Environment Protection Authority

Guide to Planning and Designing Trials in NSW

November 2025

Acknowledgement of Country

The NSW Environment Protection Authority acknowledges the Traditional Custodians of the land on which we live and work, honours the ancestors and the Elders both past and present and extends that respect to all Aboriginal people.

We recognise Aboriginal peoples' spiritual and cultural connection and inherent right to protect the land, waters, skies and natural resources of NSW. This connection goes deep and has since the Dreaming.

We also acknowledge our Aboriginal and Torres Strait Islander employees who are an integral part of our diverse workforce and recognise the knowledge embedded forever in Aboriginal and Torres Strait Islander custodianship of Country and culture.

Aboriginal artwork by Worimi artist Gerard Black

Contents

Purpose of this document

The *Guide to Planning and Designing Trials in NSW* ('the guide') is intended to be a resource for stakeholders of the NSW Environment Protection Authority (EPA) who are seeking to undertake a trial in NSW. It is not a statutory document.

For the purposes of this guide, a trial is a test designed to assess the performance of one or more variables objectively and robustly. This guide aims to help with the preparation of trial plans by outlining the factors to consider when planning and designing trials including, where relevant, NSW environmental regulation principles.

The information provided in this document is intended as guidance only. It does not take precedence over legislative or regulatory instruments, including environment protection licences, obligations under planning legislation, or specific requirements from the EPA. Following this guide does not guarantee that the EPA will approve a trial, where it is requested to do so.

Where a trial involves the EPA, we recommend you consult with us early in the process. This will ensure that any specific requirements for a trial are made clear before the trial starts.

- ***Section A*** of this document presents a standard format for designing a robust trial based on scientific principles. This can apply to a broad range of trial types and is not specific to the NSW environmental regulatory context.
- ***Section B*** applies the concepts introduced in Section A to the NSW environmental regulatory context. Please note that the guidance in this section does not cover all requirements that may apply when a trial is conducted under NSW environmental regulations.
- The ***Appendix*** includes practical tools to help with planning and designing a trial.

Part A: General guide to trials

1

Trials – an introduction

1.1 How the EPA expects this guide to be used

This document provides information on planning and designing a trial so that trial outcomes can reliably inform decisions. This document has no regulatory requirements or legislative powers. It is guidance only for the purposes of collating useful information in one place for the benefit of EPA stakeholders.

The information provided in Part A is the theory of designing a trial to meet the scientific standards of reliability, reproducibility and robustness. Part A is written as a reference document of key concepts and expects readers to conduct their own research if further theoretical information is required.

Part B is information on how, when and why trials are used for environmental regulation purposes in NSW by the EPA. This is not exhaustive information and is written to be generic to all trials that overlap with the EPA's authority. As such, it is strongly recommended that the EPA is consulted if a trial for regulatory purposes is being considered, planned or designed. Refer to section 5.4 for more information on contacting the EPA.

1.2 What is a trial?

A trial rigorously tests and evaluates strategies, technologies and/or processes so that questions can be answered using empirical data. A trial must be rigorous to ensure an idea, and its impacts, are characterised using sound evidence and risks can be appropriately identified and mitigated.

Trials may be undertaken to:

- collect data
- investigate if a proposed idea works as predicted
- investigate the validity and viability of a process
- determine effectiveness of operations and controls
- measure and assess emission performance of plant and equipment
- understand the technical feasibility of a technology
- test whether technologies can produce their intended results
- showcase feasibility to regulators and investors
- as part of an environmental improvement program
- demonstrate compliance with regulatory standards or licence limits.

In its most basic form, a trial is a demonstration of the performance, suitability and quality of a proposal. Trials rigorously test hypotheses using empirical evidence. They are typically limited by size, scale or duration and seek to understand how something behaves or responds under a certain set of conditions.

Well-designed trials can provide critical information relating to the effects of a change in the nature of an activity (e.g. change in operations, processes or systems) particularly where the impact of the change is uncertain or unknown. For example, they may be used to understand the performance, suitability or feasibility of new or updated equipment, technologies, products, control techniques or processes.

The typical stages of planning and designing trials are shown in section 7.2 of the *Appendix*.

1.3 Components of a trial

The basic components of a trial should be consistent with the scientific method. The scientific method is the standard approach to observing a phenomenon and drawing conclusions based on sound scientific evidence. It provides a reliable foundation for making decisions, formulating policies and advancing knowledge.

At a fundamental level, trials involve making observations, conducting research, developing hypotheses, experimenting, collecting data, completing analysis and making conclusions. Each of these components, and how they relate to trials, are discussed in Figure 1. The following sections give more detail on applying these components when planning a trial.

1	Observation	The process begins with observation and identifying a question, noticing a pattern, or identifying a problem that warrants further investigation.
2	Research	Now that an idea has been identified, the next step is reviewing the existing information on the idea. This may include a review of the existing literature or completed experiments to understand what is known and what gaps exist in the knowledge.
3	Hypothesis	A hypothesis is a clear, specific and testable statement about the relationship between variables. By subjecting hypotheses to trials, we can gather reliable data, analyse the results, and draw meaningful conclusions about the relationships between variables. Hypotheses are often constructed as 'if–then' statements, to understand cause-and-effect relationships.
4	Experiment	An experiment is designed and conducted to test the hypothesis. We discuss the components of conducting a trial in greater detail below. Simply, an experiment allows for multiple variables to be manipulated and measured to gather data. Any experiment should be conducted in accordance with a trial plan that has considered all of the components.
5	Data collection	Accurate and detailed records of the experimental data are collected. This may include quantitative and qualitative measurements. The data collected will be dependent on the nature of the experiment.
6	Analysis	Collected data is analysed to identify patterns, relationships and trends. Statistical methods may be required to determine the significance (how reliable the conclusions are) of the results.
7	Conclusion	Based on the analysis, the hypothesis can now be accepted or rejected. Where the outcomes will be used as proof of something to the public, the results should be recorded in a report and subject to peer review. Peer review means subject matter experts have evaluated the experimental design and validity of the conclusions drawn.

Figure 1 The basic components of a trial

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Planning a trial – general guidance

2.1 Observation and problem identification

A trial should aim to address a specific question or issue arising from real-world observations or problems. This step of the pre-trial preparation may occur informally and lead to formal trial preparation process. To set a trial up for success, it is important to clearly define the problem or question, consider the context of the issue, and undertake initial research to determine the scope of subsequent research.

Trials should be conducted in an unbiased way, align with scientific standards and seek to observe outcomes rather than to prove something specific.

2.2 Background research and literature review

Background research is an important step in the pre-trial planning phase. It helps to ensure that the trial aligns with the most relevant and up-to-date information on the trial subject. It can also help you decide if the trial is needed and viable.

Background research should include identifying and reviewing:

- past trials and projects
- site-specific conditions or constraints
- existing facilities and operations with comparable design features (e.g. inputs, infrastructure, processes, systems etc).

A review of existing literature is an important part of any background research. A literature review involves critical analyses of available information related to the trial subject. It can help to answer questions that the trial was intended to answer. The findings of a literature review can shape the trial's objectives and design. Literature review strategies can be sourced from research institutions and libraries or developed in consultation with experts.

Background research should be used to build a foundation of evidence and support for an idea or concept, and to identify gaps in the literature that the trial can address. Real-world examples of commercialised facilities or trials can be a powerful demonstration of proof of concept.

2.3 Trial objectives

Defining trial objectives is a critical step. **Clear, well-defined objectives** will help guide the entire trial process and provide **a basis for evaluating its success**.

The objectives should clearly and concisely describe the aims and goals of a trial, defining the scope for investigation. This can help inform the methods you will use and what data you should collect. It will also help you determine the relevance of information and data, when presenting results or communicating with stakeholders. Clear objectives help to align all stakeholders in their understanding of the purpose of the trial and measures of success.

In general, objectives should be:

- specific
- written in a clear, concise language that is unambiguous
- measurable and able to be evaluated using clearly defined metrics.

When setting objectives, you should be realistic about what can reasonably be achieved. You should consider the purpose of the trial and the key questions the trial intends to answer.

Once you have defined the objectives, you should consider whether a trial can answer the question(s). In other words, is a trial necessary to achieve the objectives? If you decide that a trial is necessary, and the objectives of the trial are clear, you can design the trial in a way that ensures the objectives are met.

2.4 Creating and testing hypotheses

A hypothesis is an educated guess or explanation that can be tested through experimentation or research. It must be testable and clear. A hypothesis is only accepted if the experimental data supports it.

A well-formulated hypothesis is commonly structured as an 'if, then' statement. This allows for the action and the expected outcome to be clearly linked. The statement should be clearly measurable and defined. For example, a well-formulated hypothesis might be: 'If the new filtration system is implemented, then particulate emissions will decrease by at least 20% compared to the current system.' A vague hypothesis might be 'the new system will improve air quality'.

When testing an idea or question, two opposing hypotheses are created: the *alternative* hypothesis (what you expect to occur) and its opposite, the *null* hypothesis – which is what is tested.

1. The alternative hypothesis

This is usually a statement of cause and effect. Suppose you are designing a trial to understand if adding a solvent will improve the total yield from a soft plastic recycling process. An alternative hypothesis might be:

If the solvent is added to the process, then it produces significantly greater (e.g. >10%) yield than the normal process.

