Document Control

DWR-1-SOP-001

Version 1.0

California Department of Water Resources
Division of Environmental Services
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Contents

1. PURPOSE

1.1. The purpose of document control is to ensure that all documents are:
- 1.1.1. reviewed and approved prior to their issue and distribution,
- 1.1.2. identified on an appropriate master list and distribution list,
- 1.1.3. made available to staff,
- 1.1.4. reviewed periodically, and
- 1.1.5. handled in such a way as to preclude the use of invalid and/or obsolete documents.

2. SCOPE

2.1. This procedure applies to all documents that comprise the quality management system (documents ensuring the quality of work processes) within the programs listed in Table 1. Refer to section 4.9 for a full definition of quality management system.

2.2. All documents at the Bryte Chemical Laboratory are within scope.

2.3. Other programs have latitude to determine which documents are in scope of this process and minimally should include any procedural document for water quality activities (QAPPs, SOPs, test methods, work instructions, and forms).

3. RESPONSBILITIES

3.1. Document Approvers - Responsible for reviewing and approving documents assigned to them for completeness, consistency, accuracy of the document, document type selected, and the attributes of the document. Document approvers will minimally include the QA Officer and the manager or designee for the group(s) in scope. For technical documents, a subject matter expert must also be included as an approver.

3.2. Document Users - Responsible for adhering to this procedure to maintain the integrity of the document control system.

3.3. Document Owner – Person responsible for creation, revision, and approval of the document(s). The document owner facilitates the document control system and is responsible for ensuring adherence to periodic review schedules for their document(s) when applicable. There can only be one assigned document owner. The document control SharePoint will list the document owner for each document.

3.4. Quality Assurance Officer (QAO) - Manages and maintains the document control system outlined in this SOP. QAO responsibility is DWR department-wide.

4. DOCUMENT CONTROL SYSTEM

4.1. This SOP describes the procedures for creation, migration, revision, review, and approval of documents within the document control system. The procedure also covers how documents are controlled, and the process for management of uncontrolled copies of documents.

4.2. Documents within the document control system are stored in a single-source SharePoint administered by the Quality Assurance program.

5. ACCESS TO DOCUMENTS

5.1. Approved modes for use

5.1.1. Whether using a document electronically or from hard copy, all staff are required to use the officially approved and effective document. There are three approved modes for document use:

5.1.1.1. Controlled document binders – Each work group will have a binder (or binders) with controlled copies (see 4.1) of all documents based on the needs of the group. These binders will be assigned and tracked by location in the Document Master List (DWR-1-LST-001) and on the document control SharePoint. QA manages and updates the binders and the document control SharePoint.

5.1.1.2. Electronically – Staff may use the electronic version of a document by selecting the effective document from the document list in the document control SharePoint at the time of use. This location retains all official versions of documents and is the sole source for electronic retrieval of documents within the document control system. Electronic versions must be refreshed daily from the SharePoint and must not be saved for future use on individual or group drives.

5.1.1.3. Uncontrolled printed copies – In some instances, uncontrolled versions of documents are allowed. To use an uncontrolled copy, the document must be accessed and printed from the document control SharePoint. This applies to procedure document types only (QAP, SOP, TMD, WKI - see Table 2). The allowed uses of uncontrolled documents are described in the following section.

5.2. Uncontrolled Documents

5.2.1. There are four instances for which use of uncontrolled copies are allowed.

5.2.1.1 Training – "For Training Only" should be written on the document with initial/date.

5.2.1.2 Revision– For use to draft red-lines or revision/amendment to documents. "For Revision only" should be written on the document with initial/date. An editable (Word) version of a document can be requested from the QAO or QA program staff.

5.2.1.3 External communication – For use of the document outside of the department.

5.2.1.4 Performance of tasks when a hard copy is needed - This only applies to procedure document types (QAP, SOP, TMD, WKI - see Table 2). These printed uncontrolled procedures are valid for use with the limitations described below.

5.2.1.4.1 Procedures pertaining to field activities are valid for 30 calendar days from date of printing.

5.2.1.4.2 Procedures not pertaining to field activities are valid on the date of printing only.

5.2.2. The document user will be responsible for adhering to these guidelines, and for destroying uncontrolled copies after use.

