the TNI standard to documents

7.0 Indexing

7.1.1	Ability to auto-assign unique ID to new documents
7.1.2	Ability to link paper (legacy) tracking number to new unique ID
7.1.3	Ability to maintain a master list or equivalent document control procedure identifying the current revision and distribution of documents
7.1.4	Ability to assign unique identifier. Identifier must be linked to date of issue/revision, page numbering, total number of pages or a mark to signify the end of the document and the issuer
7.1.5	Ability to categorize document according to document types and source types (i.e., document types = SOP, Method, Manual. Source types = Quality Assurance, Organic, inorganic, Microbiology)

7.1.6	Ability to add documents to a folder and attributes/indexing fields associated with that folder are auto-assigned to document
7.1.7	Ability to add meta data from the DPMS onto the document (i.e., unique system document ID placed in the document)
7.1.8	Ability to add these elements (as appropriate) to a document:
7.1.8.1	Title
7.1.8.2	Document Number (if any)
7.1.8.3	Revision/Edition Number
7.1.8.4	Date of Publication

8.0 Templates

8.1.1	Ability to use templates for documents
8.1.2	Ability to have document templates and configure:
8.1.2.1	Required fields
8.1.2.2	Where the field is on the template
8.1.2.3	Ability to insert digital signature or other electronic tracking and approval mechanism on Forms and Templates
8.1.2.4	Ability to easily insert blocks of language (standard boiler plate language)
8.1.2.5	Ability to link documents
8.1.2.6	Spell check and grammar check
8.1.2.7	Ability to have EBMUD header
8.1.2.8	Automatically enumerate sequentially
8.1.3	Ability to assign a workflow to documents created from templates
8.1.4	Ability to add these elements to a document:
8.1.4.1	Document number
8.1.4.2	Effective date
8.1.4.3	Revision number
8.1.4.4	Page numbering indicating total number of pages
8.1.4.5	Authorizing signatures/unique login ID
8.1.4.6	Revision History

9.0 Roles/Privileges

9.1.1	Ability to assign user roles that have different privileges in the DPMSS including but not limited to access, editing, approval
9.1.2	Ability to restrict access to invalid and obsolete documents based on roles. These documents are retained for historical purposes/legal preservation but not accessible to all staff
9.1.3	Ability for new documents to be initiated by role-based users (ex. Lab Manager, QAO or Section Supervisors)
9.1.4	Ability to restrict user to only see the published version of a document unless user has permission to see draft, archived and published versions
9.1.5	Ability to allow authorized editions to be available to all lab staff
9.1.6	Ability to restrict confidential documents by role-based security
9.1.7	Ability to default documents to 'read only' unless the user has privilege to edit
9.1.8	Ability to assign/re-assign role/privileges if user is unavailable. (User can control role/privileges. Administrator is on EBMUD side, not the vendor)
9.1.9	Ability to store staff credential documents with user profile

10.0 Workflow (Refer to Workflows included in Appendix 3)

10.1.1	Built upon a robust workflow engine with configurable business rules
10.1.2	Has a user-configurable, interactive, visual workflow designer
10.1.3	Ability to use a hierarchical approval process based on user's role and security
10.1.4	Ability to change workflows based on updated compliance requirements
10.1.5	Ability to track workflow steps, person who executed and date stamp
10.1.6	Ability to have workflow to review, approve, execute, track and close documents
10.1.7	Ability to have multiple reviewers give comments/edit a document simultaneously or sequentially
10.1.8	Ability to assign roles to users so that workflow is designed for roles not users (able to swap people in and out of roles)
10.1.9	Ability to assign tasks to someone else if primary person is out of the office (use of roles not assignment to specific person)
10.1.10	Ability to create workflows that allow multiple phases and tasks can be moved back and forth in the workflow
10.1.11	Ability to copy, edit and create new workflows with minimal assistance from the vendor