2. The null hypothesis

A null hypothesis is the opposite of your alternative hypothesis. It is what you will **disprove** to accept the alternative hypothesis. In the example above, the null hypothesis might be:

If the solvent is added to the process, then it produces ***no significant difference*** *in product yield compared to the normal process.*

Therefore, if the results meet the standard of 'no significant difference' the alternative hypothesis must be rejected. Some basic examples of null and alternative hypotheses are shown in Table 1.

Table 1 Examples of alternative and null hypotheses

Alternative hypothesis	Null hypothesis	Information needed to reject the null hypothesis
Some swans are black	No swans are black	To observe one swan that is black
There is a correlation between hours of sleep and academic performance.	There is no correlation between hours of sleep and academic performance.	To observe a correlation between hours of sleep and academic performance.

2.5 Defining success

In the pre-trial planning stage, it is important to define the criteria that will be used to measure success, and how those criteria relate to the trial objectives. Defining success in this way helps to manage stakeholder expectations and clarifies the primary focus areas of the trial for the project management team. You can use this to identify the variables that need to be monitored and tracked to manage success.

Consider: *what are the specific, measurable outcomes that will indicate success or failure of the trial?*

The success of a trial can be measured in many ways and will depend on the perspective of the stakeholders involved in the trial. For example, the project manager may consider that a project is successful if it is completed on schedule and within budget. This measure of success provides no consideration to the project objectives. Other stakeholders may also have different views on project success. Where a trial is conducted appropriately and the outcomes of a trial lead to accepting the null hypothesis, this outcome may still be considered as a successful trial, because robust data has been collected and overall understanding has been enhanced.

The criteria used for determining success should be clearly defined, specific to the trial, unbiased and measurable. 'Unbiased' means choosing measurements that are observational rather than confirmatory (e.g. understanding the impacts of a process rather than trying to prove that impacts do not occur).

2.6 Trial scope

2.6.1 Project constraints

Project constraints are the limits within which the trial must operate. They will shape the overall design of the trial. The constraints may be related to many factors including time, resources, physical space, regulatory requirements and risks. Constraints should be identified early because they can have a profound influence on the viability of a trial design. Some potential constraints you may need to consider are listed below.

Regulatory constraints

- Can the proposed activities be lawfully undertaken on the site?
- Are regulatory and planning approvals required?
- Are there standards or regulatory limits you are required to meet?

Time constraints

- Does the trial need to be completed by a certain date?
- Does the trial depend on temporal factors (e.g. daily or seasonal cycles)?
- How long will it take to obtain necessary approvals?
- Where are materials coming from? What are the lead/lag times?

Resource constraints

- What labour is required? Are appropriately skilled and trained people available?

- How much will the trial cost? Are sufficient finances available?
- Can you source the required materials? Can they be sourced all year?
- Are sufficient materials available?

Risks

- Are there potential risks to human health and the environment?
- Are there risks to the business, including operations and reputation?
- What are the financial risks?
- Can the risks be mitigated?

Physical constraints

- Where will the trial be undertaken?
- Is there sufficient space available at the project site to conduct the trial and store input and output materials?
- Where is the project site located? (e.g. how far to travel to site, proximity to neighbours, etc.)
- Can the project site be accessed safely?

This list is not exhaustive as the constraints of a trial are dependent on its particular circumstances. A flow chart may be a useful way to map constraints.

2.6.2 Duration and scale

Trial duration: The duration of the trial should be defined, based on the expected and realistic time frame needed to achieve the trial objectives, and considering the constraints identified. The duration should align with the scope of the trial, the time needed for data collection and analysis, and the time necessary for approvals and decision-making.

Trial scale: Define the scale of the trial with respect to factors such as the geographical reach, the number of participants, and the extent of resources required. Tailor the scale to meet the objectives while considering the physical and logistical constraints and risks associated with the proposed scale (e.g. impacts of windblown dust from large stockpiles, site access and truck movements, incidents from an increased number of staff and contractors). Large trials may trigger the need to obtain approvals and licences from consent authorities and regulators (e.g. an environment protection licence from the EPA). You should consider this when deciding on the scale of the trial.

2.6.3 Trial environment

The trial environment should reflect the objectives of the trial. Choosing an appropriate trial environment depends on what the trial intends to achieve, what it intends to measure and what the hypothesis is. Depending on the nature and location of the trial, you may be required to seek informed consent from any communities who could be affected by the trial. This requirement is determined by the scale of the trial and the consultation requirements for relevant approvals and licences. To determine whether consultation is required, seek advice from the relevant consent authority.

The environment chosen for a trial depends on the objective of the trial. Common environments for trials addressing environmental questions are set out in the table below. There may not be a clear distinction between different trial environments and there may be some overlap between applications of the different trial environments listed.

Table 2 Common trial environments and their applications

Trial environment	Application
Modelling and simulation	Predictive models can be used to forecast the possible outcomes of real-world experiments. They help us predict how changes in one variable might affect others under real-world conditions. These models can take many forms, such as empirical, computer and mechanistic models.
Laboratory or benchtop	Laboratory trials are conducted under fully controlled conditions rather than in the 'real world'. The information from laboratory trials can: • be used to understand what might happen during full-scale operations • be used to demonstrate that risks and potential impacts can be mitigated and managed appropriately • reduce the chance of field trial failure, helping to save more money and time • provide information about experimental error and data variability.
Pilot-scale in controlled environment	Pilot-scale trials apply laboratory or benchtop outcomes at an increased scale in a controlled environment and are designed to simulate real-world conditions. This trial environment bridges the gap between laboratory scale and field/commercial-scale trials although it is not always a necessary midpoint.
Field	Field trials directly test how an idea works in live environments. The two sub-types of a field trial include: • Agricultural trials of interventions that provide benefit or other alteration to environments used for agricultural purposes. • Manufacturing trials looking at manufacturing processes including new processing technologies, material replacements, process optimisation, etc.

2.6.4 Stakeholders

Consultation with all relevant stakeholders should inform the design of the trial. You should consult both internal (staff) and external (contractors, investors, government, etc.) stakeholders that represent each critical component of the trial, because they are all integral to the success of the trial. Stakeholders for a typical project include:

- the project team (e.g. plant managers, coordinators, operators, technical specialists)
- overseers (e.g. plant owners, people leaders, investors)
- technology providers
- consultants (e.g. sampling, planning, engineering)
- subject matter experts or scientists
- regulators (e.g. NSW EPA; NSW Department of Planning, Housing and Infrastructure; local council)
- data collection team
- data analysis team.

You should clearly define the roles and responsibilities of all key stakeholders. All the specific aspects of the trial for which they are responsible should be identified and agreed to. You should also identify reporting lines and provide clear guidance on how decisions will be made.

Stakeholders may have different views on the purpose and objective of a trial. They may also have different expectations of what the trial aims to achieve, and the definition of success, based on their interest and level of involvement in the trial. For this reason, it is important that you make clear the objectives of the trial.

3

Detailed trial design

3.1 Operating and process conditions

All key operations and processes involved in the trial should be identified and described. This will help to identify potential risks and indicate likely sources of variability and uncertainty, which can be used to determine which parameters to monitor.

At a minimum, the process description should:

- describe the type of processes involved (e.g. physical, chemical or biological)
- identify the key plant, machinery and control equipment used
- outline the expected operating ranges, including baseline operating conditions.

If you are using innovative and/or new technologies, you may need to provide more detailed descriptions than for more traditional or well-understood technologies.

A flow diagram is a useful way to trace the process from beginning to end and show all inputs, outputs and processing steps.

Inputs: The plan should describe all material inputs and, where applicable, the energy inputs. Any environmentally significant characteristics of material being processed should also be described. For certain material types, it may be necessary to identify or describe the source or origin of the materials.

Outputs: The plan should identify and describe the expected outputs likely to be produced during the trial. Outputs may refer to both the products and by-products of the process. Products are the product streams intentionally produced. The quality, consistency and composition of the product should be defined to ensure the desired outputs are being achieved. By-products are secondary products that are produced unintentionally or incidentally: they may include, emissions (air, water, noise etc.), residues, effluents and wastes.

Control environment/baseline data: Establish the control environment to ensure a baseline for comparison. Define the conditions under which you will run the trial and identify factors that may impact the outcomes.

3.2 Data selection

When designing a trial, it is important to identify what the data collected during a trial may be used for and how it relates to or helps achieve the trial objectives. For example, data may be used to:

- confirm baseline levels
- measure changes in operations or emissions
- understand range and variability
- demonstrate compliance
- improve system understanding (cause and effect)
- satisfy regulatory obligations (e.g. emission limits)
- evaluate effective responsive management of controls or mitigation measures (e.g. management of dust from fugitive sources, noise impacts, odour, clean-up of leaks and spills, remediation of contamination).

A common mistake made when collecting data involves failing to collect the correct type and quantity of data required to sufficiently answer the question posed (the objective). For example, for the listed uses above, different data will need to be collected, requiring diverse and tailored monitoring approaches.

To help identify the data required for your purposes, you should consider the following:

- What will the data be used for?
- Which parameters need to be monitored?
- What type of data is needed and how frequently should it be collected?
- How much data is needed, over what time period?
- What factors might affect data collection (e.g. physical limitations such as the distance from laboratory, safety, variable operations)?
- What equipment and technology are needed to collect the data?
- How will you store, manage and access the collected data?
- Who will be collecting, reviewing and processing data?
- What quality assurance and quality control procedures will you need to ensure data quality?
- How will the data be displayed and reported?
- What special skills and/or training will be required?

