



Department of
Environment and Conservation

Our environment, our future



DEC Nature Conservation Service

Biodiversity

Standard Operating Procedure

Preparation, review, approval and amendment of standard operating procedures

SOP No: 1.1

Prepared by:

Resource Condition Monitoring Team
(Significant Native Species and Ecological Communities)

Prepared for:

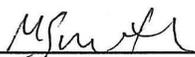
Department of Environment and Conservation

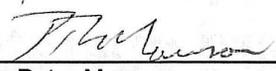
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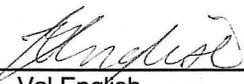
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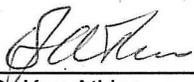
Approvals

Version 1.0

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1. Dr Ken Atkins, Manager, DEC Species and Communities Branch
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Table of Contents

1	Purpose	2
2	Scope	2
3	Definitions	2
4	Procedure Outline	3
4.1	Preparing or Amending a Standard Operating Procedure	3
4.1.1	Identifying the need for a new Standard Operating Procedure	3
4.1.2	Amending an existing Standard Operating Procedure.....	4
4.1.3	Authorship of Standard Operating Procedures	5
4.1.4	Format and Content	5
4.1.5	Naming and Citing Standard Operating Procedures.....	5
4.1.6	Storing and sharing of documents	5
4.2	Submission	5
4.3	Classification	6
4.3.1	DEC Review.....	6
4.3.2	Expert Review	6
4.3.3	Director Nature Conservation Approval	6
4.3.4	Animal Ethics Committee Approval Required.....	6
4.4	Review	6
4.5	Approval.....	7
4.5.1	Signatures	7
4.5.2	Director Approval	7
4.5.3	Allocation of a Standard Operating Procedure Number	7
4.5.4	Allocation of a Version Number	7
4.5.5	Notification of Approval	8
4.6	Deployment	8
4.6.1	Implement Changes to Databases	8
4.6.2	Publish on Internet or Intranet.....	8
4.6.3	Broadcast Email.....	8
4.7	Deletion	8
4.8	Archiving	8

SOP No 1.1 Preparation, review, approval and amendment of standard operating procedures

4.9	Animal Ethics Committee Approval (FAUNA ONLY)	8
5	Timeline for approval	9
6	References	9
7	Appendix I Reviewer questions and letter template.....	10

1 Purpose

This Standard Operating Procedure (SOP) outlines the process for preparing new and amending existing SOPs relating to DEC activities for flora, fauna and ecological communities, and the process for having these reviewed and approved. Once approved, these SOPs are considered to be formally accepted as 'DEC standards'.

SOPs relating to monitoring activities provide quality assurance for data by helping to ensure that monitoring is undertaken consistently. This is particularly important for long term monitoring projects that aim to observe trends over time, where data must be compatible.

For a procedure to become standard it must be reviewed and agreed upon by suitably qualified people (for example, the Animal Ethics Committee for fauna-related SOPs). This SOP outlines the review and approval processes required for this agreement. Reviewers assess the SOP for clarity and technical soundness to help ensure that data collected using the SOP are consistent and of a high quality.

2 Scope

This SOP applies to SOPs developed by the Department of Environment and Conservation (DEC) for work undertaken within the Department involving native species and ecological communities.

Standard operating procedures may be authored by DEC staff, NRM groups, consultants, researchers and any other people monitoring significant native species and ecological communities or undertaking fauna handling for research or management purposes. However, other agencies may have their own processes in place for approving SOPs and DEC approval may not be required or appropriate for their operations.

3 Definitions

Amendment: A change to a procedure that may involve a major or minor revision.

Author: The writer or compiler of the SOP.

Chief Investigator: Person identified in a DEC Animal Ethics Committee Approved project that is responsible for the project. They may also be referred to as the project leader.

Major revision: Changes to the procedure that affect the technical content or process of the SOP.

