IEP Standard Operating Procedures Template

Version: 1.0

Status: Approved

Effective Date: 11/5/2021



Interagency Ecological Program

**Instructions for completing template**
Note that this instruction section (pages 1-3) should be deleted for your final document.

The intent of this template is to provide a resource to any IEP staff in need of a SOP template and may serve as suggestions for bolstering other SOP templates already in use. It is the intent of the DUWG QA Subcommittee that this template contributes to increased consistency in SOPs across the IEP and further support data that is well-documented and of known quality. Use of this template is not required for inclusion of studies in the IEP Workplan, but SOPs using this template should be referenced in study proposals, study plans, and metadata. The template also has optional sections detailing background and station locations. This content is very important but should be detailed in the metadata, and the study plan or Quality Assurance Project Plan (QAPP). If those documents are not publicly available, those sections should be included in the SOP.

This template has sections denoted and color coded as required, recommended, and optional. Additional sections may be added as your program requires. All required sections should appear in all SOPs. If the section is not applicable, then it should still be included with a statement that the section is not applicable. The sections covered in this template are summarized below.

**Required**

Scope and Application

Personnel Requirements

Safety

Sample Management

Equipment and supplies

Procedure

QA/QC

Data Analysis and Calculations

Data Reporting

References

Revision History

**Recommended**

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Approval page

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Calibration & Maintenance

Past SOP editors & Collaborators / Acknowledgements

Appendices

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Background

Contact Information

Maps / Stations

Technical Considerations

Reagents and Standards Preparation

New Year Prep

Corrective Action

Pollution Prevention & Waste Management

**Style**: Recommended Keep Word style functions the same as the template. You can find the style that is used by clicking the text and it will be highlighted in the “Styles” section on the Home tab. All section headers will have a style of Heading 2, and all subsections will have a style of Heading 3. The body of the document should have a style of “list paragraph”.

Follow your program or agency’s guidance on ADA accessibility of documents [including font type, size (12 pt at minimum), and alt text for images, figures, and tables].

**Bulleting sections**: Recommended Bullet sections with nested section numbers as appear below. However, this is not as crucial as content, and programs can utilize whichever organization system works best for their needs.

* + 1. Section
	1. Subsection
		1. Sub-subsection

**Header & Footer**: Required Enter the following information into the header:

* Working title
* Status: will generally be “effective” for your current documents. Other status designations can also be used based on the needs of your group. For example, DWR utilizes the following status designations – in-process, in review, approved, effective, retired, obsolete, and published. For an explanation of these designations, refer to DWR-1-SOP-001.
* Effective Date: the date that this current effective document was put in place.

Please note that most screen readers cannot read headers, footers, and watermarks. In order to be ADA compliant, duplicate the information from the heater on the title page of your SOP.

**Versioning**: Required A clearly laid-out document versioning process ensures that staff are using the most current effective version of an SOP. Additionally, when document versioning is in place, reconstruction of the data/records at specific time intervals can be more accurately evaluated. Versioning is meant to track documents and changes over time, which requires consistent naming, version numbers, and effective dates on each document.

For example, a new document once approved is given a version number of 1.0. When changes are needed, the document will undergo revision and be reviewed. With each internal revision, the version increases in number by 0.1. Once the revisions are approved and the revised document is made effective, the document would be version 2.0 and so on. Using the example table below, we could more easily determine that data generated using QA Process A in October 2019 used version 2.0 of this document. Current use of QA Process A would utilize version 3.0 of the document.

|  |  |  |
| --- | --- | --- |
| Document name | Version | Effective Date |
| QA Process A | 1.0 | 07/04/2012 |
| QA Process A | 2.0 | 01/08/2018 |
| QA Process A | 3.0 | 09/16/2020 |

Once a new version is made effective, the SOP is distributed to all staff/programs within scope. Ideally, all prior versions of the printed SOP are retrieved and either discarded or retained for reference. To prevent inadvertent use, electronic versions and retained printed copies of retired/superseded documents are recommended to be modified to include a watermark or visible indicator that the version is no longer current.