For further detailed guidance on how to identify the type, quality and quantity of data needed, refer to US-EPA QA/G-4 – *Guidance on Systematic Planning Using the Data Quality Objectives Process*.[1]

3.2.1 Data analysis plan

The methods used for analysing collected data need to be considered at the early planning stages of the trial. They may be informed by the types of data collected, the amount of data and the hypotheses you are testing. Considering the data analysis methods early will help you design the monitoring strategy.

Having a clear understanding of why you are collecting the data will help you design the sampling program and the subsequent data analyses. You should establish a robust plan for data analysis which defines the statistical methods, tools and techniques you will use to interpret the collected data and draw meaningful conclusions.

3.2.2 Measurement variables

Measurement variables are the variable components of a system that will be monitored and analysed during a trial. They should be well defined prior to beginning a trial.

Investigating the relationships between the measured variables will help to understand whether their interactions are causal. Causal relationships are interactions between two or more variables

[1] U.S. Environmental Protection Agency (EPA), *Guidance on Systematic Planning Using the Data Quality Objectives Process* (EPA QA/G-4) (2006). Available at https://www.epa.gov/sites/default/files/2015-06/documents/g4-final.pdf

where changes in one variable (the cause) directly influence or produce changes in another variable (the effect).

See section 4.3.2 for more information on the difference between causation and correlation.

When defining the measurement variables, you should identify which are **dependent variables**, **independent variables**, or a combination of both:

- An **independent variable** is the factor or condition that is changed in an experiment or trial to understand how it affects something else. The 'something else' is the dependent variable.
- A **dependent variable(s)** is measured during an experiment or trial to capture change as something else is altered. The dependent variable 'depends' on the independent variable.

Examples of dependent and independent variables include:

1. Plant growth experiment. Dependent variable: plant height. Independent variable: amount of water.
2. Study effort and performance. Dependent variable: test scores. Independent variable: hours studying.
3. Fertiliser in agricultural settings. Dependent variable: crop yield. Independent variable: fertiliser use.

3.3 Data collection methods

Data collection methods are most effective when a robust plan is in place to ensure the type, frequency and quantity of data collected is appropriate. Depending on the trial design, data may need to be collected continuously, at regular time intervals (sub-hourly, hourly, weekly, etc) and/or at certain progress points (trial stages).

The data being collected should effectively represent what is done during the trial and address the hypotheses that are being tested. It can be important to consider collecting as much data as possible as it may not always be obvious what information is necessary to accurately describe the outcomes until the trial is under way. To capture the right data, think about how to represent:

- measurement ranges and scales
- spatial and temporal variation
- frequency of data collection
- number of samples
- type of monitoring (continuous, periodic, etc.)
- process type (e.g. batch, continuous, one-off).

The approach used to collect the required data should consider aspects such as sample size, repetition of trials, sampling locations and timing. Considering these components in your approach helps to provide confidence that the conclusions drawn from the data are accurate and representative. A detailed, site-specific sampling plan should be used to describe all aspects of the data collection methods.

3.4 Monitoring and measurements

The approach used for monitoring and measuring data during a trial will depend on the purpose and aims of the trial. Monitoring is crucial in any trial, and it is important to carefully design a monitoring strategy so that it captures key system components. You will need to think carefully about the design of the program, the data it will generate, and how you will use the data.

A monitoring strategy should be fit for purpose and allow for meaningful interrogation and interpretation of the data for downstream decision-making. The frequency of sampling and monitoring locations should be sufficient to characterise the nature of the operations, including any temporal and spatial variability.

A well-designed monitoring network should include a feedback system that allows the data to be used to inform the next stages of the trial, and/or to identify emerging issues, so that the trial design and mitigation strategies can be adjusted as necessary.

Measurement is used to determine the actual value of the characteristics of something (e.g. mass, volume or concentration). Measurements can be used to compare values against specific limits and standards. For example, measurements might be used to understand the concentration and composition of fuel and emissions of pollutants. Some data, such as specific pollutant emission concentrations, can only be determined by measurements.

Monitoring is related to observing, recording and detecting. It may be qualitative or quantitative and is used to understand how a system is behaving or performing. For example, you could use monitoring to determine if a process is starting to approach an operating or licence limit (e.g. air emission limit, processing rate limit, temperature limit) or operating outside normal conditions.

3.5 Sampling plans

The approach used for monitoring and measurements should be detailed in a site-specific sampling plan. This plan should describe all aspects of a monitoring program. The contents of the sampling plan will serve as the foundation for the trial report.

The sampling plan should address the factors that will be controlled to ensure a representative sample is collected. Sampling plans should be based on good environmental monitoring practices and be prepared in accordance with applicable published standards, methods or guidance. Wherever reasonable, sampling plans should also be based on appropriate statistical methods.

At a minimum, you should consider and account for the following matters when developing a sampling plan:

- What is the purpose/objective of the sampling?
- What data needs to be collected and why? (See section 3.2.)
- Which sampling strategy will be used, including
  - where, when and how samples will be collected
  - what sampling methods will be used
  - how many samples will be collected and at what frequency
  - who will be conducting the sampling, and are they appropriately trained/accredited

- How will samples be handled, transported and stored?
- What records need to be made and retained? (See section 3.5.3.)
- How will records be managed and secured? (See section 4.1.)
- What process conditions (e.g. high load, batch process, product type) are being tested?
- What factors (e.g. variability, timing, interferences) might affect the sampling?
- What measures will be used to ensure the integrity, accuracy and representativeness of the sampling?

All sampling and analysis should be conducted by appropriately trained and certified people and accredited facilities.

Prior to sampling, it is important to consider how the measured data will be used and what levels of detection are required. For example, for comparison against guideline values, regulatory limits or detecting a change in key variables. The sampling approach should aim to achieve a minimum level of detection of the measured substance(s) at the same sensitivity of the set value it is being compared to. For example, when comparing against a limit of 0.05 ppm, aiming to achieve a method sensitivity of 0.01 ppm may be appropriate.

When designing the sampling approach, you should consider the expected concentration of analyte you are sampling for, the sensitivity of the method you are using, and the achievable detection limits. You can contact an analytical laboratory for an estimate of the achievable *limit of reporting* (LOR) per sample (another term for the LOR is the *practical quantification limit* (PQL)).

The LOR is the smallest concentration of an analyte that a laboratory can confidently report. You should consider the achievable LOR before sampling to ensure that you collect sufficient samples to reach the LOR. When reporting data that is below the LOR, the actual LOR should be reported (e.g. <0.01) rather than simply saying '<LOR' or something similar.

The methods used, monitoring locations, sample size, sampling duration and sampling frequency will depend on the nature of the process you are investigating and the data required to achieve the objectives of the trial. Sampling timing and duration should be appropriate for the operating processes and behaviour of the plant. For example, processes may be continuous (constant), continuously variable or batch processes. You can use the results of preliminary studies, desktop investigations and modelling, where these are available, to inform the sampling strategy.

Note: When the trial must conform with a standard or regulatory requirement, the standard or regulatory instrument may define the minimum frequency of sampling, the sampling duration and the sampling method.

3.5.1 Accounting for variability

To ensure that the data collected during a trial is representative of the process you are investigating, you should design the sampling strategy to account for data variability. Many factors can cause process variation. They include:

- heterogeneous mixtures of materials
- process conditions (e.g. insufficient mixing)
- changes in site profile or landform (e.g. dispersion of chemical contaminants)
- batch processes or intermittent operations; changing inputs or material suppliers

- time dependence (e.g. diurnal or seasonal effects).

The degree of variability (e.g. low, medium, high – see Figure 2 below), and the associated effects, will depend on many factors specific to the system you are investigating.

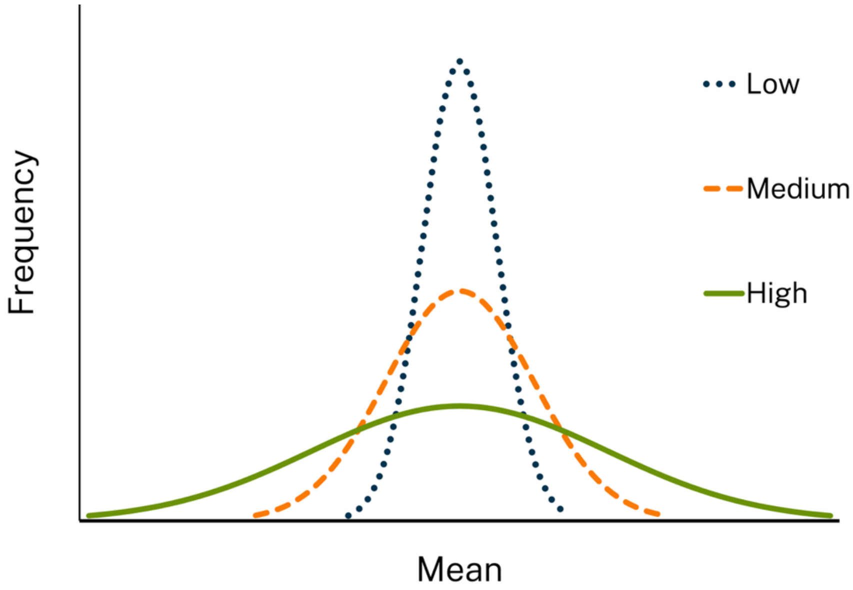

Figure 2 Data variability example graph. Source: EPA

Identifying and anticipating variation can help to tailor a sampling program to ensure you collect data over the range in which a system or process operates. Therefore, when planning the sampling program, you should have some understanding of the actual or expected spatial and temporal variability of the measurement parameters.