Minor revision: Changes to a procedure that do not affect the technical content or process of the SOP (eg grammar or spelling corrections, renumbering sections, changing the title etc).

Project leader: Person responsible for a monitoring project. For DEC Animal Ethics Committee approved projects this would be the Chief Investigator.

Review: Process by which a procedure is assessed for clarity and technical soundness such as whether data collected are consistent and of a high quality.

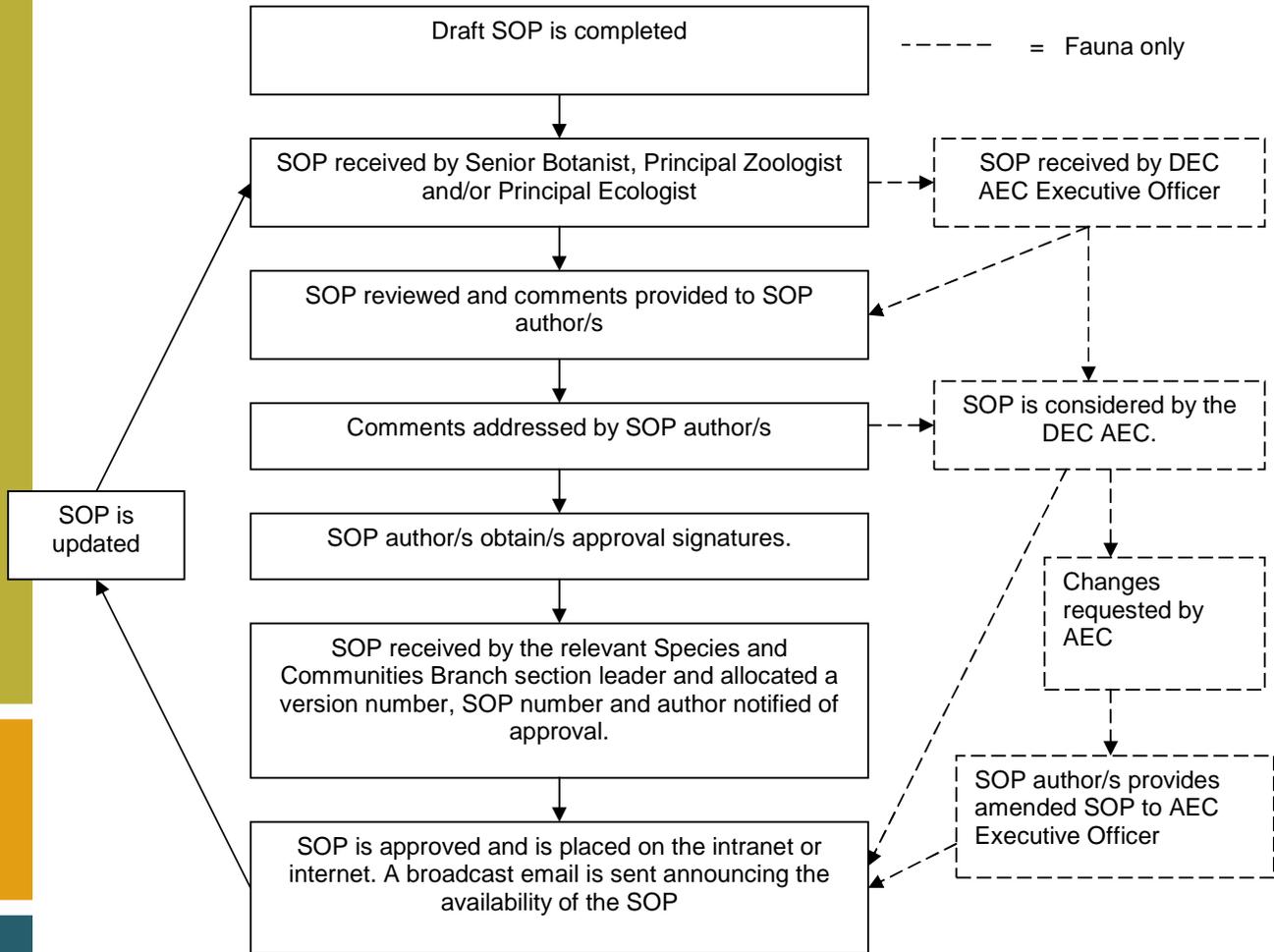
Standard Operating Procedure (SOP): Presents details on how specific aspects of the components described in a monitoring procedure or other flora, fauna or ecological communities procedure will be carried out. They are written in the form of instructions, with step-by-step details of how to carry out each procedure.

