Western Australia Nurse Practitioner

BUSINESS CASE AND CLINICAL PROTOCOL TEMPLATES

Department of Health
Government of Western Australia

Office of the Chief Nursing Officer
Suggested citation

Copies of the templates and the guiding framework are available from:

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Department of Health
Government of Western Australia
189 Royal Street
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Australia 6004

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Graphic Design by Michelle Cabrera
**Introduction**

This generic template has been developed by the Office of the Chief Nursing Officer to assist health services/organisations to apply in writing to the Director General of Health for an area to be designated. The template is intended to be read in conjunction with the clinical protocol template and the *Guiding Framework for the Implementation of Nurse Practitioners in Western Australia* (2003).

The template contains sections which must be included in the application however, additional information to assist the Director General of Health to consider the application may be incorporated. It is important to note that the application including the business case and clinical protocols must be signed off by the most senior officer of the health service/organisation.

**Title Page**

(HEALTH SERVICE OR ORGANISATION LOGO HERE)

THIS DOCUMENT IS CONFIDENTIAL

Name of Health Service or Organisation:

Name area to be considered for designation:

Name of Manager/Director of Nursing

Name: ___________________________ Title: ___________________________

Address: ______________________________________________________________________

Telephone: ____________________________ Fax: ___________________________

E-mail: _______________________________________________________________________

Signature: ___________________________ Date: __/__/__

**Recommending Officer**

(Most Senior Officer in the Health Service/Organisation)

Name: ___________________________ Title: ___________________________

Address: ______________________________________________________________________

Telephone: ____________________________ Fax: ___________________________

E-mail: _______________________________________________________________________

Signature: ___________________________ Date: __/__/__
Document Approval and Version Control

The business case should be a managed document. The document should only be authorised for submission to the Director General of Health once all signatures have been obtained.

Table of Contents

This allows for easy access to information included in the business case.

Executive Summary

The Executive Summary should summarise the business case. The summary should be able to stand alone as a logical, clear and concise overview of the business case. It is important to highlight the key issues that support the introduction of the role of a nurse practitioner in a specific designated area. It is recommended that the Executive Summary be written after the main document is formulated. The summary should be no longer than two pages and may include:

- problem or opportunity description;
- need or needs identification;
- current situation;
- proposed solution;
- expected benefits;
- evaluation and audit;
- resources; and
- funding provision.

Background

Use this section to introduce the business case and outline the problem or opportunity. Briefly, describe what has happened in the past, the current service delivery, or the gap in the current service. What is the rationale or reason for applying for the designation of an area at this particular time?

Context

Provide a brief but comprehensive description of your health service or organisation. This may include but not be limited to: mission statement, style of management, outline of services provided, staffing; location, and size of service. Information brochures and material describing your service may be included as an Appendix.

Proposed Area to be Designated

Define and describe the proposed designated area, include the following details:

- the client group/the intended target population;
- description of the relevant environmental conditions;
- assessment of how the needs are currently being met, or not met; and
- an analysis of the gap between the current service delivery and the stated objective(s).
Aims and Organisational Objectives

Outline the aim of the health service/organisation in applying for designation of a specific area. State the objectives for introducing nurse practitioners into the service. How do the aims and objectives relate to the organisational goal(s)?

Indicate how the service provided by the nurse practitioner will reflect the philosophy of the health service or organisation.

Demonstrate a Clear Understanding of Legislation and Codes of Practice that Govern the Role of the Nurse Practitioner

Legislation relevant for the designation of a site and nurse practitioner practice:
- Nurses Act 1992
- Medical Act 1894
- Misuse of Drugs Act 1981
- Pharmacy Act 1964
- Poisons Act 1964
- Poisons Regulations 1965
- Radiation Safety Act 1975
- Road Traffic Act 1974
- Nurse practitioner Code of Practice 2003
- Nurses Code of Practice 2000

Evidence of Demand/Need for Nurse Practitioner in your Area

Outline the need for nurse practitioner skills in your health service/organisation through feedback from patients, the community, medical practitioners and other health workers. This must be supported by evidence, for example, research, audit and needs analysis.

Key Objectives of the Nurse Practitioner Role

The key objectives of the nurse practitioner role in the designated area:
- objective description;
- objective description; and
- objective description.