5.2.3. For uncontrolled documents used for "performance of tasks when a hard copy is needed", documents must be destroyed prior to expiration. It is the document user's responsibility to ensure no expired uncontrolled documents are retained. QA is responsible for verifying

that no expired documents are present when conducting internal audits. Violations of this requirement will be documented, tracked, and investigated to determine root causes and actions needed to prevent recurrence.

5.2.4. The Quality Assurance Officer and Quality Assurance Program will not be responsible for documents sent outside of the department, or for keeping these documents current.

5.3. Controlling Forms and Templates

5.3.1. Forms, which also can be used to generate bound logbooks, can be printed from the document control SharePoint as needed. These documents are controlled by version number and effective date.

5.3.2. Once data are transcribed to a printed form, the document becomes a record, and is subject to any applicable record retention schedules and processes. Forms, once they become records, are not controlled through this document control process.

5.3.3. Templates can be used in creation of new documents. The current effective version of a template can be downloaded as needed from the document control SharePoint to start the process of creating a new document. Unless expressly required through program procedures, templates are not required to be used in the creation of documents and serve only to improve convenience and consistency.

5.3.4. Forms and templates are tracked in the Document Master List (DES-1-LST-001) and in the document control SharePoint. Location information will not be required.

6. DOCUMENT LIFECYCLE

6.1. Document Status

6.1.1. The document lifecycle covers all stages from document creation to retirement.

6.1.2. The lifecycle stage of any specific document is listed as the document “status” in the header of that document. The different document lifecycle stages (status) are described below.

6.1.2.1. In-process: Document is in a draft form as a result of creating a new document or revision of an existing document and is not ready for review. In-process documents will have a “IN-PROCESS” watermark. See section 7.1.5 for instructions on creating the watermark.

6.1.2.2. In Review: Document is in a final draft form ready for review by all identified approvers. These documents will have a “IN REVIEW” watermark. Use instruction in section 7.1.5 for creating a watermark.

6.1.2.3. Approved: Document is approved by all approvers and is ready for use for any training required prior to becoming effective. If no training is required, this stage can be skipped, and the document made immediately effective. A document with status of “approved” provides assurance for trainers and trainees that the document has been appropriately reviewed and approved by subject matter experts and representatives of all programs within scope.

6.1.2.4. Effective: Approved document ready to be used as a finalized document within the document control SharePoint. Effective dates are assigned at this time.

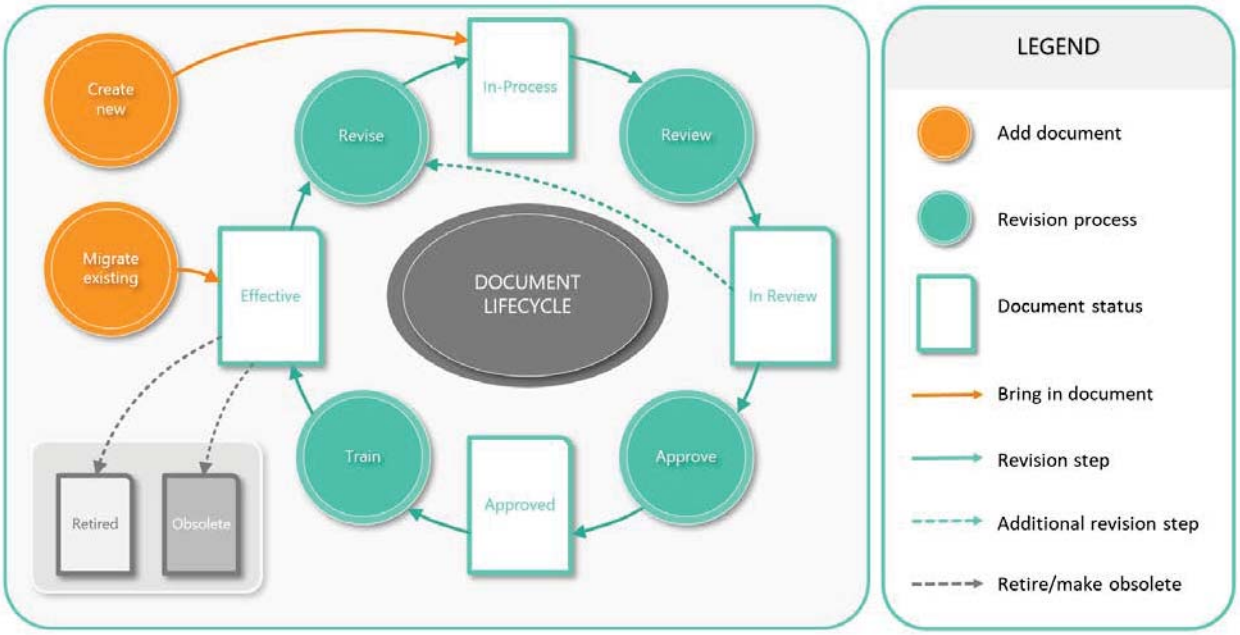
6.1.2.5. Retired: An older revision of a document that was replaced during the process of editing/revision. Retired documents cannot be used to perform tasks and are retained for information only.