Section Leader: The relevant person in charge of the Section. In Species and Communities Branch, this is the Principal Ecologist, Senior Botanist or Principal Zoologist or Branch Manager (positions current as at April 2009). In DEC this can be the Project Leader, Nature Conservation Coordinator, District or Regional Manager or other equivalent position.

4 Procedure Outline

The following diagram summarises the procedures described in the following sections for the review, approval and updating of standard operating procedures.

Figure 1: Summary flow diagram of review, approval and updating procedures for standard operating procedures.



4.1 Preparing or Amending a Standard Operating Procedure

4.1.1 Identifying the need for a new Standard Operating Procedure

SOPs identify the minimum key components of a procedure so that they are consistent between users. They are designed to capture core components that are common to everyone who uses the technique so that broad agreement can be reached on a standard approach. Once these are agreed, individual parties can add additional elements that are specific to their projects.

Such an example is the SOP for producing Universal Bait (see SOP 9.7) which documents the procedure for preparing and storing the bait which consists of peanut butter, rolled oats and sardines. When Universal Bait is used to trap Gilbert's Potoroo it is modified by the addition of Pistachio essence, in this case, a new SOP does not need to be prepared because the core elements of the technique have not changed. However, the Monitoring Protocol or *Application for Approval to Undertake Research Involving Vertebrate Animals* must record that universal bait contains an additional ingredient specific to that project.

To write a SOP it is critical that the purpose of writing the SOP is understood. It is intended that SOPs

will have broad application and so must be written in such a way that they are relevant to a variety of projects that may use them.

A SOP may be written to apply to a specific species or project if the procedures are widely agreed upon and recognised as best practice. This is particularly relevant to significant species of fauna for which many have quite specific methods of capture, observing and monitoring that are not relevant to other species or even other species within their taxonomic group. However, a SOP can be a dynamic document updated as new information and techniques become available.

Wherever possible projects should follow procedures outlined in existing SOPs. To find out if there is an existing SOP for the required procedure, these should be available on the website <http://www.dec.wa.gov.au> (from June 2009).

4.1.2 Amending an existing Standard Operating Procedure

A SOP should be amended where;

- The SOP contains an error in the procedure, or more information is needed to better explain the procedure
- A technique used to perform the procedure has changed because of new technology; or
- The procedure must be changed because it no longer meets a standard of approval, (for example Animal Ethics approval, or because legislation which affects the procedure has changed).

As new or different information becomes available, it may be necessary to review the SOP to ensure that the procedure it describes is still relevant. This review should also consider whether an amendment is necessary, for example whether such an amendment would unnecessarily affect the continuity of monitoring data. It is a requirement of Section 2.2.17 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (Australian Government 2004) that this is undertaken for SOPs approved by the Animal Ethics Committee (AEC) at least every three years.

It is also possible that during the course of a monitoring project there may be a need to deviate from the SOP. These deviations may be

- 1) temporary in nature and for a specific purpose, or
- 2) for experimental purposes with the aim of improving procedures.