Note: Generally, the more variable a process or system, the more frequently it needs to be monitored. You should consider continuous monitoring systems where a process varies so frequently and significantly that intermittent sampling would be unrepresentative.

Understanding variability is also critical to analysing and interpreting data. For example, data that is averaged may not accurately reflect the actual range and intensity of a measured parameter.

Example: It is understood that air temperature typically varies over a 24-hour period. A sampling program used to monitor the variation in temperature should be designed to capture data over the 24-hour period. Sampling for less than 24 hours would not accurately capture the variability.

3.5.2 Sampling quality assurance

The sampling quality assurance (QA) and quality control (QC) measures are those activities used to ensure data collected via the monitoring strategy is reliable and representative. Before you begin collecting data, you need to determine how you will ensure it is accurate, precise and valid. Quality objectives should be specific, measurable and relevant.

QA typically refers to the steps taken to maintain the quality of a sampling program. It is used to assess, control and improve the quality of data. For example, you might use QA procedures to describe how you will undertake monitoring. These steps could include documenting your procedures, training staff, monitoring design, managing and analysing your data, and implementing specific QC measures.

QC describes how the validity of specific sampling and analytical procedures are determined. QC options for a monitoring program might include field blanks, duplicate samples, lab replicates, calibrations, maintenance, audits, spiked samples etc.

The sampling plan should describe all QA/QC procedures in detail.

3.5.3 Sampling records management

The sampling plan should describe what records you will retain and how and where you will store them. Records required to be retained as part of a sampling program typically include:

- sampling and analytical reports
- process and operational data
- details of any factors, conditions or interferences that may have affected the monitoring results
- field data sheets/logbooks
- calculations (e.g. spreadsheets or workbooks)
- details about the sampling and analysis methods used
- calibration records for equipment used.

3.6 Risk management

An essential aspect of any trial plan is to properly identify and assess the risks associated with the trial and nominate adequate mitigation measures. This guide focuses on the risks posed to human health and the environment during the trial. However, you should also consider broader risks, such as operational risks, that might affect your ability to carry out a trial. Discussion of operational risks is outside the scope of this document.

When planning a trial, the health and safety of people is a critical consideration, there are legal obligations under work health and safety laws. Guidance on work health and safety is outside the scope of this guide. For matters relating to workplace health and safety in NSW contact SafeWork NSW (www.safework.nsw.gov.au).

The approach used for assessing and managing risks should be robust, fit for purpose and specific to the proposed trial. At a minimum, you should consider the information provided under sections 3.6.1. to 3.6.3. when developing a risk management strategy.

3.6.1 Identifying risks

The aim of this step is to critically review all components of the trial and identify any potential risks. For example, you may consider:

- the type of activities you will undertake and the associated hazards
- the size, scale of operations and the duration of the trial
- the characteristics of materials used
- where activities are occurring
- who will be involved in the trial
- the complexity of the trial project and associated risks.

3.6.2 Evaluating risks

It is important that you evaluate the risks associated with a trial, including the likelihood and severity of harm occurring. To do this, you may need to assess elements of the surrounding environment. For example, you may need to consider potential for impacts to neighbouring dwellings and occupants, land and water resources and air quality.

The risk assessment should include information about:

- the circumstances or events that could lead to any hazards occurring
- the potential impacts if the hazard occurs, (e.g. impacts on environment or human health, product quality, reputation)
- the likelihood of hazards occurring. This may be expressed using a risk matrix (consequence versus likelihood) to rate the hazard from low to very high
- management or mitigation of the risks.

Example: A trial involving odorous materials should consider the likelihood of any impacts on neighbouring facilities throughout all stages of the trial and associated activities (such as receiving, storing, handling and processing the odorous materials), as well as emissions from any waste by-products.

3.6.3 Risk mitigation

A risk management plan should include details on how you will mitigate risks. You need to show that the management practices implemented during the trial will minimise identified risks as far as practicable. Risk management plans answer questions such as:

- How will you prevent the release of contaminants to the environment if the system does not perform as expected?
- Are the controls appropriate for the emission source, considering the composition and concentration of contaminants?

Additionally, a risk management plan should identify triggers for halting the trial. For example, where a change occurs or where an outcome is different than expected.

A risk management plan should:

- include both proactive and reactive measures for identifying and responding to risks. Nominated triggers and corresponding actions should be clear, auditable and measurable (where practicable)
- establish clear and effective communication and action procedures to ensure the right people are notified, warned and quickly provided with the information they may need to act appropriately.

The ‘right people’ include:

- people who may need to be involved in incident responses
- staff (management, environmental, operations, etc.) at the premises
- EPA staff
- other relevant authorities (Department of Planning, Housing and Infrastructure; Fire and Rescue NSW; NSW Health; and local councils)

- industrial, commercial and residential neighbours, and other members of the community.

The plan should also:

- identify properly trained staff
- ensure incident management information is up to date and accessible
- include an outline of the safety management systems you will adopt and a commitment that you will develop a comprehensive safety management system before the trial starts
- describe how you will handle materials and manage stockpiles, including planned storage and containment and the associated monitoring measures used to prevent pollutants such as odour, vapour, dust and leachate migrating from the stockpiled materials.

3.6.4 Risk assessment

A typical risk assessment should include, as a minimum, the following.

Risk identification and assessment

- Identify hazards associated with the proposed trial.
- Describe the circumstances or events that could lead to the hazards occurring.
- Assess the likelihood of hazards occurring.
- Identify potential for discharges of pollutants to air, water and land.

Mitigation and controls

- Identify and evaluate options to avoid, mitigate or control impacts.
- Describe how risks remaining after mitigation will be addressed.

Management measures

- Describe proactive and reactive procedures for identifying and responding to incidents.
- Propose measures to track and assess risks, including monitoring, sampling, observing, reviewing and reporting.
- Describe training, certification or assessment requirements.

Waste management

- Identify the types of wastes and by-products the trial is likely to produce.
- Detail the waste management plan for the trial (transport, storage, land application, etc.).

Predicted impacts

- Assess the scale and nature of likely impacts, including cumulative effects.
- Identify sources of emissions and types of release.
- Identify nearby receptors and places likely to be impacted.

4

Data management and reporting

4.1 Record keeping and documentation

Accurate records are essential for providing evidence about how a trial is being run, how the operations are performing, and for capturing any unpredicted outcomes. Accurate records are also needed for replicating and reporting results and demonstrating compliance. Accordingly, records management is a critical component of any trial. You should record all data and information generated or collected during a trial (including unsuccessful/abandoned trials) and maintain those records, ideally in a digital format.

All records should be saved in multiple locations to prevent loss. A general rule of thumb is that if data is not saved in at least three locations, it is not safe. Records can be stored in a variety of forms, such as written documents, electronic files and databases. If data is transformed during statistical analysis, you should keep records of both the raw and transformed data.

Any data necessary to show compliance against a regulatory requirement should be retained in whatever manner and for whatever length of time required by the specific legislative instrument.

Activities that generate records might include:

- operational and process monitoring
- emissions monitoring
- corrective actions
- incident and emergency responses
- training
- research and development
- assessment of the system performance
- community consultation
- performance evaluations, audits and reviews.

4.1.1 Data security

Data security must be properly managed to avoid risks to information collected throughout the trial such as unauthorised access, modification or destruction.

You need to protect data while still maintaining reasonable availability and access. This will require you to appropriately assess and manage data security risks and develop and implement appropriate solutions. The solutions should be implemented at the start of the project and used throughout the trial. The solutions should also be regularly reviewed to ensure they remain fit for purpose.

4.2 Data analysis

Data analysis is an integral component of the trial process and should be performed using appropriate methods, procedures and statistical techniques. Data should be summarised and presented in a format that allows it to be accurately analysed.

Suitable methods of data analysis should be used to assist with the interpretation of results. Choose the method according to the objective of the trial and, the type and quantity of data collected. There are various methods, techniques, and software packages available for performing data analysis.

Discussion on different methods of data analysis is outside the scope of this guideline. We recommend you seek independent advice on statistical analysis techniques for your data analysis if needed.

Before the data is analysed, you need to decide how you will treat certain data types. For example, data analysis, and the conclusions drawn from it, can be greatly influenced by:

- **Missing data**. This can occur for a variety of reasons including sampling error, instrument failure, power loss or plant shutdowns. All missing data should be investigated, noted and explained.
- **Outliers**. These may occur due to variations in processes or sampling, or transcription errors. If undetected, this data can have profound effects on statistical analyses and can lead to incorrect conclusions and flawed decision-making. Outliers should be investigated, not dismissed. During a trial, outliers may provide insight into critical aspects of the system being investigated.

4.3 Interpreting results

Collected data should be reviewed within appropriate time frames, and compared with previous results, established guideline values, and any regulatory requirements (where applicable). The systematic review of monitoring results helps to:

- assess overall performance against established criteria
- identify emerging problems and trends
- understand how a system/process behaves
- demonstrate compliance
- reduce uncertainty
- identify biases or errors
- help determine priorities for improving processes
- inform the next stage of the trial.