Job Description

A job description for the nurse practitioner in the specific designated area must be included. Describe the role of the nurse practitioner in the health service/organisation. Define the role within the context of the clinical practice in the designated area you are applying for, including but not restricted to, responsibility, authority and accountability. The following are the key headings that should be included in the job description:
- position identification;
- reporting relationships;
- positions under direct supervision and control;
- partnerships/professional support relationships;
- key responsibilities and aims of the position;
- statement of duties including:
  - clinical practice
  - education, training and professional development
  - team/partnerships arrangements
• research, audit, evaluation
• leadership
• quality management
• key outcomes;
• selection criteria (essential and desirable);
• appointment factors; and
• certification.

**Role Definition**
Describe the role of the nurse practitioner in the health service/organisation. Define the role of nurse practitioner within the context of the clinical practice in the designated area you are applying for, including but not restricted to, responsibility, authority and accountability. Indicate how the service provided by the nurse practitioner will reflect the philosophy of the health service or organisation.

**Scope of Practice**
Description of the nurse practitioner scope of practice in the designated area:
• in scope of practice;
• in scope of practice; and
• in scope of practice.

**Outside the Scope of Practice**
The legislation framework for the implementation of nurse practitioners allows for a broad scope of practice. However, the clinical protocols developed for the specific designated area define the nurse practitioners scope of practice. Describe what is considered outside the scope of practice in the specific designated area.

Items specifically OUT of the scope of practice are:
• out of scope of practice;
• out of scope of practice; and
• out of scope of practice.

**Demonstrate how Employing a Nurse Practitioner will Enhance the Services Provided by your Health Service/Organisation**
Identify how employing a nurse practitioner will enhance the health service/organisation and the expected outcomes.

**Expected Benefits**
State the current practice position and project expected benefits for patients or the community from the service provided by a nurse practitioner. Clearly, identify the benefits expected to accrue from the nurse practitioner role in the designated area.
The following benefits are expected to be achieved:
• benefit description;
• benefit description; and
• benefit description.
Relationships within the Designated Area and Other Key Services

Implementation of the role of the nurse practitioner will only be achieved by the development of positive partnerships and collaboration with medical practitioners and other key health workers.

List all relevant parties who will be inherent within the consultation process to develop the new service. Describe how the health service/organisation will develop the new service in collaboration and partnership with these key groups and stakeholders.

Identify the process of how the nurse practitioner will work in partnership with the medical practitioners and in collaboration with other key health workers within the designated area of practice.

In conjunction with the nurse practitioner role in the designated area there are other key services which have a relationship or impact on the delivery of care. Outline all other relationships and describe how they will be assisted to adjust and become accustomed to the new role.

Identify the networks that will be available to support the role of the nurse practitioner. Include the availability of this support and how it will be accessed.

Resources

To ensure that the nurse practitioner is able to work as effectively and efficiently as possible, identifying and securing the necessary resources must be undertaken before any nurse practitioner position is filled. It is imperative that the nurse practitioner has support of the health service or organisation, medical practitioners and other key health workers in their challenging new role. Indicate resource requirements for the work being proposed. Ensure that requirements for both human resources and environmental resources are included. Identify clearly the resources that will enable the nurse practitioner to function successfully and safely in the role.

Resources that will enable the nurse practitioner to function successfully in their role include:
- adequate staffing in terms of administrative support;
- appropriate facilities such as suitable clinical space, office space and furnishings;
- diagnostic and therapeutic equipment as required for practice in the designated area;
- appropriate information technology and access to support as required;
- access to appropriate communication links with medical practitioners and other health professionals via telephone, fax, teleconference, video link and e-mail;
- access to research applicable to the area of practice such as library resources, access to tertiary institutions and the Internet;
- opportunities for State wide or national networking;
- opportunities, encouragement and support for undertaking professional development relating to the area of practice; and
- facilities to evaluate their work, undertake research and develop and provide evidence-based services.

Constraints

Describe the key issues which may hinder the attainment of the objectives. This section should list and describe any constraints which may effect the implementation of nurse practitioners such as the clinical environment, technology or access to resources. Constraints are factors that will limit the agreed scope of practice of the nurse practitioner.
- constraint description;
- constraint description; and
- constraint description.
Impacts on the Health Service/Organisation

This section outlines any possible impact the role of nurse practitioner may have on the patient, community, stakeholders, employees and other health care professionals. Describe any implications on the health service or organisation following the implementation of the role of the nurse practitioner. Any possible issues that may affect the implementation of the role of the nurse practitioner need to be identified. Outline a risk assessment strategy for the new service.