These may not always be sufficient reasons to amend a SOP. However, where there is a deviation from the approved SOP, the project leader must document the reasons for it and how the data have been affected (including the dates during which the monitoring took place). This should be documented and stored:

- in the Monitoring Protocol or in a document maintained with the Monitoring Protocol (where there is one);
- in file notes on the file for the project or the file for the SOP;
- in the relevant field in the project database (where possible);
- in the project data metadata statement;
- in the file containing the *Application for Approval to Undertake Research Involving Vertebrate Animals* (where applicable);
- in any reports using the affected data.

Where the deviation from the SOP results in permanent change to the procedure this should be reflected as either a new procedure or an amendment to the existing procedure.

To amend an existing SOP, the person proposing the changes should submit the existing SOP with changes marked in track, or otherwise highlighted, using the procedure outlined in Figure 1 above. Amendments do not need to be made by the original author of the SOP although collaboration is encouraged. The relevant Species and Communities Branch (SCB) section leader will use their discretion to decide on the appropriate level of review. Amendments and versions need to be tracked in the Revision History Log contained within the SOP.

4.1.3 Authorship of Standard Operating Procedures

Standard operating procedures may be authored by DEC staff, NRM groups, consultants, researchers and any other people monitoring significant native species and ecological communities or undertaking fauna handling for research or management purposes. However, only those SOPs that are authored by DEC staff need to be approved through the process described in this SOP. Other agencies may have their own processes in place for approving SOPs and DEC approval may not be sufficient within those jurisdictions.

4.1.4 Format and Content

There are a wide variety of procedures for which a SOP may be written. It is therefore difficult to provide all the appropriate headings in a template. A basic template should be available on the website <http://www.dec.wa.gov.au> (from June 2009) and its use is recommended. Authors should consult existing SOPs to guide the content and level of detail required. Note that additional sections are required for SOPs that involve fauna and which require approval from the DEC Animal Ethics Committee (i.e. impacts, ethical considerations and competencies).

4.1.5 Naming and Citing Standard Operating Procedures

SOP titles should be concise but descriptive enough to indicate which technique the SOP provides instructions to undertake. If the SOP is specific to a project or species it should indicate this in the title. A suggested citation is to be provided in the introductory pages of the SOP. Each SOP will be allocated a unique number and this can be cited when referring to a SOP in a Monitoring Protocol, license application or other documentation.

4.1.6 Storing and sharing of documents

To ensure that documents are more easily stored, located, reviewed, and placed on the website as necessary, they should be named in a compatible format. The format for this convention is:

SOPnumber_subject_site*_object_versionnumber_date

*Note that site can be substituted with the project title.

An example is:

3.1_Fauna_Mixing_Universal_Bait_V1.1_20080825

The title should be written in either camel case (where the first letter of each word is capitalized) or in the format above. Thus the above example in camel case would appear as:

3.1FaunaMixingUniversalBaitV1.1_20080825

Once the SOP has been reviewed and approved through this process it will be assigned a SOP Number, which will be placed at the beginning of the filepath.

4.2 Submission

All new SOPs and amendments to existing SOPs are to be submitted to the relevant section leader of Species and Communities Branch. These Officers are required to view the SOP as custodians of the corporate threatened and priority flora, fauna and TEC databases to ensure opportunities for data aggregation are considered. They will also decide on and guide the appropriate review and approval process for the SOP depending on the broadness of its application and implications for stakeholders involved.

Fauna related SOPs received by the Principal Zoologist will be forwarded to the Executive Officer of the Animal Ethics Committee to arrange consideration and approval by the Committee (see Section 4.10).

If the SOP is generic or applies to more than one subject area (flora, fauna and/or ecological communities), then it may be referred to more than one person, with each recipient being advised of the other recipients.

SOPs may be submitted for review to:

Species and Communities Branch
Department of Environment and Conservation,
Locked Bag 104
BENTLEY DELIVERY CENTRE WA 6983

Where there is a need for approval to be sought from outside of Species and Communities Branch (SCB) the relevant SCB officer will determine who this is. Where appropriate, the author of the SOP should identify potential reviewers to assist the reviewing officers.