To support control of SOP versions, it is recommended to use a document control system. For an example of a document control system in use, refer to [DWR-1-SOP-001](https://github.com/InteragencyEcologicalProgram/Open-Data-and-Data-Publishing/blob/master/Resources/Document%20Control%20System%20Example.pdf).

Note: Ideally, staff are trained on an approved SOP, and the SOP is made effective only after all, or a significant portion of, staff performing the method have received training.

**Document References**: Recommended It is highly recommended to make references to other documents that may have additional detail or information applicable to the execution of the method described in the SOP. These references can be made in any section of this SOP, and access should be detailed in the references section. If access is not publicly available through hyperlink or other means, then include the document as an appendix to this SOP.

The remaining pages in this document are listed in order by section. An explanation of each section is included and can be deleted to insert your own content. It is recommended that the font size and style selections are retained in your finished document. However, if you find something that suits your program better, please use that and share your formats with the DUWG QA Subcommittee. We recognize that this template should continuously improve, and we rely on your input to do that.

Title of Document

version x.x
Status:
Effective Date:

**Title Page**: Recommended Copy/paste your department &/or program logo. We recommend a maximum width of 2.5” but no smaller than 1.5”, but this is subject to your aesthetic choice. Please only use the most recent high resolution official logo available. The current 2” IEP logo is included below as an example. The title page should consist of a concise title and supporting images &/or department/program logo. The working address of your department/division can be a useful addition. All logos should be marked as decorative for accessibility purposes.

(insert logo image)


Department
Division
Street address
City, State, Zip Code

## Approval Page

**Approval Page**: Recommended You can use two columns if more space is needed. Each signature line and approver information area were individually inserted in this template on the approval page as a stand-alone table. The template includes 5 individual tables. Additional tables can be copy-pasted if more approvers are required. To remove approver tables, hover cursor over each table needing removal and click on the + in the top left, right click > Delete Table.

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**Contents**: Recommended List of section and page numbers in the document. You can also include list of tables and figures. This template Contents section does not need to be edited directly. Once the content of your document is entered and unused “recommended” or “optional” sections are removed, then the Contents section below can be updated by clicking in the table, in the top left clicking “Update Table…”, and selecting “Update entire table”. This functionality works by pulling in all Styles for Heading 2 (section titles) and Heading 3 (subsection titles), which is the reason it’s recommended to not modify the styles.

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Acronyms & Abbreviations

Optional: This section can be a separate page (or pages) and includes definitions for all abbreviations and acronyms. Include this section if there are more than ~4 abbreviations that are needing to be explained. Alternatively, the section could be named "definitions" or “glossary" and would include all definitions that will explain both the terminology and the abbreviations used in the SOP. Acronyms should only be used for terms repeated often throughout the SOP and should be defined at first use, even if present in this section.

Scope and Application

Required: Ensure that all programs, divisions, branches, etc. within scope of the method are listed here. This section is a concise 2-3 sentence overview of the basic objectives of the method, and what programs and/or locations are within scope. The "what", "where", how, "who", and “when” of the method. A brief summary of the method (without technical details) can also be included covering how the method is used to support your listed objectives. This summary can be limited to a sentence or two for small procedures.

Background

Optional: It is recommended that the background of the method be documented in the metadata and Study Plan, or QAPP. The reason for choosing this method may change, and the method could be used in multiple studies for various purposes. In lieu of a Study Plan or QAPP, the background can be documented here. This content includes an introduction that explains “why” this method is being used, optionally including any background information, history, legal framework, or regulatory requirements if relevant.

Contact Information

Optional: This section may include contact information for the team of people performing the process.

Personnel Requirements

Required: This section describes the skill set(s) required for those performing the method and the required number of individuals to perform the work. This section is always required if there is a safety component (such as needing to handle acid). All training (safety or technical) should be described in this section. The training described should include all training required to safely and effectively perform the method, including the need to be trained on the content of the SOP. Any additional personnel requirements should also be described.

Map or Stations

Optional: It is recommended that the locations where the method is performed be documented in the metadata and Study Plan, or QAPP. This is because the method could apply to multiple projects in various locations. In lieu of those documents, the locations can be documented here. This would include visual representation of locations where the method will be performed. Can also reference a table listing sampling site coordinates if one exists and is included as an appendix.