6.1.2.6. Obsolete: A document describing a process that is no longer performed.

6.1.2.7. Published: (not in Figure 1) The published status is reserved for reference documents only. These documents are retained by the document control system for ease of use and storage in one centralized location for items such as user manuals, certificates of analysis, or other externally created references.

NOTE: "In-process" and "In Review" documents will have revision numbers ending in .1, .2, etc. while approved and effective documents will always end in .0. A document "In Review" can return to "In-process" if edits are required based on feedback from approvers during the review process. The use of "In-process" and "In Review" draft documents can be utilized in whatever manner best fits the uses of each program. "In-process" and "In Review" documents can be retained in the document control system as needed; however, retention of these documents is not required.

Figure 1: Document Lifecycle Flowchart



7. PROCEDURE

7.1. Creating a document

7.1.1. When creating a new document, a template may be used. Templates, if available, can be downloaded directly from the document control SharePoint.

7.1.2. It is the responsibility of the author to identify the approvers, including subject matter experts for technical documents. At minimum, approvers must include the QAO and a representative or designee of each group within scope of the document. All approvers will need to be included on an Approvers Page directly after the title page.

7.1.3. Document headers and footers should be used as appear in this document and will include title, document control number (DCN), status, effective date, and revision number.

7.1.4. Newly created documents will be assigned a status of in-process and an initial revision number of 0.1.

7.1.5. A watermark of "IN-PROCESS" will be applied to all in-process documents. In MS Word, the watermark function can be found in the Design tab > Watermark > Custom Watermark, within the Text field, type IN-PROCESS.

7.2. Document Naming Conventions

7.2.1. The Document Control Number (DCN) is a unique number generated by the document owner and/or QAO upon creation of a new document or migration of an existing document. Each DCN will be unique, and these numbers cannot be shared between documents. The DCN will be generated using the following naming convention:

DCN prefix – Document Type abbreviation – Sequential/Unique Number

7.2.1.1. DCN prefix – The DCN prefix is a unique designation for each applicable program within a division consisting of a 3-character Division abbreviation followed by a program number. See Table 1 for applicable DCN prefix designations.

7.2.1.2. Document Type abbreviation – Document types are designated by a unique 3-character abbreviation. These document types are designed to be expanded as needed to incorporate program needs. See Table 2 for the approved list of abbreviations for document types.

7.2.1.3. Sequential/Unique Number – Each document coming into the document control system will be given the next sequential number (starting with 001) based on each unique "DCN prefix-Document Type abbreviation" designation, or a unique number as determined by that program.

Table 1: DCN Prefixes listed by Project, Division, Office, Program

Project	Division	Office	Program	DCN prefix
DWR wide			QA Program	DWR-1
State Water Project	Division of Operations & Maintenance	Assistant Division Chief 1	Water Quality & Special Projects Support	DOM-1
	Division of Environmental Services	Office of Water Quality and Estuarine Ecology	Bryte Chemical Laboratory	DES-1
			Environmental Monitoring Program	DES-2
			Environmental Monitoring Program - Field	DES-3
			Municipal Water Quality Program – Field Support	DES-4
			Aquatic Ecology	DES-5
			Special Studies	DES-6
		Office of Regulatory Compliance	Suisun Marsh Branch	DES-7
Integrated Watershed Management	Division of Regional Assistance	Northern Region Office	Water Quality Section	DRA-1
		North Central Region Office	Water Quality Evaluations Section	DRA-2
			Surface Water Data Section	DRA-3
		South Central Region Office	Special Studies and Technical Support Section	DRA-4