4.3 Classification

The relevant SCB section leader will classify the SOP using the guidance contained in the following sections.

4.3.1 DEC Review

'Simple' SOPs may only require review and approval by the relevant SCB section leader. Alternatively the relevant section leader may request review from other DEC staff. Representatives from Science Division, Regional Services and/or Nature Conservation Divisions may be chosen.

DEC reviewers will be provided with up to six weeks to comment.

4.3.2 Expert Review

Expert review will be required if the proposed procedure is:

- Technical and requires expert knowledge to assess;
- Widely significant, involving or affecting several stakeholders; or
- Controversial; or politically sensitive.

The DEC AEC may also request expert review for the above reasons.

Expert reviewers will be provided with up to six weeks to comment.

4.3.3 Director Nature Conservation Approval

Director Nature Conservation approval will only be required in cases where the SOP may be controversial, politically sensitive or have far-reaching impacts/implications. In general, approval at this level will be at the recommendation of the relevant SCB section leader or the Manager of Species and Communities Branch.

4.3.4 Animal Ethics Committee Approval Required

Approval from the DEC AEC will be required for any procedure that involves the use of animals. Fish and invertebrates are exceptions to this requirement, although projects involving these groups are still encouraged to gain approval from the DEC AEC. DEC AEC approval will be required if proposing to use wet pitfall traps for invertebrates because the risk of vertebrate by-catch is high.

SOPs requiring approval from the DEC AEC should address additional sections that cover "Level of Impact", "Ethical Considerations" and "Competencies".

Approval of SOPs from the DEC AEC cannot be obtained out-of-session and must be submitted for consideration at one of the committee's five regular meetings during a year (February, April, June, August and October).

4.4 Review

The relevant SCB section leader will guide the review process based on the classification of the SOP. If the SOP requires AEC approval then the AEC Executive Officer will guide the review process.

There are two main purposes of review:

1. To obtain expert advice.
2. To obtain input from stakeholders affected by the SOP.

Expert advisers and stakeholders play a role in reviewing the SOP and provide comments and advice on how it may be improved. Major stakeholders may also have the additional role of approving the SOP.

Review of SOPs may thus involve:

- DEC Regional Services (eg project leader, regional ecologist or nature conservation coordinators);
- DEC Nature Conservation Division (eg Species and Communities Branch, Nature Protection Branch);
- DEC Science Division;
- other DEC Divisions, where specialist expertise may be relevant to the SOP;
- DEC Animal Ethics Committee; and/or
- Selected experts (eg chosen based on familiarity with technique).

It is recommended that review and approval be obtained from representatives of at least two of these categories.

Reviewers will be contacted to determine their availability to provide comments within the required timeframe. If available they will then be sent the covering letter and reviewer questions in Appendix I together with the SOP being considered. Once received by the relevant SCB section leader, the reviewers' comments will then be sent to the author of the SOP. The author of the SOP needs to consider the comments and make appropriate changes to the SOP. The author of the SOP must provide the revised SOP together with a summary addressing the reviewers' comments to the relevant SCB section leader for final approval.

Reviewers may request that their identity be kept confidential.

The review process must consider systems or databases that may require modification to accommodate the requirements of the SOP. For SOPs approved by the DEC Animal Ethics Committee the Animal Ethics Database needs to be updated to include the new or amended SOP and the accompanying competency requirements.

Reviewers will be provided with up to six weeks to comment. The author will be given two weeks to make amendments to the SOP in response to reviewers' comments, obtain signatures from relevant stakeholders and resubmit it for final approval.

4.5 Approval

4.5.1 Signatures

Signatures must be obtained from relevant stakeholders to indicate endorsement of the procedure. The author of the SOP will identify who the relevant stakeholders are (as indicated on the signature page at the beginning of the SOP) and arrange signatures following final edits addressing reviewers' comments.