An independent peer review can help you evaluate results and assess the trial's outcomes against its objectives.

4.3.1 Data visualisation

Visualisation is useful for data analysis. While tables are necessary to record the data, it is usually very difficult to identify patterns in tables of numbers, particularly for large datasets. Visual displays (e.g. graphs) can present complex datasets simply and concisely. Plotting data can help reveal outliers or unusual results and identify patterns. Visual displays can reveal more than the statistical properties of a dataset can on their own. When choosing how to visually display data, it is important to consider why the data was collected and the intended audience. The visualisations used should best represent the variables of interest.

Figure 3 exemplifies how data visualisation can help with data interpretation and analysis. The pie chart makes it difficult to determine the actual contribution of each country or how the countries compare with each other, whereas the bar graph clearly shows the values and the scale of the differences.

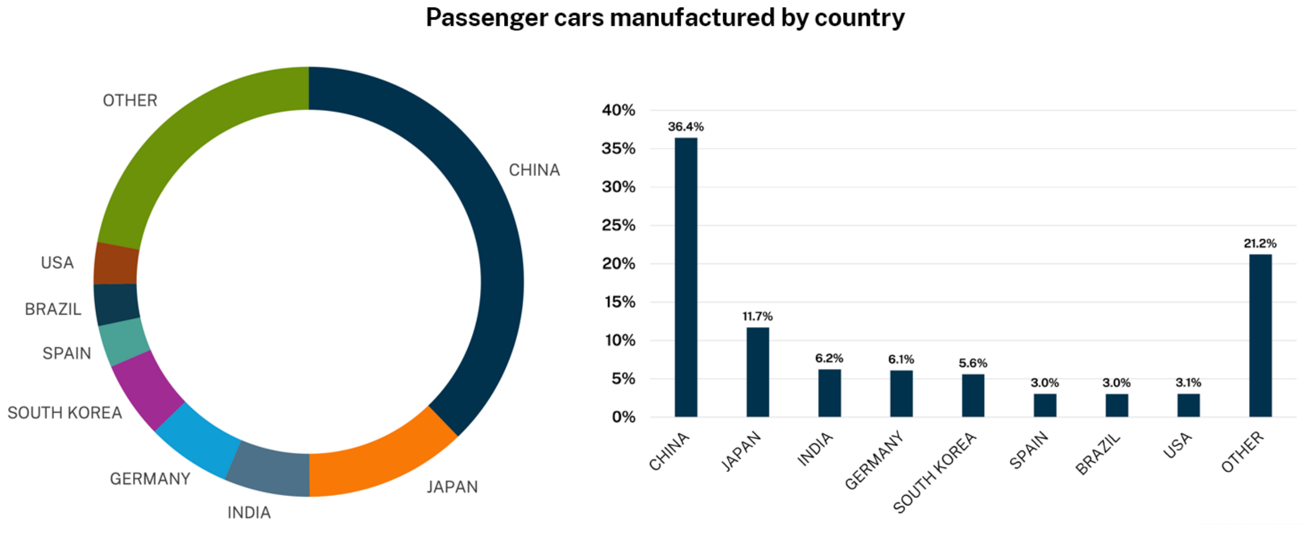

Figure 3 Different options for data visualisation. Source: EPA

4.3.2 Identifying causation and correlation

During a trial, distinguishing between causation and correlation is essential for drawing accurate and meaningful conclusions.

Identifying **causation** involves establishing a direct cause-and-effect relationship, where changes in one variable led to corresponding changes in another. A rigorous experimental design, that includes randomisation and controlled conditions is essential to isolate the impact of the independent variable. Please note that this is not a simple exercise and can demand a high level of resources to achieve.

Correlation indicates a statistical association between two variables, but it does not imply a cause-and-effect relationship. Trials should employ robust statistical analyses to differentiate between coincidental relationships and those that signify a genuine cause-and-effect link. Proper controls, randomisation, and consideration of confounding variables are essential to ensure that observed correlations are not misleading. The EPA strongly recommends that you seek statistical expertise, if your organisation does not have these capabilities in-house.

Figure 4 illustrates how correlation can be incorrectly interpreted as causation. The two datapoints seem to match one another, suggesting a relationship between the two variables. However, no causal relationship can be drawn from this data alone.

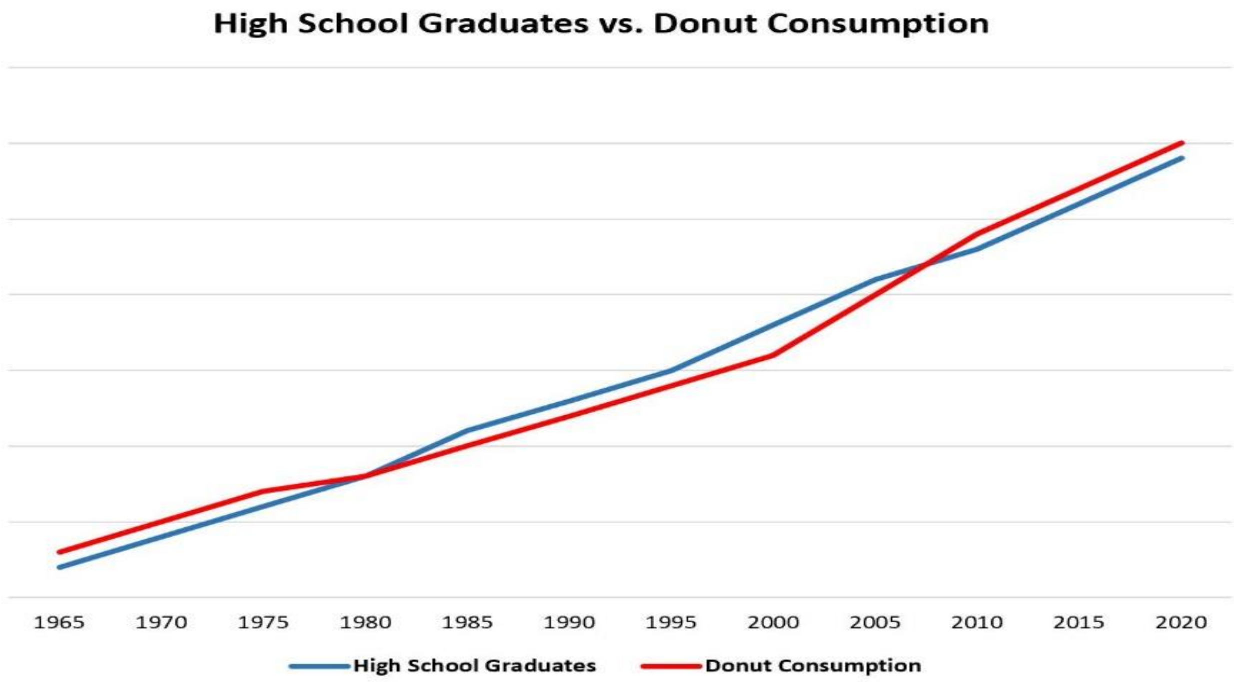

Figure 4 This graph incorrectly associates two variables that have no direct causal relationship because of the similar shape in data distribution. Source: https://www.statology.org/spurious-correlation-examples/

By rigorously addressing causation and correlation, trials can provide reliable insights into the effectiveness and implications of interventions, contributing to a detailed understanding of system behaviour and evidence-based practices.

4.3.3 Data quality

Running trials and collecting data can be expensive, time-consuming and resource intensive. It is therefore important that formal QA/QC procedures are followed to ensure the integrity of the collected data (see also 3.5.2).

A good QA/QC program for data analysis uses simple yet effective statistical tools for screening data. This could include a mixture of graphical (histograms, boxplots, time sequence plots, control charts, etc.) and descriptive (mean, standard deviation, coefficient of variation, etc) tools that summarise the dataset and extract important information such as relationships and variability.

A trial may involve acquiring data from external sources (i.e. not generated by you). Data from external sources may be incomplete, outdated or inaccurate. You should verify that any data you use is reliable, accurate and complete.

All data processing and analysis should be undertaken carefully. Graphs, tables and reports should be checked for completeness and accuracy. Mechanisms for evaluation of results should be documented, with responsibilities, accountabilities and reporting requirements defined.

The treatment of 'unusual' observations or 'outliers' should be consistent, documented, and based on sound analytical techniques. Care needs to be exercised in the labelling and treatment of potential outlying observations.

4.4 Conclusions and reporting

Reporting includes the internal and external reporting of information pertinent to the trial. Accurate, timely reporting supports effective decision-making.

The results should be discussed in the context of the objectives of the trial. The interpretation of results should be concise, expressed in non-technical terms and supported by the data. Visualisation methods, such as graphs or trend charts, should be used to support interpretations and conclusions.

Trial reports should include summaries of monitoring data, performance evaluation and any significant operational problems that occurred during the trial. The results should be presented in a concise statistical summary. The report format will depend on the nature and purpose of the trial and the stakeholders you are reporting to. While there is no specific ‘template’ for reporting trial results, there are traditionally accepted styles for reporting and essential elements you should include. Below is a typical format.

An executive summary that expresses the technical findings in relation to the objectives of the trial, succinctly and in plain English.