Impact of the change on the health service/organisation, including:

- who will be affected?
- how they will be affected?
- when they will be affected?
- why they will be affected?

Promotion of the Nurse Practitioner Role

Describe how the health service/organisation will market the service and provide information on the new role to, for example, patients, community, employees and health care professionals.

Estimated Investment

Provide evidence of funding available to support the role of the nurse practitioner. Detail how the nurse practitioner position will be funded within the current health service or organisation budget.

Estimates provided should include:

- description of costs;
- both tangible and intangible costs;
- description of allowances made and contingencies included.;
- estimated recurrent costs; and
- source of the funds should be clearly identified.

Indemnity

Identify the arrangements for professional indemnity. Provide evidence of acceptance by the health service or organisation of the legal principle of vicarious liability of the nurse practitioner in the designated area of practice.

Clinical Governance Framework

Provide evidence that the Western Australian clinical governance framework will be adopted. In committing to the clinical governance framework, employers have a responsibility to ensure that there are systematic mechanisms in place to assist nurse practitioners to promote and develop quality activities. Health service/organisations must ensure the protection of established high standards, promote and support a learning environment and assure clinical decisions are based on currently available evidence of effectiveness. Demonstrate a commitment to a model of continuous improvement.
Audit and Evaluation

Demonstrate a commitment to audit and evaluate the service in the designated area. Describe the evaluation of the nurse practitioner role in the designated area. Evaluation of the nurse practitioner service in the designated area must include assessment of quality dimensions of safety, intended outcomes, effectiveness, appropriateness, consumer participation, access and efficiency of the service. The evaluation is to be based on the Western Australian clinical governance framework by the Office of Safety and Quality in Health Care, Department of Health. This is based on four pillars; clinical performance and evaluation, professional development and management, clinical risk and consumer value. The evaluation plan should identify an appropriate set of performance indicators for each service. These indicators will be used to provide data for benchmarking purposes. Included in the evaluation plan must be details of items to be evaluated and the process for data collection, collation, analysis and reporting. The evaluation plan must also include:

- ongoing monitoring and review of the service, consistent with the principles of continuous quality improvement, performance management, and local health service evaluation strategies;
- formal evaluation of nurse practitioner services, to be completed one year from the commencement of the service delivery in the designated area.

Health services/organisations are required to forward their evaluation report with the Annual Report to the Director General of Health.

Statistics

The health service/organisation must agree to provide statistics on the service delivered by the nurse practitioner and data relating to the designated area when requested by the Department of Health.

Annual Report

The health service/organisation must agree to submit an annual report to the Director General of Health on the designated area and the service provided by the nurse practitioner.

Implementation Plan

The plan is the ‘road map’ used by the nurse practitioner implementation team to deliver the agreed health service/organisation aims and objectives to introduce the nurse practitioner service in the designated area. It is essential that an outline of the implementation plan be addressed and may include:

- project plan;
- consultation plan;
- resource schedules;
- quality procedures;
- reporting procedures;
- risk management planning; and
- evaluation plan.

Glossary and Appendices

Appendices can help the document to flow better, by extracting supporting information such as audit and research that supports the business case out of the body of the document for reference.

Please note application to the Director General for designation must be in writing and include the business case and the clinical protocols.
Introduction

The amendments to the Poisons Regulations 1965 requires that before the Director General of Health can designate an area, clinical protocols for the specific area must be approved by:

- the officer of the department who is principally responsible for providing advice on matters related to nursing (currently the Chief Nursing Officer);
- the person holding or acting in the office of Executive Director, Personal Health Services in the department (currently the Chief Medical Officer); and
- the person holding or acting in the office of Executive Director, Population Health, or if there is no such office at the relevant time, the office of Executive Director, Public Health and Scientific Support Services in the department (currently the Executive Director of Population Health).

During the parliamentary process, clinical protocols were described as an essential component of the business plan, that must be developed by a multi-disciplinary team, and peer reviewed prior to the submission of an application to the Director General of Health.

Clinical protocols must reflect the legislation that regulates the practice of the nurse practitioner in the designated area. Clinical protocols must be developed to assist nurse practitioners to make appropriate decisions about a patient’s specific clinical needs. They should be designed to assist nurse practitioners to assess and implement the current best evidence into practice to ensure the optimum and appropriate outcome for their patients. The purpose of these clinical protocols is to cover the areas of advanced practice now permitted under the nurse practitioner legislation. Evidence based protocols and policies already in place or developed in the future that guide other aspects of nursing practice will also be drawn on to ensure the best possible outcomes for the recipients of care.