4.5.2 Director Approval

Approval from Director Nature Conservation may be sought on the recommendation of the relevant SCB section leader or manager. Director Nature Conservation approval may only be sought after reviewers' comments have been addressed and all other stakeholders have signed/endorsed the procedure.

4.5.3 Allocation of a Standard Operating Procedure Number

A SOP will be allocated a SOP number after it has been approved. SOP numbers will be allocated by the relevant SCB section leader. They will be numbered by adopting the approach proposed to be used in the Animal Ethics Database that involves placing SOPs in categories (eg Fauna Observation, Fauna Capture, Remote Observation etc) and then each SOP within those categories being numbered sequentially. The first digit in a SOP number will therefore refer to the category and the second digit will refer to the specific SOP.

4.5.4 Allocation of a Version Number

The version number will be allocated by the relevant SCB section leader when the SOP is approved. Version numbers increase incrementally by hundredths (e.g. version 1.1, version 1.2, ...etc) for minor

changes. Major revisions should be designated with the next whole number (e.g. version 2.0, 3.0, 4.0 ...). The revision history log must be filled in whenever an alteration to the version number is made (including approval for the first time).

4.5.5 Notification of Approval

The relevant SCB section leader will notify the author of the SOP via email that it has been approved along with any conditions applied to approval (eg amendments to systems or databases to accommodate the SOP).

4.6 Deployment

4.6.1 Implement Changes to Databases

Where a new or an amended SOP requires the collection of additional data then new field/s may need to be created in the database to hold this information. The version of the SOP (and/or MoP) that guided the data collection should be recorded against the data that the project has collected. This could be done by either recording the SOP (and/or MoP where appropriate) number in the relevant database (where this is possible) or by recording it in the relevant metadata statement.

4.6.2 Publish on Internet or Intranet

It is the intention that all SOPs will be made available to the public via the internet and specific reasons must be provided if a SOP is to only be available via the intranet.

The relevant SCB section leader will provide the approved SOP to Strategic Development and Corporate Affairs for addition to the website with the appropriate level of access.

4.6.3 Broadcast Email

Emails will be sent by the relevant SCB section leader to notify relevant staff and stakeholders of the approval and availability of SOPs on the internet or intranet. The Executive Officer of the DEC AEC will be responsible for sending broadcast emails notifying staff of DEC AEC approved SOPs.

4.7 Deletion

Standards evolve over time as techniques, technology and business processes change. SOPs that are considered no longer valid will be withdrawn from availability over the internet or intranet.

4.8 Archiving

Copies of every version of SOPs must be archived and each SOP will have a corporate file. SOPs relating to monitoring significant or threatened species and ecological communities will be archived at DEC Species and Communities Branch in Kensington. The SOP must be accompanied by a note explaining that it is now an archived SOP, and is no longer being used but is relevant to data collected before a specified date.

4.9 Animal Ethics Committee Approval (FAUNA ONLY)

SOPs that have the potential to impact the welfare of animals must comply with Section 2.2.17 of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. It is a requirement of the Code of Practice that SOPs be reviewed regularly by an AEC at least every three years.

SOPs involving fauna will be forwarded to the Executive Officer by the Principal Zoologist and usually accompany an Application for Approval to Undertake Research Involving Vertebrate Animals. The Executive Officer will provide the SOP to the DEC Animal Ethics Committee for consideration at the next general meeting.

Address for sending applications and SOPs for AEC approval is:
Executive Officer, AEC
Department of Environment and Conservation,
Locked Bag 104, Bentley Delivery Centre WA 6983.
E-mail: animalethics@dec.wa.gov.au

Phone: (08) 9334 0438
Fax: (08) 9334 0278

The committee will either endorse the SOP, request amendments or request that the SOP be reviewed externally. If external review is requested by the committee, the Executive Officer will make the arrangements. Reviewers will be contacted to determine their availability to provide comments within the required timeframe. If available they will then be sent the covering letter and reviewer questions in Appendix I together with the SOP being considered.