Table 2: Document Type Abbreviations with Descriptions

Category	**Type**	**Description**	**Document Type Abbr**
Governance	Glossary	An alphabetical list of terms with explanations about a specific subject.	GLO
	Master List	A master list for documents or other items such as equipment and vendors.	LST
	Manual	A document describing the Quality Management System (QMS) and policies governing the organization. This document type is not for equipment manuals, which would be reference documents.	MNL
Procedure	Quality Assurance Project Plan	Documents the planning, implementation, and assessment procedures of, and how specific QA and QC activities will be applied during a project	QAP

	Standard Operating Procedure	A document that describes how a process is to be performed with detailed steps.	SOP
	Test Method	Instructions describing the methodology and equipment used to achieve accurate and precise test results for specific attributes.	TMD
	Work Instruction	Documents that support SOP by providing more guidance and details about a specific task. This can be accomplished using flow charts, diagrams, or other references	WKI
Quality	Investigation Document	Protocols and reports to support corrective and preventative actions, root cause analysis, and other investigational issues. This also includes responses to internal audits and agency audits.	INV
	Technical Document	Protocols and reports to support technical or analytical decisions. A quality assurance study plan is an example of a technical document.	TEC
	Training Document	A training document includes presentations, curriculum, learning plans, and training modules. This can include documents used to train on specific analytical test methods, techniques, instrumentation or software.	TNG
	Validation	LAB ONLY: Documents supporting specific processes, process changes or studies for analytical test methods. This includes method detection limit studies, initial demonstration of capability studies, protocols and reports for alternative test methods.	VAL
Template	Form	Forms are documents with blank areas to record the performance of specific tasks.	FRM
	Document Template	A document containing a specified format and structure that users must follow to create the document type described in the template.	TEM
External	Reference	For reference and scanned or otherwise included “as is”. Reference documents are not required to be approved and cannot be used to meet quality system requirements. Reference documents include user manuals, standard certificates of analysis, and communications to external agencies.	REF

7.3. Migrating an Existing Document

7.3.1. Migrated documents are assigned a DCN, a version number of 1.0, and the revision history will state that it was a migrated document.

7.3.2. Migrated documents are moved "as is" into the document control system from their former document management system (if any), with the exception that migrated documents will include the headers and footers as appear in this document and a revision history at the end of the document.

7.3.3. The content and appearance, besides the exceptions above, are not changed.

7.4. Revising a Document

7.4.1. Once documents are in the document control system (by creation or migration), they can be continuously improved through the revision process. This cyclical process has 4 main components: revise, review, approve, and train. Refer to Figure 1 for a visual representation of this process.

7.4.2. Additions or revision to documents must utilize this revision process and go through the appropriate approval steps. Hand-written instruction or amendments on QA-controlled copies are not allowed.

7.4.3. The revision process is performed by the document owner. Document revision can be initiated by any staff within scope of the document. However, requests for changes/revisions to documents shall be made to the document owner, who will evaluate the proposed changes and decide upon their appropriateness. Notifying the document owner, group representatives within scope, and the QAO or a member of QA Program staff early in the process may be beneficial. Coordination of meetings to discuss all changes for the revision may be useful.

7.4.4. Identify the appropriate approvers for any revision. At minimum, approvers must include the QAO and the manager(s) or designated approver(s) of the group(s) within scope of the document.

7.4.5. Compile all changes for the active revision into the same working in-process document. Changes to the text in revised documents can utilize the track changes function in Microsoft Word. Editable Word versions of existing documents can be requested from QA Program staff. Uncontrolled copies may be used (see section 5.2.1.2), and manual red-lines retained on these copies. Note that these uncontrolled copies, which will be flagged with "for revision only", are not to be used to perform normal work processes.

7.4.6. Update the Revision History table at the end of the document to include the description and justification for change separately for each section that is being revised.