Technical Considerations

Optional: This section describes the known considerations that should be taken into account for data collection, processing, and analysis, and any steps that should be taken to address those considerations. For example, in the laboratory, high turbidity can interfere with proper measurement of chlorophyll-a by spectrophotometry, as the increase of suspended particles in the water makes it difficult to adequately analyze the particles on the filter and can cause measurement error. This can be accommodated in the field procedures by decreasing the volume of sample filtered from 500 mL to 250 mL if the turbidity is above 20 NTU. For example, in the field, beach seines can only be conducted where there is no vegetation.

Safety

Required: This section includes a list of protective equipment that should be worn when performing the procedure, any precautions that should be taken while performing the procedure, and specific warnings about any hazardous materials used in the procedure. SOPs for field work should dangers associated with field sampling such as any potential dangers with lifting heavy objects, boat safety, or safety regarding remote locations. Biological and chemical hazards should be noted. Address any hazards associated with reagents and standards, and hazardous materials storage and disposal. Safety related storage requirements such as flammable storage lockers, or proximity to reactive chemicals should be detailed here. Other safety documents can be referenced that describe safety procedures more thoroughly.

The level of detail should be specific enough that hazards of the action are clearly laid out. MSD sheets should be referenced if necessary. If a Job Hazard Analysis needs to be done, then it should be referenced in this section. Any potential injury to the employee performing the action should be specified. Refer to the personnel requirements section for any specific safety training that is necessary.

Sample Management

Required: This section contains procedures to ensure that sample integrity and custody are maintained and documented from sampling through disposal.

Chain of Custody

Chain of Custody (COC) forms are utilized to provide the written documented history of a sample and are intended to be used for sample tracking. Reference your COC form in this section or include in an Appendix. Enter the detailed instructions in this section that allows for proper execution of COC form entry.

If your program doesn’t have a COC form, one should be generated. COC forms should include revision identification, page numbering and the total number of pages.

The minimum information on a COC form should include the items listed below. Entry into the form should be initiated by the sampler at the time of collection.

* Project name
* Sampler name
* Sample location
* Field ID number
* Date & time of collection
* Number of samples
* Sample type and sample volume, if applicable
* Preservative, if applicable
* Analyses to be performed, if applicable

Include information of how the COC form will be used after sample collections such as (1) the original COC record should accompany samples when transported or when custody transfers, and (2) the original COC should be returned to and retained by the project manager after sample disposal or the completion of the study. Include clarifying information in this section, such as COC forms may also include field measurement data and observations concurrent with sampling processes.

Sample Collection, Preservation, Shipment and Storage

This includes requirements for temperature, chemical preservation, container type, labelling, storage, shipping and holding time. A table is often beneficial for programs with complex sampling plans.

Guidelines from the laboratory you are using should be consulted. Include any sample holding times or temperatures. Include instructions for the chain of control. Reference any SOPs necessary for sample collection, preservation, shipment, or storage. Include tables of holding times if necessary.

Equipment & Supplies

Required: This section includes a list of all apparatus used, from instruments to beakers and pipettes; and all supplies used, such as filters and disposable items. It is recommended to have a subsection of equipment that includes all reagents and standards used, purchased or prepared for use in the method, including all pertinent information about those products, such as concentration, manufacturer, CAS number, and purity/grade. Enough information should be included that a relatively new analyst can determine what supplies to order when required. Brand names and specific part numbers can be listed and are often helpful, but it is recommended that you specifically allow equivalent items by adding an equivalency statement so you do not lock yourself in to a specific brand or part that may not be available when you need additional supply. (Example: Alconox brand soap or equivalent phosphate-free laboratory soap.)

An equipment and supplies list is meant to be all-inclusive. List all equipment and supplies, including incidental items (materials, reagents, chemical standards). Use generic terms in addition to specific brand-name items.

Cleaning and Preparation

Recommended: This section includes step-by-step instructions on cleaning equipment and preparing for method processes, including supplies used. If highly detailed or lengthy, this section may best be contained in an appendix. Notes on proper handling can also be important. For example: do not store ropes or spools inside sampling buckets as this could contaminate the equipment or result in nicks and scratches.