The Executive Officer will then contact the author of the SOP to make amendments or address reviewers' comments as necessary and to notify when the SOP has been approved for use.

Once a SOP has been approved the Executive Officer enters the details of the SOP into the Animal Ethics Database and allocates a number. The SOP will be linked to the required competencies in the database.

The Executive Officer sends a copy of the completed SOP to the Web Administrator for inclusion on the intranet and/or Resource Centre as instructed by the Principal Zoologist.

5 Timeline for approval

A minimum of 8 weeks should be allowed for approval of a SOP from submission to posting on the website.

SOPs that require approval from the DEC AEC will be constrained by committee meeting dates. It should be noted that SOPs submitted to the AEC Executive Officer after October will not be considered until the following year because the December AEC meeting is devoted to considering Annual Reports only.

6 References

AUSTRALIAN GOVERNMENT, (2004). Australian code of practice for the care and use of animals for scientific purposes. Prepared by the National Health and Medical research Council, Commonwealth Scientific and Industrial Research Organisation, Australian Research Council, Australian Vice-Chancellors Committee. 7th Edition.

OAKLEY, K.L., THOMAS, L.P. and FANCY, S.G. (2003). Guidelines for long-term monitoring protocols. *Wildlife Society Bulletin* 31(4): 1000–1003

7 Appendix I Reviewer questions and letter template

Standard Questions for Reviewers of Standard Operating Procedures for Significant Native Species and Ecological Communities

The following questions should be considered by reviewers of SOPs:

SOP Title	<hr/>	
Purpose	Is the purpose of the SOP clearly stated?	Yes [] No []
	Is it required/justified? (does it apply to a procedure that may have ongoing or broader use)	Yes [] No []
	If possible, comment whether the proposed SOP duplicates or complements existing SOPs?	
	<hr/>	
	<hr/>	
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Clarity	Is the SOP clearly presented and easy to understand?	Yes [] No []
Policy and Legislation	Is the SOP compliant with relevant legislation and policies?	Yes [] No []
Stakeholders	Have the needs of stakeholders been considered and incorporated as appropriate into the SOP?	Yes [] No []
Technical content	Is the SOP consistent with accepted technical practice in the relevant area?	Yes [] No []
	If not, does the proposed activity provide an acceptable alternative method?	Yes [] No []
References	Are references provided that support the use of the procedures as a standard?	Yes [] No []
	Do the procedures represent best practice?	Yes [] No []
If an amendment to and existing SOP	Is the amendment justified?	Yes [] No []
	Have the implications of the amendment been considered and satisfactorily addressed?	Yes [] No []
	Is the amendment an improvement on the existing version?	Yes [] No []
Recommendation	Should the SOP be approved?	Yes [] No []
	If not, why not?	
	<hr/>	
	<hr/>	
	<hr/>	
	If so, should conditions be applied and what are they?	Yes [] No []
	<hr/>	
	<hr/>	
	<hr/>	
Confidentiality	Do you wish your name to be kept confidential?	Yes [] No []

Insert your ref
Insert our ref
enquiries
phone
fax
email

NAME
ADDRESS

**REQUEST TO REVIEW A STANDARD OPERATING PROCEDURE (SOP)–
{TITLE}**

Thank you for agreeing to review the enclosed draft Standard Operating Procedure titled “{TITLE}”.

SOPs are prepared to document a standard process of undertaking an activity to ensure consistency of practice and aggregation of outcomes. As such, review by relevant stakeholders is essential to ensure a SOP will be accepted and used in future activities.

Reviewers’ names will be kept confidential unless they indicate that this is not necessary.

We would appreciate your response by {Date}. However if you are unable to complete the report in that time could you please contact me.

Thank you once again.

Yours sincerely,

{NAME}

{BRANCH}

Date