An introduction, clearly stating the trial objectives, with reference to previous trials or related trials (where applicable)

Project overview, describing:

- the trial location and design
- the duration of the trial
- scope of works
- all sampling and/or monitoring locations including any schematics, diagrams or photos
- methods of sampling and analysis
- operations and process conditions.

Results — descriptive and detailed presentation of results, including, but not limited to:

- meaningful summaries of results
- overview of the data analysis methods used
- description of the QA/QC procedures used to ensure the integrity of the data
- discussion of the results
- data interpretation and implications for management
- comparative assessment against regulatory limits or standards.

Conclusions drawn from the results.

Recommendations for future work

Reference details for literature cited in the report.

Appendices, for information that is too detailed or distracting to be included in the main body of the report, such as analytical reports, chains of custody, maps, reports, data tables etc.

Part B: Designing and planning a trial in NSW

5

Regulatory context

5.1 Role of the NSW EPA

In NSW, the EPA is the primary environmental regulator. Our statutory role includes protecting, restoring and enhancing the environment and reducing risks to human health in NSW.

The EPA pursues effective environmental stewardship by reducing the discharge of substances likely to cause harm to the environment to harmless levels. Any proposed trial must therefore show that it poses minimal risk of harm to the environment and human health.

Trials provide essential information regarding the level of risk associated with activities, and the necessary mitigation measures required to ensure the safeguarding of the environment and human health, before they are implemented at larger scale. Therefore, information gathered during a trial is important to the regulatory decision-making process.

This section of the guide sets out the information and evidence the EPA typically needs for decision-making, and which you should consider when designing a trial.

The typical stages of planning and designing trials appear in a flow chart in section 7.2 of the *Appendix*.

5.2 Understanding your regulatory obligations

The key legislative instruments governing activities affecting the environment include the *Protection of the Environment Operations Act 1997* (POEO Act), the *Contaminated Land Management Act 1997* (CLM Act) and the *Environment Planning and Assessment Act 1979* (EP&A Act). Note that the EPA does not administer the EP&A Act.

It is important for those seeking to undertake a trial in NSW to be aware of, and comply with, all applicable laws, including environmental and planning laws. You are responsible for identifying applicable legislative requirements and for designing the trial to comply with those requirements. You must clearly identify all applicable standards, specifications or limits that will affect the trial, or that the amended process will need to comply with. For example, section 128 of the POEO Act makes it an offence to exceed standards of air impurities.

Where approval to undertake a trial is necessary, the approval may be subject to conditions (see section 6.5). For example, approval conditions may specify that environmental management strategies be developed, implemented and maintained for the duration of the trial period. All conditions must be complied with throughout the trial period.

Some of the legislation broadly applicable to trials is listed in the 'frequently asked questions' (FAQs) webpage for this guide. Please refer to the FAQs for more information or contact the EPA to learn more about any specific regulatory obligations. However, the EPA is an independent regulator and does not perform the services of, or negate the need for, a suitably qualified consultant or legal adviser. We cannot provide legal advice relating to your proposal, and we encourage you to seek such advice regarding your regulatory responsibilities.

5.3 Requesting a trial

Trials may be requested for various reasons and the nature of the request will depend on the process and/or material, the business activity, the industry, and the potential environmental impacts associated with proposed activities (e.g. remediation of contamination). Either the EPA or proponents (individuals and corporations) can request a trial. The way you can request a trial will depend on whether you hold an environment protection licence (EPL) or not, as discussed below:

EPL holders

If you are an EPL holder and want to request a trial, you will need to check your licence conditions, to see if they allow the trial. If they don't, you will need to seek a variation to your EPL to allow you to undertake the trial. See the EPA's Guide to Licensing. If you are still unsure after checking that guide, contact us.

Others

If you do not hold an EPL, you must find out if you need an EPL before you start the trial. See the EPA's Guide to Licensing. If you are still unsure after checking that guide, contact us.

Considerations for both

Anyone planning a trial should determine at an early stage whether they have all necessary planning approvals from the relevant consent authority (or authorities). Seeking confirmation from the consent authority early in the process will help to identify what approvals are necessary. The consent authority can advise you about the development consent procedures, modifications, and the application of the EP&A Act. Note that a trial that triggers the need for consent from relevant authorities must have consent in place before the trial starts.

To undertake a trial on a premises, you may need to obtain permission from the landowner. You may also need to engage or consult with the community around your facility, to inform it of the proposed trial and any associated risks of impacts, or changes in the nature or scale of operations.

Applicants seeking to undertake a trial in NSW should also ensure that the proposed trial aligns with broader EPA and NSW Government regulatory schemes and policies. For example, any trials proposing to re-use waste will need to comply with the EPA's resource recovery framework. Please refer to the resource recovery orders and exemptions webpage on the EPA website.

5.4 Contacting the EPA

Once you have determined the scope and objectives of the trial, it is important to contact the EPA to discuss the trial design, any necessary approvals, and the supporting information you should prepare. Before you meet with us, you should do all necessary background research (see section 2.2). This will ensure that you consider contemporary knowledge when designing the trial and that the concepts being trialled are technically feasible.

You can contact the EPA via Environment Line: 131 555 (NSW only) or info@epa.nsw.gov.au. See also www.epa.nsw.gov.au.

To **discuss planning requirements** with the relevant authority, contact your local council or head to planning.nsw.gov.au.

Before you contact us, consider the following questions

- Do I need an EPL to conduct this trial?
- Does my EPL cover the activities I intend to undertake during the trial?
- Do I need to apply for a licence variation to conduct the trial?
- Do existing EPL conditions need to be altered to facilitate the trial?

Things we will want to know about your proposed trial

Overall

- Who is undertaking the trial?
- What are the objectives of the trial?
- Where and when will you be undertaking the trial?
- Do you have all necessary approvals from the relevant consent authority for the proposed trial to be lawfully undertaken at the proposed premises? (See section 5.3)

Processes and procedures

- What activities/processes/treatments will be performed/used during the trial?
- Will the trial follow an established procedure?

Materials

- What materials will you use during the trial?
- Have the materials been analysed and/or characterised?
- How much material will be used?
- Where will the material come from?
- What will happen to any product or waste arising from the process?
- Can the material be lawfully accepted, stored and processed at the premises?

Risks

- What risks are associated with the trial activities?
- What controls will be put in place to mitigate risks?

6

Planning a trial

6.1 Information requirements

During the early phases of planning a trial, you should discuss the purpose of the trial with all relevant regulatory bodies (e.g. NSW Department of Planning, Housing and Infrastructure, local council and/or the EPA). This will help to determine whether approval for a trial is necessary, what regulatory requirements you will need to comply with, and the type of information that should be collected during the trial.

The information needed to support a proposal for a trial will depend on the specific details of the proposed trial and level of risk involved. We recommend you discuss your proposed trial with us while you are still in the planning stage (see section 4.7).

While we may ask for some information specific to your proposal, there is fundamental information needed to support all proposals. You should, at a minimum, provide:

- an overview of the trial
- a statement of the purpose/objectives of the trial
- a detailed trial plan (see section 6.2 and the *Appendix*)
- all information, data and evidence necessary to show why you are proposing the trial
- copies of all referenced sources
- copies of all necessary approvals and permissions to confirm the trial can be carried out lawfully
- a description of the materials that will be used and how they will be handled, including
  - how much material will be used
  - where you will source the materials
  - how you will transport, store and process the materials
  - how you will deal with any waste products or outputs
- a fit-for-purpose risk assessment that clearly identifies the risks and associated controls, including
  - the pollution caused or likely to be caused by carrying out the proposed work
  - a characterisation of the material inputs
  - the likely impact of that pollution on the environment
  - practical measures you could take to prevent, control, abate or mitigate the pollution and protect the environment from the impact of that pollution.

You must supply accurate and representative information to support your application. A person who supplies false or misleading information to the EPA within an application may be guilty of a serious offence. If you provide false and misleading information, appropriate decisions about risk cannot be made, and this has the potential to adversely impact human health and the environment.

6.2 Trial plan

Pre-trial planning is critical to the success of a trial. A trial plan outlines the trial design and purpose of the trial. The EPA regards a comprehensive and well-structured trial plan as an invaluable tool for any project, as it provides clarity of purpose and describes a transparent, auditable approach for conducting a trial.

The level of detail included in a trial plan should reflect the size, scale and risk of the proposed trial. In general, as the scale, intensity or risk of a project increases, the trial plan should become more detailed. See the *Appendix* for a trial plan design template.

A trial plan is not a regulatory requirement for undertaking a trial; however, we may ask you to prepare one. A trial plan will:

- show you have considered how to manage risks
- make the trial more likely to succeed
- give the EPA greater confidence that the trial will be undertaken in a controlled, coordinated manner
- help you communicate with various stakeholders, including the community, about the trial and its associated risks. This raises community awareness and buy-in.

The *Appendix* includes an example of a design template for preparing a trial plan.

6.2.1 Trial scenarios

When planning a trial, you should consider how the data obtained during the trial will be used. We may use the data in future licensing decisions. If the data collected during the trial is of insufficient quality or quantity, is incomplete or is unrepresentative, it may not be suitable for decision-making. We may require additional information to support or supplement the data collected. You may need to run further trials to collect the necessary data.