10.1.12	Ability to configure serial, parallel, and branched workflow (e.g., anyone can approve, all can approve; review by multiple users)
10.1.13	Workflow status prominently displayed in all documents
10.1.14	Automated notifications to user that an item has been newly assigned responsibility (Ball-In-Court) to that user
10.1.15	Automatically route documents without human interaction based on workflow rules
10.1.16	Ability to set a review schedule depending on the type of document
10.1.17	Ability to skip steps in a workflow (i.e., SOP is reviewed, and a new edition doesn't need to be published. Need to skip publishing step but still track that review occurred)
10.1.18	Ability to set an interval for document review and document that review has occurred
10.1.19	Ability to display current workflow phase
10.1.20	Ability to query documents by workflow phases
10.1.21	Ability to generate a report that can display the workflows of outstanding items
10.1.22	Ability to identify documents with retention deadlines
10.1.23	Ability to notify when retention deadline is approaching and prompt user to approve removal
10.1.24	Ability to document the root cause investigation and subsequent corrective action
10.1.25	Ability to create, assign, track, review, approval, and completion in the life cycle of Corrective Actions/Preventative Actions
10.1.26	Ability to require a reason when a document approval is rejected
10.1.27	Ability to auto-publish a document after review and auto-move current document into archive
10.1.28	Ability to auto-publish a document with a user defined publish date

11.0 Alerting

11.1.1	Automated reminder notifications to user that an item's due date is nearing
11.1.2	Automated reminder notifications to user that an item's due date is past due
11.1.3	Ability to set expiration date on a document and receive notification when expiration is approaching
11.1.4	Ability to have notifications sent when a document needs to be reviewed when the document has been added, when the review due date is approaching and when past due
11.1.5	Ability to send out email alerts during workflow phases of:

11.1.5.1	Document edit/approval
11.1.5.2	Training
11.1.6	Ability to configure alerting frequency (i.e., high frequency when due dates are approaching)
11.1.7	Ability to notify users when a step is waiting for their action
11.1.8	Ability to send alerts to specified people/user roles based on review schedule
11.1.8.1	60 days (for example) before Review date, Section Supervisor is notified
11.1.9	Ability to specify the lead time for alerts
11.1.10	Ability for alerts to be sent to user role and not individual (if user is out, their back-up with the same role would receive the alerts)
11.1.11	Ability to notify all staff when a new document is available and advise staff to dispose of any hardcopies or saved electronic version of the document
11.1.12	Ability to send out notifications for training

12.0 Auditing/Exportability/Reporting

12.1.1	Ability to export revision history for a document
12.1.2	Ability to share a folder with an external auditor for ease in document sharing
12.1.3	Ability to generate reports that are related to document control, CAPA (Corrective and Preventive Action), training, etc.
12.1.4	Ability to reference specific clauses of TNI standard to documents, CAPA items and training items
12.1.5	Ability to assign TNI standard references to a document
12.1.6	Ability to have internal auditing trail functions and audit logs for record changes and traceability
12.1.7	Ability to provide tools for internal auditing: template and workflow
12.1.8	Ability to generate data for KPI reports to show workflow performance (for example time for review, approval by user)
12.1.9	Ability to export reports showing:
12.1.9.1	Workflow and phase status
12.1.9.2	Reviewer and Approvers, date, and time stamp
12.1.9.3	Changes to the document
12.1.10	Ability to schedule when certain reports are generated (daily, weekly, monthly, etc.)
12.1.11	Ability for user to download document and associated files

Appendix - 2

Table 1: List of Quality Management System Records

Type of Record
Management Review Record
Training Records
Purchased Consumables
Sublab Register
Data Packet
Chain of Custody
Lab Report
Data Revision Change
Logbooks
Certifications, Permits
PT Study Result
Internal Audit
External Audit
Corrective Action
Maintenance Record
Calibration Record
NCCAR Record
Customer Satisfaction Complaint Record
Lab Staff Signature Register
Equipment Operating Manuals
Certifications, Permits
Warranties and Service Agreements