Cleaning processes can include daily instructions as well as weekly/monthly/annual routine maintenance. Some typical examples of process steps for cleaning and preparation are bulleted below; however, this is not an all-inclusive list. The list below is also not detailed enough and may not be in the correct order for your process. Equipment used will be different between programs. An important consideration is whether the instructions are detailed enough that an entry level employee can perform the tasks as written with no additional guidance. Each equipment type may need separate and specific cleaning instructions depending on equipment manufacturer requirements.

* Visual inspection: Examine equipment for damage (scratches, tears, dents, cracks, hole, etc.) and replace if needed. Examine equipment for visible contamination (dirt, rust, biomatter) and wipe/clean/rinse off excess
* Rinse with tap water (can specify hot or warm here) followed by lab grade water
* Wash using lab grade soap (can specify actual brands such as Liquinox or Alconox if desired) using a soft brush to remove surface deposits
* Rinse with tap water followed by lab grade water
* If rust or other deposits remain, scour with a soft brush or clean cloth with a paste of baking soda and water, repeat water rinse steps
* Rinse with ethanol or methanol to remove organic compounds
* Air dry at room temperature away from any sources of contamination
* Cover cleaned equipment with clean aluminum foil until use.

Reagents and Standards Preparation

Optional: Standard preparation instructions, including routine standard concentrations used, will be included here. For each prepared reagent, the listing will include preparation instructions unless the reagent is a common stock reagent such as water or a standard concentration acid. Expiration dates and preservation-related storage requirements of reagents and standards will be defined in this section, such as protection from light.

Calibration and Maintenance

Recommended: This section includes detailed instructions for calibration, maintenance and troubleshooting of equipment or instruments used for the method. Include calibration frequency, acceptable range of measurement, and preventative maintenance schedules, if applicable. May also include troubleshooting guidance. Can reference separate SOPs and user manuals or can include as an appendix.

Procedure

Required: This likely will be the biggest section in the document. Add subsections for each specific method/process, making sure to select Heading 3 for the subsection title style which will allow for automatic addition to the table of contents. This section prior to the subsections can summarize the procedures that the subsections detail to give the reader an overview of the procedures or any relevant background information.

Procedure Subsections

Multiple processes can be nested under the Procedure section as subsections and each subsection should describe a specific procedure in detail. A suggested style is in a numbered, step-by-step fashion, with each step being concise enough so that the procedure can be repeated by someone else with similar knowledge and training. Multiple processes can be nested under the Procedure section as subsections. This format is preferred when many different processes are described. These subsections should be in chronological order to reflect the workflow of the series of procedures being described. Make sure to keep naming consistent throughout the procedure subsections for equipment and other technical terms.

Include the circumstances in which the methods outlined in this SOP may be deviated from. It is also recommended to include specific “notes”, or items that staff should be aware of, while performing these procedures to help guide them. These could be safety related or a warning to prevent a mistake from occurring. For example, if a numbered step says to “lower the instrument over the side of the vessel and into the water”, an associated note would be to “avoid placing the instrument near the propellers of the vessel”.

Quality Control /Quality Assurance (QA/QC)

Required: QA: This section details management (or secondary) review and oversight at the planning, implementation, and completion stages of the analytical data collection to ensure that data provided are of the quality required. These secondary review steps are critical to ensuring the quality of your data. Record of this review & oversight can be accomplished with approval lines on reports or electronic signatures or using other methods; however, this documentation is critical to demonstrate adherence to quality assurance requirements.

QC: This section details the activities required during data collection to produce the data quality desired and to document the quality of the collected data. Preparation of QC samples are detailed in this section. This section should list all of the sampling batch, instrument, and data quality control that must be performed with this method, including but not limited to:

* For water quality sampling: duplicates/replicates, blanks (equipment, method, reagent, bottle, temperature, etc.), spiked samples
* Or biological data sampling: double checking species ID by alternate staff, or repeating ID subsample for 10% of the data collection to verify consistency in identification
* For instrumentation/measurement data: calibration, interference checks, instrument performance checks, spiked samples and instrument blanks.
* For data quality control: describe all procedures used for ensuring data quality, such as datasheet checks, flagging, missing values, and data corrections.