For example, if you intend to use the data to support a request to transition from a trial to an ongoing activity, the EPA will consider the data obtained during the trial when setting EPL conditions relating to the operation and environmental performance of the activity. The conditions will probably reflect the operating scenarios and level of performance achieved during the trial. You should therefore design the trial so that it generates data that covers the anticipated range, scale and design of the plant or process under all expected future operating conditions.

Example: Facility A proposes to alter the mix of materials used in its manufacturing process. The new mix will contain an amount of product Y. The facility undertakes a staged trial to test the new mix, where the proportion of product Y used was 10%, 20% and 30%. After successfully completing the trial, Facility A applies to vary its EPL to allow the new material to be produced containing up to 50% product Y. The EPA advises that the data provided does not support the application, and will only approve up to 30% because the trial only investigated mixes with a maximum of 30% of product Y.

Where the trial is to explore how an output (e.g. pollutant emissions) varies in response to a change, the change should be sufficient to cause a statistically significant change in the measured outputs. For example, in the scenario above, it may be necessary to trial scenarios where >50% of product Y is incorporated, to learn if there is a statistically significant impact on the outputs (e.g. air emissions) from the introduction of the new product.

6.3 Evaluating risk

Many factors may contribute to the potential for risks to occur during a trial. The risks associated with a trial should be adequately assessed and mitigated. Where approval is required, the approval authority must be satisfied that the level of assessment and proposed mitigation measures are appropriate.

Some factors to consider when assessing risks in a trial include: the size, scale and duration of the trial; the location of the trial and distance to receptors; the characteristics of the materials being used; how materials are handled, stored and processed; the type of activities undertaken; and the controls and mitigation measures in place to prevent or minimise impacts occurring. Refer to section 3.6 for further information on conducting a risk assessment.

We expect you to use a systematic approach for identifying and evaluating risks. A structured, comprehensive risk assessment gives greater confidence regarding the management of the trial and may lead to a more efficient review of applications.

Evaluating risk can be complex and there are likely to be situations where you will need the assistance of experts for a particular project. There are also certain situations where you may be legally required to undertake activities in a certain way, including involving external experts. An example of such a situation would be a trial carried out on contaminated land.

6.3.1 Risk-assessing trials that are new to NSW

The trial may involve new or innovative technologies, processes or inputs unknown to the EPA. While we strongly support innovation, there is inherent uncertainty associated with novel techniques and methods. The level of assessment should be appropriate for the associated uncertainty and should be supported using evidence and data.

When relying on data and performance information from external sources for your trial proposal, it is crucial to contextualise this information within the NSW environmental regulatory framework. The emission performance of facilities must be shown to comply with the applicable limits specified in NSW regulatory instruments. Such comparisons ensure that the proposed trial aligns with local environmental requirements.

Where there is a lack of existing data available, further research may be needed prior to progressing to a field trial. This may include academic studies, modelling or laboratory-based experiments.

6.3.2 Characterisation of materials

To allow for full consideration of the risks associated with a trial, the EPA needs to have a good understanding of the materials being used. All material inputs should be appropriately characterised, and risk assessed.

The characterisation should be used to identify the composition of the material, identify any physical, biological, chemical and/or other contaminants present, and assess the potential risks associated with these contaminants, taking into account the conditions of the trial.

6.3.3 Environmental impacts

When planning a trial, it is essential to identify and evaluate the risk of environmental impacts due to activities associated with the trial. You need to consider the factors that could contribute to impacts occurring (e.g. operational, environmental, temporal, spatial), the level of assessment required, and if an assessment is legally required.

The level of assessment required should be fit for purpose and site-specific. For simple and low-impact trials, a simple impact assessment may be appropriate. More complex trials may require a more robust assessment of impacts.

An impact assessment may be legally required in some circumstances, such as:

- where development consent is required from the consent authority
- where an EPL, issued by the NSW EPA, is required and/or
- where there is a statutory notice or direction requiring one.

In both instances, we encourage you to discuss your proposal with the relevant authority, which should be able to advise on the level of assessment required.

Where an impact assessment is necessary, it should be undertaken in accordance with EPA guidance (where available). We have guidance for the assessment of impacts for noise (*Noise Policy for Industry* (2017)) and air pollution (*Approved Methods for the Modelling and Assessment of Air Pollutants in NSW* (2022)).

If you are unsure what level of impact assessment is required or if you need specific guidance, it is recommended you seek advice from a suitably qualified expert or consultant.

6.4 Sampling for regulatory purposes

When designing a trial for regulatory purposes, the methods used for sampling and analysis need to be carefully considered. If testing during the trial is required under a condition of a licence or statutory notice or other EPA administered legislation or policy, then the sampling and analysis may need to be conducted using methods approved by the EPA, which you can find on the EPA website:

- **Air pollutants**
  Approved Methods for the Sampling and Analysis of Air Pollutants in NSW (2022)
- **Water pollutants**
  Approved Methods for the Sampling and Analysis of Water Pollutants in NSW (2022)
- **Environmental noise**
  Approved Methods for the Measurement and Analysis of Environmental Noise in NSW (2022)
- **Contaminated land**
  Sampling Design Part 2 – Interpretation: Contaminated Land Guidelines (2022).

We recommend you use approved methods for sampling and analysis where data from the trial is needed for regulatory decision-making. Seek guidance from the EPA if you are unsure which methods to use.

If there is no approved method for an analyte relevant to your trial, contact us to discuss appropriate test methods. We will generally not approve the use of a method unless we are satisfied it is fit for purpose and has been appropriately validated.

Typically, all sampling and analysis conducted for regulatory reporting is required to be carried out by a facility accredited under ISO/IEC17025 to perform the method.[2] The accreditation must be current and issued by an independent accreditation body, such as the National Association of Testing Authorities (NATA) or an equivalent accreditation body.

Note: monitoring required by an EPL, including monitoring performed during a trial, may require you to publish monitoring data. See the EPA's guide, Requirements for publishing pollution monitoring data, for further information.

6.5 Conditions of a trial

Where approval is required to undertake a trial, it may be subject to strict conditions. The detail contained within the trial plan may be used to form the basis of the conditions.

The EPA will make decisions about conditions in regulatory instruments in accordance with its statutory obligations. They may be broad, to set the bounds of the trial such as the size, scale, duration, and intensity of activities undertaken. They may also be specific: for example, they may specify how much material you can process, the operating hours, or testing and reporting requirements.

Other regulators or consent authorities may also issue specific conditions of approval for the trial. For example, the Department of Planning, Housing and Infrastructure, may issue conditions of approval as part of the development consent for the trial or as a separate instrument.

A trial must be undertaken in accordance with any conditions of approval. You must comply with all EPL conditions and other applicable legal requirements, such as planning approvals, applicable legislation and mandatory policies. Please contact the EPA if you have concerns or questions regarding conducting the trial in accordance with the specified conditions.

Note: Where the EPA is considering a trial in relation to environment protection licensing under the POEO Act, applicants should be aware that we may require further assessment, and you may need approvals, before you can transition from a trial to ongoing operations. Where this involves licensing conditions under the POEO Act, we will consider matters listed under section 45 of the POEO Act when making a determination of this kind.

[2] International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories* (2017)

7

Appendix

7.1 Trial plan design

This section includes a template design for trial plans. We recommend that trial plans developed for undertaking trials in NSW for regulatory purposes use a similar format and structure to this template.

7.1.1 Purpose

The purpose of the trial should be clear and concise, typically no more than a couple of sentences and should describe ***why*** you are doing the trial (see section 2.3, *Trial objectives*, for more information).

In this section of the trial plan, you should start with a clear statement, such as:

The purpose of the trial is to …

Then:

- state the overall aim of the trial
- list (in order of priority) the specific objectives.

Example: *The purpose of this trial is to understand the change in air emissions (concentration and mass rate) when the coal-fired boiler is co-fired with liquified natural gas (LNG). The objectives are:*

1. to learn how the fuel mix ratio (x% coal to y% LNG) effects boiler output efficiency
2. to learn which fuel mix ratio will result in the greatest overall reduction in air pollutant emissions, and
3. confirm the plant complies with all applicable air emission standards when using the fuel mix ratio identified in step (2).

Note: you should clearly identify all applicable pollutants and standards.

7.1.2 Trial plan overview

This section should provide a comprehensive and consolidated description of the trial (***what***), including a description of ***how*** the trial will be conducted, ***where*** it is to occur and during which time frames (***when***). Section 3, *Detailed design*, gives more information.

What: You should explain as concisely as possible the key aspects of the trial – what will be done during the trial period. Where a trial is composed of multiple stages, each stage should be sufficiently detailed.

Tip: A table or chart can help clearly show the different stages of a trial.

How: You should provide details of the specific steps that will be performed during the trial. Identify and detail all inputs, outputs and processes.

Tip: Process diagrams and flow charts can help describe the systems and process flow of a trial.

Where: Describe where the trial will take place. This description should include the specific locations within a premises where activities will be performed, and all plant and equipment involved.

Tip: Use site maps and schematics to support the description.

When: Identify the key dates associated with the trial, including the start dates, end dates and proposed duration. For a trial with multiple stages, give the key dates and duration for each stage.

Tip: A timeline of events can help show the timing of trial activities and identify project milestones.

7.1.3 Defining success

The trial plan should include measurable success criteria. The criteria should be achievable in the time frame allowed, with the resources available. Some of the first questions to ask include:

- Why are we doing this and what are we trying to achieve?
- What are we comparing this to?
- What metrics can we define and use for measuring success?
- Are there any standards we need to meet?
- Are there any specific guidelines and/or industry codes we should follow?