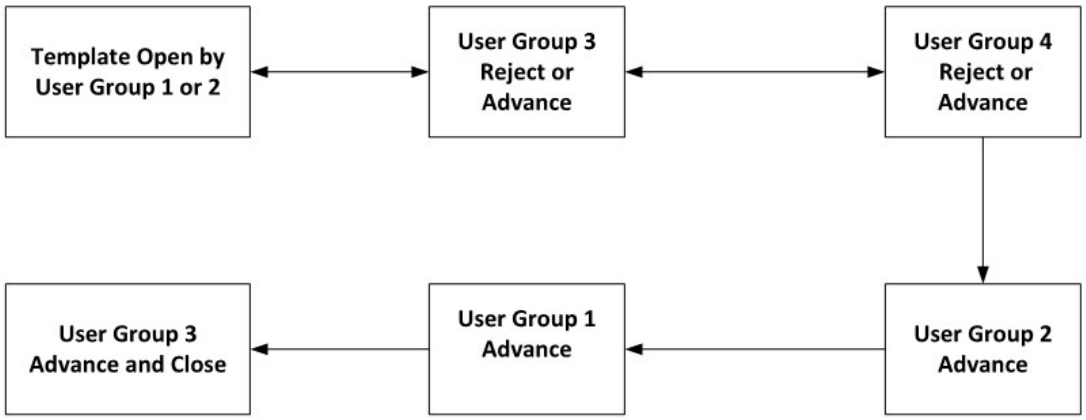
Table 2: List of Controlled Documents with Authorizing Approvers

Document	Source of Document	Authorization Approvers	Review
Policies	Internal	Lab Manager	3 Years
Quality Manual	Internal	Lab Manager, QAO, Supervisor	Yearly
Chemical Hygiene Plan	Internal	Lab Manager, CHO, QAO	Yearly
SOPs	Internal	Lab Manager, QAO, Supervisor	Yearly
Worksheets	Internal	Supervisor	Yearly
Operator Aids	Internal	Supervisor	Yearly
Data Review Checklists	Internal	Supervisor	Yearly
Forms &Templates	Internal	Supervisor, QAO	Yearly
Audit Templates	Internal	QAO	Yearly
Instrument Manual	External	Supervisor	Yearly
Instrument Software	External	Supervisor	Yearly
Reference Methods	External	QAO	Yearly
Fed Regulation 40 CFR 136	External	QAO	Yearly
Fed Regulation 40 CFR 141	External	QAO	Yearly
Referenced Standards	External	QAO	Yearly
Cal Regulations	External	QAO	Yearly
Sub Lab Certificate	External	QAO	Yearly

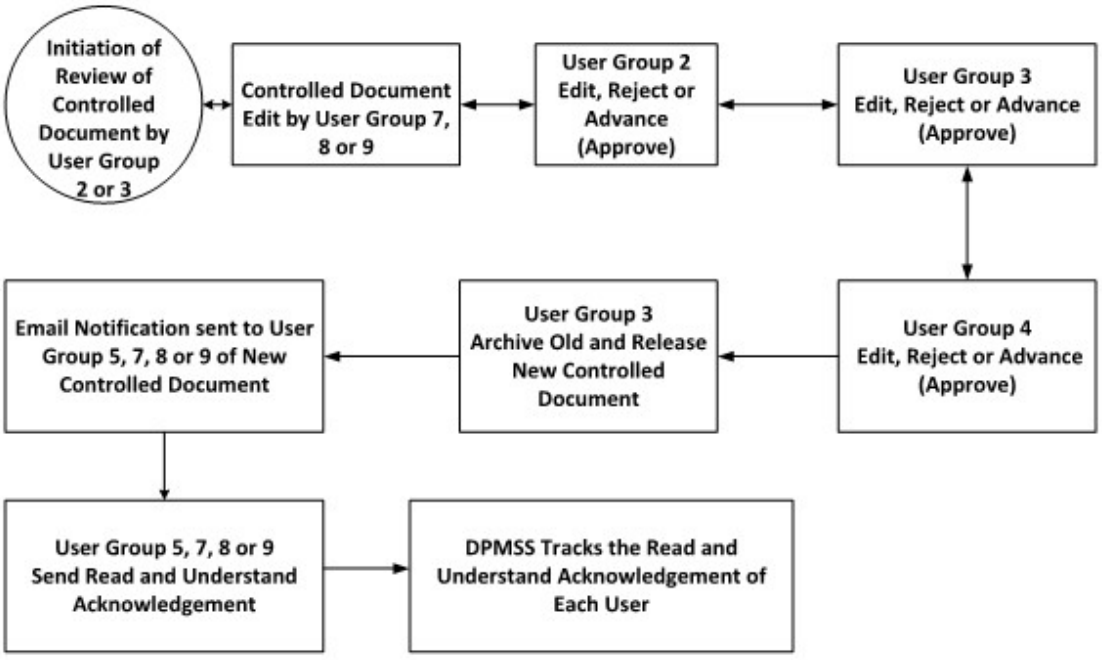
Appendix – 3

User groups = distinct groups of one user or many users that are clustered together based on similar roles and responsibilities in the DPMSS
Double arrow = workflow is advanced to next step or rejected and sent back to prior step
Single arrow = workflow is advanced to next step