Proper documentation provides evidence that QA/QC procedures were properly executed. Fillable forms or sections within existing forms with proper version control and revision histories are highly recommended and are a good way to document QA/QC processes while also improving consistency, traceability, legal defensibility and ease of use.

New Year Preparation

Optional: In this section, annual maintenance tasks to prepare for the next calendar year are described, including preparing/updating log sheets, labels, and data sheet folders, archival of the previous year's records, verifying supplies of consumables, and checking calibrations or other equipment maintenance.

Corrective Action

Optional: This section describes corrective actions and contingencies for handling out of control or unacceptable data, and steps for addressing any issue that impacts data quality. Corrective actions should be documented and could include details such as date/time, location, persons involved, description of the issue, root cause analysis, corrective actions installed, and known impact to data or data quality. Additional considerations could include listing out the data flags that could be used for specific occurrences, and scheduled reassessment to determine that the corrective action was effective in preventing recurrence and/or eliminating the issue.

A robust method of corrective action could benefit from a standard form to document the steps taken, and to have the proper level of visibility, oversight, and approval within the organization.

Data Analysis & Calculations

Required: This section describes how results are processed and calculated. Data analysis can include instructions for data processing in regards to standardization and quality control, reduction, application of correction factors, and software used.

Calculations should be described in detail, including the formula(s) used, as well as definitions of each variable and units used. Insert formula by going to Insert > Symbols > Equation >Insert New Equation.

*Relative Percent Difference*$$\%RPD=\frac{C1-C2}{\left(C1+\frac{C2}{2}\right)}\*100$$

 *Where*: C1 = Primary sample result (units of result, for example mg/L)
 C2 = Sample duplicate result

Data Reporting

Required: Data reporting can include information about data flagging and processing prior to publication, in addition to how data are provided and/or reported to the public, permitting or granting agencies. If data are uploaded to data repositories (e.g. CNRA, EDI), this section can also include information about where data are uploaded, quality status indicator (ex: provisional), instructions for publishing data, and frequency of data upload. This section can also include information about how data are peer-reviewed prior to reporting, and describe additional documentation (e.g. metadata, processing code) that should be provided with reported data. If available, may reference open data policies.

Pollution Prevention & Waste Management

Optional: This section provides an overview of techniques and processes to limit pollution into the environment when performing the methods. It also lists the proper process for waste streams including collection, labelling, storage and disposal of waste. This includes acid/base solutions, and hazardous materials (such as formalin).

References

Required: A list of all documents referenced within the procedure and/or used in creation of document content.

Revision History

Required: This section is comprised of a compiled list of all revisions to the document. A table in the recommended format is included below. Each revision will list the description of each change together with the section changed and the justification. This running list allows for quick assessment of how the process has evolved over time, allowing for a more accurate determination of data quality & interoperability. Note: Retired or superseded documents should be retained to provide a historical reconstruction of the document’s revisions and changes.

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| --- | --- | --- | --- | --- |
| **Revision** | **Effective Date** | **Section** | **Description of Change** | **Justification of Change** |
| 1.0 | TBD | All | New document | Creation of new document |

Past SOP editors & Collaborators / Acknowledgements

Recommended: A list of all contributors (authors and/or editors) to the SOP should be cited in this section. Contact information should also be available for the contributors so that they can be contacted about any questions regarding the procedure.

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| --- | --- | --- | --- | --- | --- | --- |
| **First Name** | **Middle Initial** | **Last Name** | **Organization** | **e-mail address** | **ORCID ID (optional)** | **Author/ editor** |
| Jane  | I | Doe | DWR | Jane.Doe@water.ca.gov |  | Author |

Appendices

Recommended: The appendices should include any companion documents relevant to the method such as field sheets, checklists, or references used during application of the method. Listed below are some of the more common appendices. Use any that apply and add others as needed.

### Safety Plans

### Job Hazard Analysis

### Checklists

### Permitting

### Cleaning Protocols

### Equipment SOPs/User Manuals

### Navigation Guides

### Field Forms

### Calibration Sheets