7.4.7. Document revisions can be performed at the pace best suited to the individuals or team performing the revision. There is no default expiration or deadline for in-process documents, and these can proceed to the review step when ready.

7.4.8. In-process documents are not required to be retained in the document control system. The in-process status is used solely as an aid to the revision, review and approval processes.

7.4.9. Once all revisions are in final draft form, change the status of the document to "In Review".

7.5. Reviewing a Document

7.5.1. Facilitation of the review process is the responsibility of the document owner.

7.5.2. Approvers are responsible for review of all document changes.

7.5.3. Documents with "In Review" status are not required to be retained in the document control system and are managed by the document owner.

7.5.4. Approvers: Review the document content to ensure accuracy and that revised processes are applicable and relevant to your program.

7.5.5. Track changes can be used to document comments and suggested edits. Teams can also utilize shared documents if desired. Open dialogue between the document owner, QA, and all approvers is encouraged.

7.5.6. Review can be an iterative process, with document going from in review back to in-process several times if needed. Refer to Figure 1 for a visual representation of this process. When a document goes back to in-process, the document revision should be incremented up by 0.1 by the document owner.

7.5.6.1. For example, if document in review at revision 2.1 required additional edits, the feedback and changes would be incorporated by the document owner into revision 2.2 and then sent back out for review. This working revision numbering is not required and is included as a suggestion to more efficiently organize and retain all edits and comments.

7.5.7. The review process is intentionally unstructured and can proceed in a manner best suited to the individuals involved.

7.5.8. Once all approvers are satisfied with the current revision, the document can proceed to the approval process.

7.6. Approving a Document

7.6.1. The document owner is responsible for facilitation of the approval process.

7.6.2. Approvers are responsible for ensuring that the content of the revision is accurate and applicable to their program which includes the revision history table that explains the changes and their justification.

7.6.3. The distinction between an approved document and an effective document is to allow enough time for any required training to take place prior to the revised document being used. This step is necessary to retain control over changes to documents.

7.6.4. If training is not needed, the document can skip approved status and go directly to effective. Refer to section 7.7.3.

7.6.5. Once a document is ready for approval, the document owner shall change the status to "Approved". The revision number will also be changed to the next sequential number ending with ".0".

7.6.6. All approvers must sign the Approved version of the document, whether on hard copy or electronically through DocuSign.

7.6.7. Once all signatures are obtained, the final Approved document shall be uploaded into the document control system by the QAO or QA Program staff. Once in the document control system with an approved status, the document can be used as the official document for any training that is needed before becoming effective. Uncontrolled versions of these "for training" documents can be printed using the process outlined in section 5.2.1.1.

7.6.7.1. For example - A document currently in revision 4.0 requires updating. The in-process revision number would initially be 4.1 to undergo the revision process (refer to section 7.4-7.6). After going through review and once the document is ready for final approval, the document will be assigned a status of Approved and a revision of 5.0. Approval signatures would be obtained from all approvers at this time. Once all approval signatures are obtained, the QAO or QA Program staff will upload this final approved document to the SharePoint so that programs can use the document to perform training. If no training is required, the document status would be elevated to effective and moved to the SharePoint (see section 7.7.4).

7.7. Training on an Approved Document

7.7.1. The document owner is responsible for determining if an approved revision requires training prior to the document becoming effective. The training requirements may range from none to highly structured depending on the needs of the program and the nature of the document. Training requirements can include read and understand only, instructor led training, qualification exercises, or other requirements. Note that newly created documents may also require training. The QAO and QA Program staff can assist with determining the most applicable training pathway.

7.7.2. Document owner: Once training is completed, notify QAO or QA Program staff.

7.7.3. QAO or QA Program staff: Elevate the document status to effective and ensure that the previously approved document is no longer in the document control system. Update the effective date and notify all staff within scope that the document is now effective.

7.7.4. As noted in section 7.6.4, a document that does not require training will skip the approved status and be elevated to effective after all approval signatures are obtained.

7.8. Retiring a Document

7.8.1. The retirement process is performed by the QAO or QA Program staff.

7.8.2. When a document revision is approved during the revision process to become the newly effective document, retire the previous document revision.

7.8.3. Update the header of the retired document to include a status of "retired" and add an additional section to record the "retired date". For retired documents, both the effective date and the retired date will be listed in the header. The retired date will be the same date as the effective date of the new effective revision.