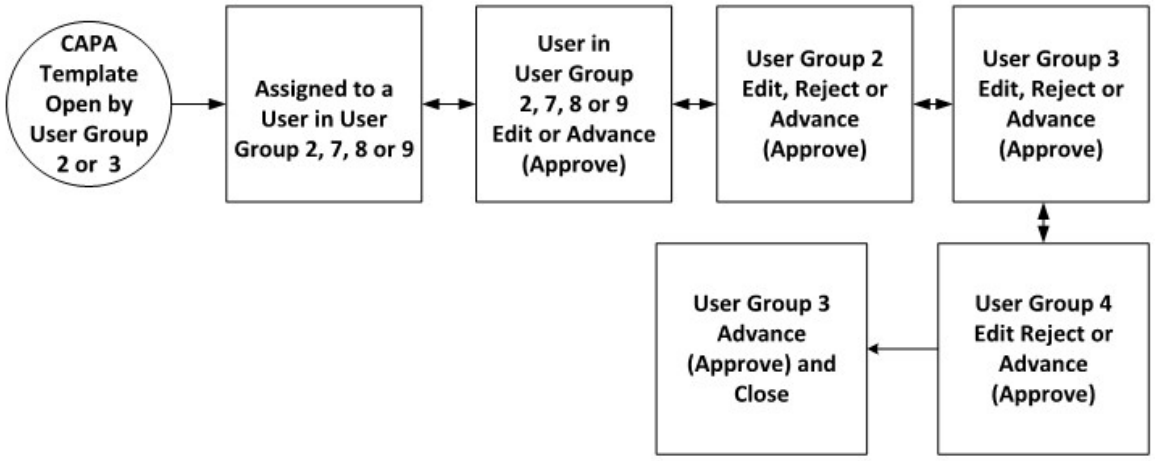
Workflow #1



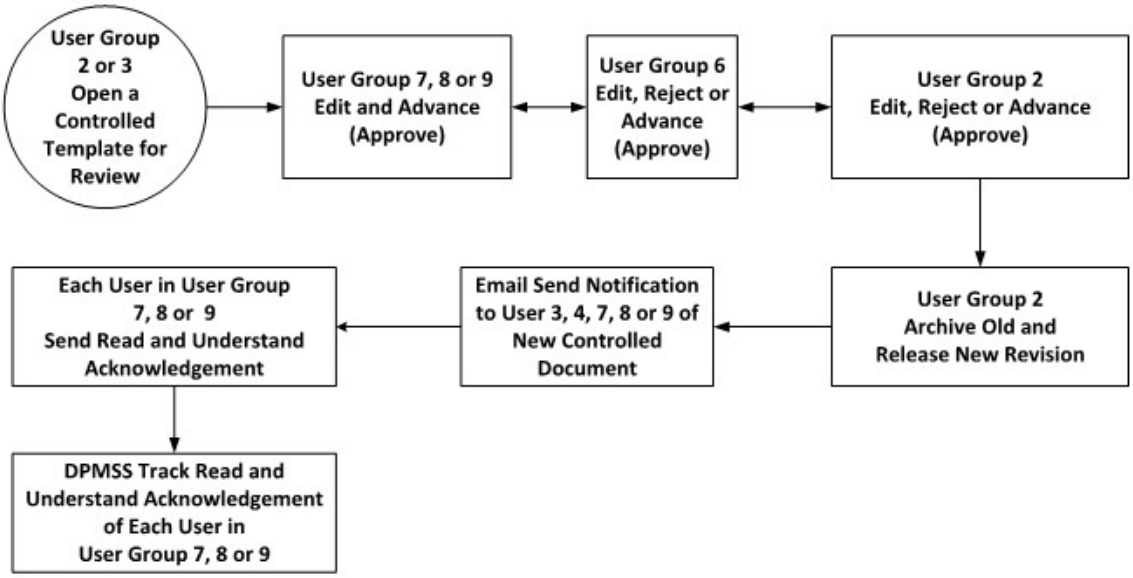
Workflow #2



Workflow #3



Workflow #4



Workflow #5