The metrics used for defining success should align with the purpose of the trial. They should provide clear guidelines or targets for determining if the purpose of the trial has been achieved.

Example: In the above example, the purpose of the trial was to verify the air emission performance of a coal-fired boiler when it is co-fired with liquified natural gas. Success in this example will be defined as:

1. Achieving an overall boiler efficiency of <insert value>% when compared to being fired on coal only
2. an overall decrease in measured air emissions by a minimum of z%
3. 100% compliance with all applicable air emission standards

7.1.4 Roles and responsibilities

The plan should identify all key personnel involved in a trial: internal employees, external contractors and consultants. The plan should also identify key stakeholders, including internal stakeholders, and stakeholders that will be directly reported to during the trial. At a minimum, the plan should include:

- names and contact details of responsible individuals
- a discussion of the specific roles and responsibilities of individuals and organisations involved in the trial
- an organisational chart with lines of communication
- preferred methods of communication
- a list of people or organisations requiring notification and what they will be notified about (e.g. NSW EPA, local council, community groups, neighbouring facilities).

Example: Use a table with similar headings to those below to clearly indicate roles, responsibilities and contact details.

Name	Role	Organisation	Contact details	Responsibilities	Reports to	Preferred contact	When to notify
1.							
2.							

7.1.5 Process overview

In this section, you should provide sufficient detail for the EPA to understand all key processes involved in the trial. This will help to identify potential risks and indicate likely sources of variability and uncertainty. A detailed process description can also help to identify key parameters that should be monitored to allow for meaningful data interpretation. The plan should include the following:

- general description of the process
- details of the physical, chemical and/or biological processes involved
- flow diagrams, tracing the process from the beginning to the end
- a brief description of the plant, machinery and control equipment involved
- a summary of key operating parameters including baseload (normal) and targeted operating/process conditions (e.g. fuel types, feed rates, mixing temperatures, etc)
- a description of all controls and treatment plant
- details of inputs and outputs (products/residues/effluents) from processing
- details of the targeted processing activities for each stage of the trial
- the layout of all the key physical elements of the project (buildings, processing equipment, stockpiles, structures etc)
- where it is new or innovative
  - describe the technology and explain why it is new/innovative
  - give details of any existing statutory approvals and associated conditions and constraints in Australia and elsewhere
  - provide specific references to existing and past operations and/or trials where the technology has been used (where possible)

Tip: You can use a table to compare the new technology to existing technologies. This can make it easy to see the similarities and differences between technologies.

7.1.6 System inputs and outputs

The plan should describe all inputs and outputs, including (but not limited to):

- the physical, chemical and/or biological state of material being processed and produced
- energy inputs and outputs e.g. heating, air, water, steam, electricity, fuel
- any environmentally significant characteristics of material being processed or produced e.g. whether it is explosive, flammable, oxidising, poisonous, infectious, corrosive or toxic

- the source or origin of the input materials, including, for example, where and how it was produced
- details of the anticipated outputs (e.g. discharges, emissions, concentration levels, residues, effluents). This may include a mass balance (to be supported with verifiable details from any previous trials)
- wastes.

7.1.7 Trial scenarios or operating conditions

The plan should outline the distinct scenarios and settings under which the system will be trialled, including:

- details of the physical, chemical and/or biological processes that will be involved
- the target operating and process conditions (e.g. feed rates, temperatures, pressures, production/application rates)
- the operating status of all controls and treatment plant
- expected timing and duration for all operational phases (e.g. start-up, stable load, cool down)
- proposed safety precautions to be applied.

7.1.8 Sampling plan

Include a table showing the following (include schematics, if helpful):

- description of each sampling or measurement location
- explanation of why the sampling location has been chosen
- which specific process or operating conditions will occur at the time of sampling
- how representative the sampling location is expected to be
- number of tests/samples
- sample type and target analyte/s
- rationale for the selected analytes to be tested
- sampling method, frequency and duration
- method of analysis
- sample handling requirements to ensure sample integrity.

Refer to section 3.5, *Sampling plans*, for more information.

7.1.9 Quality Assurance/Quality Control

Quality objectives should be specific, measurable and relevant. Refer to section 3.5.3, *Sampling Quality Assurance*, for more information.

You should determine which processes need to be monitored and measured. To guarantee valid and auditable results, the monitoring, analysis, measurement and evaluation methods should be predetermined. Other factors that should also be determined are:

- when the monitoring results should be evaluated

- how the performance and effectiveness of the QMS (quality management system) will be evaluated.

All documents should be retained as the evidence of all determining results.

7.1.10 Results, analysis and interpretation

Refer to section 4.2, *Data analysis and interpretation*, for more information.

Results analysis and interpretation should be planned in advance to the best of your ability. In your plan, consider:

- how will the results be interpreted
- whether a statistical specialist is required to ensure comprehensive interpretation
- how the outcomes will be communicated
- how the effectiveness of the mode of communication will be assessed (e.g. are visualisations the most effective way to communicate the data? See section 4.3.1, *Data visualisation*).

7.1.11 Reporting

Refer to the list of recommended components in a report listed in section 4.4, *Conclusions and reporting*.

7.2 Typical stages of planning and designing trials

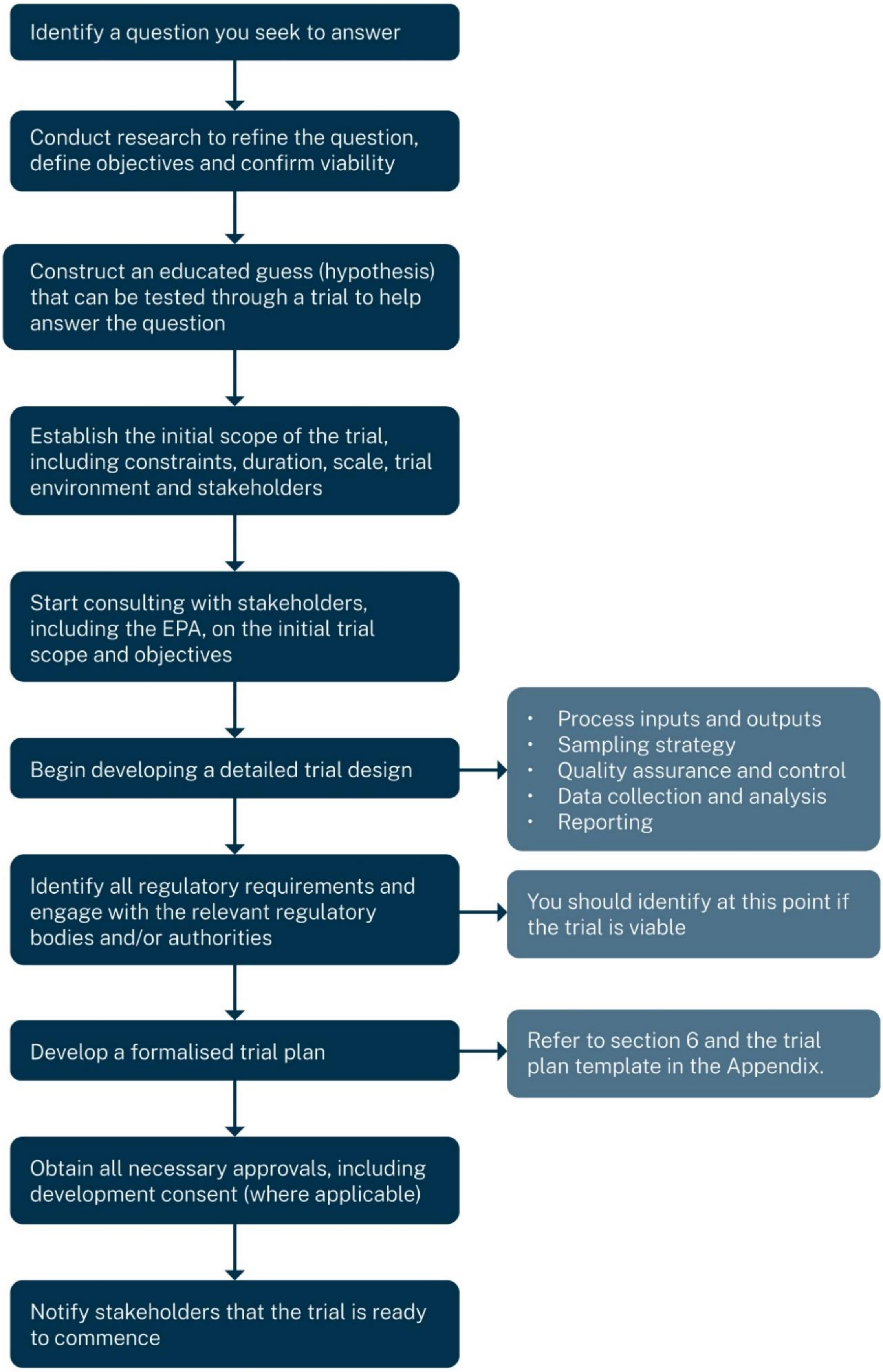

Figure 5 Simple flow diagram of trial planning and design process in NSW

Published by NSW Environment Protection Authority

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ISBN 978 1 923328 40 2
EPA 2025P4638
November 2025