7.8.4. Ensure that both the newly retired and effective documents are uploaded and available in the document control system at the same time. All retired documents of a document will be retained in the document control system and will allow users to easily determine what revision of a document was effective on any given date.

7.8.5. Retired documents cannot be used to perform current work. Current work must utilize the effective revision of the document.

7.9. Making a Document Obsolete

7.9.1. The QAO or QA Program staff is responsible for the coordination of an evaluation prior to making a document obsolete, and this evaluation will include approvers and/or representatives from all programs within scope. The process to make a document obsolete can be initiated by any staff member.

7.9.2. A status of obsolete means that the entire process or procedure that the document describes is no longer used or no longer applicable.

7.9.3. Obsolete documents will be retained in the document control system and can provide historical context for past processes.

7.9.4. To make a document obsolete, the Approval Page of the document will be replaced with an Approval to Obsolete Page, and approvers and/or representatives from all programs within scope are required to sign prior to the document becoming obsolete.

7.9.5. Change the header information to include a status of “obsolete” and replace the effective date with “obsolete date”. Previous revisions of the same document do not require further change since there will no longer be an effective version of the document.

7.9.6. Update the Revision History table to include a justification for making the document obsolete.

7.10. Publishing a Reference Document

7.10.1. The process of publishing a document is facilitated by the QAO and/or QA Program staff and can be initiated by any staff member.

7.10.2. The published document status applies to reference documents only. Publishing a reference document serves to retain the reference material in the document control system for easy reference. Reference documents are not subject to expiration dating or revision processes and cannot be used to meet quality system requirements. Reference documents can be useful in the creation of procedural documents within DWR programs.

7.10.3. Examples of reference documents include user manuals, certificates of analysis, and other documents originating from external sources.

7.10.4. QAO and/or QA Program staff: Upload the document “as is” into the document control system, adding DCN, published date, and a status of “published” to the header.

8. DEFINITIONS

NOTE: Definitions of document types not covered in this section can be found in the description column in Table 2.

8.1. Controlled Copy - Hard copy of a document which is printed and labeled “Controlled Copy” with a QAO (or QAO designee) approval signature and date present. These controlled copy locations are tracked in the document control SharePoint and in the Document Master List DWR-1-LST-001.

8.2. Document - Any information or instructions including procedures, test methods, forms with instructions, schedules, equipment manuals, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. Documents are further divided into categories: (1) Governance, (2) Procedures, (3) Quality Records, (4) Template, and (5) External.

8.3. External document – Also called reference documents, these documents are used as a reference and scanned or otherwise included "as is". They are not required to be approved and cannot be used to meet quality system requirements. These documents include user manuals, certificates of analysis, and communications to external agencies.

8.4. Governance Document – A high level document that provides strategic focus and direction.

8.5. Lifecycle Status - Also signified by "Status" in document headers, these are the different states a document goes through from the time it is created until it is obsolete. The following can be the status of documents within this document control system: in-progress, in review, approved, effective, retired, and obsolete. External documents will be given a status of published.

8.6. Master List - A comprehensive list of all documents which includes the DCN, Title, Version number, Effective Date, Author, Owner, and Controlled Copy Location(s).

8.7. Migrated Document - Documents that are moved "as is" into the document control system, assigned a DCN with a version number of 1.0 and a status of effective. These documents are moved "as is" from their former document management system (if any). The content and appearance, besides the header/footer information, are not changed. Migrated documents are assigned a version number of 1.0, and the revision history will state that it was a migrated document.

8.8. Procedure – A document that details the activities or processes and the specific steps needed to be taken. They explain exactly how a task is performed, contain enough detail for all steps to be completed, and describe a task from beginning to end.

8.9. Quality Management System - A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

8.10. Quality Record – A document that provides evidence of various actions taken to demonstrate compliance with procedures (instructions), e.g. activities, events, and investigations.

8.11. · END OF DOCUMENT · - This statement is inserted at the end of the content of all procedure document types.

· END OF DOCUMENT ·

Revision History

Revision	Effective Date	Section	Description of Change	Justification of Change
1.0	TBD	All	Approval by QA Committee	New document