The appropriate level of evidence must be included for all information included in the clinical protocol. Clinical protocols are subject to auditing, monitoring and quality assurance processes. The use of the clinical protocol, developed as part of the process to designate an area, is restricted to nurses who are registered with the Nurses Board of Western Australia as a nurse practitioner and employed by the health service/organisation for the specific designated area.

Definition

The template developed by the Office of the Chief Nursing Officer is based on the National Health and Medical Research Council, A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines (1999). The National Health and Medical Research Council (1999), use the following definition to define clinical protocols:

Clinical Practice Guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances

(Field and Lohr 1990).

Principles

It is suggested that the development of clinical protocols follow the principles outlined in the National Health and Medical Research Council guidelines (1999). These guidelines are appropriate to use when considering the effectiveness of treatments or procedures. However, nursing care also draws on studies other than effectiveness and for these other types of research evidence different criteria for determining the level of evidence is required. The Joanna Briggs Institute is currently developing criteria for assessing research other than studies of effectiveness and these criteria will be published on the Institute’s website (www.joannabriggs.edu.au). The development and evaluation of clinical protocols described by the National Health and Medical Research Council state that interventions should be identified to ensure the best possible health outcomes and be based on the best available evidence.

Amongst the basic principles for developing clinical protocols outlined by the National Health and Medical Research Council (1999) is the process must be developed by a multi-disciplinary team and include those who are expected to use them, including consumers. Each protocol should be relevant to the target
population and take into account the geographical, clinical and cost constraints as well as accommodating patient preferences. A review of each clinical protocol must occur on a regular basis by an appropriate multi-disciplinary clinical team.

The steps in developing the protocols such as convening a clinical protocol panel, establishing objectives, peer review and the structure of the clinical protocol is outlined in chapter five of the *Guiding Framework for the Implementation of Nurse Practitioners in Western Australia* (2003).

**Title Page**

**Nurse Practitioner Clinical Protocols**

**for the**

**Management of ………………..**

The heading should clearly indicate the health service/organisation, designated area, whom the clinical protocol is written for and the clinical condition it covers. In addition a statement outlining the types of patients to be cared for under the clinical protocol should be included.

**Clinical Protocol Development Panel**

The name, position, professional qualifications and health service/organisation of those responsible for developing the clinical protocol must be clearly presented and each member must sign off on the completed protocol.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Professional qualification</th>
<th>Organisation</th>
<th>Signature</th>
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<tr>
<td>Name</td>
<td>Position</td>
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<tr>
<td>Name</td>
<td>Position</td>
<td>Professional qualification</td>
<td>Organisation</td>
<td>Signature</td>
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</tbody>
</table>

The list should include staff from each of the professional groups associated with the implementation of the clinical protocols in the relevant area, for example: nurses, doctors, pharmacists, allied health professionals, health service managers and consumers. Membership of this committee may include:

- nurse practitioner (potential) or the senior clinical nurse specialist most likely to be expected to use the clinical protocol;
- medical, nursing and allied health professionals with relevant specialist expertise;
- consumer representative that will be receiving the treatment based on the developed clinical protocol;
- a radiology representative (particularly when the clinical protocol will involve the ordering and interpretation of diagnostic imaging tests);
- a pharmacy representative (particularly when the clinical protocol will involve the prescription of schedule 4 medications);
- a pathology representative (particularly when the clinical protocol will involve the ordering of pathology tests);
- experts in research and protocol development within the health organisation;
- representatives from the quality and evaluation sections of the health organisation; and
- other relevant experts.
External Peer Review Panel

Include the name, position, professional qualifications and organisation of those externally reviewing clinical protocols. Each member of the external peer review panel must sign off on each clinical protocol. The external review panel may mirror the clinical protocol development panel and should include expert clinicians in the field, experts in research, public policy analysts, allied health professionals and consumer representatives.

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Professional qualification</th>
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Statement of Intent

Intention of the clinical protocol and how it is to be used in conjunction with the full range of clinical and diagnostic tools available to health professionals. Clinical judgement and input from other members of the treating team should be taken into consideration. Development and evaluation of clinical protocols should focus on health outcomes. Clinical protocols should be designed to:

- improve the quality of health care;
- reduce the use of unnecessary, ineffective or harmful interventions; and
- facilitate the treatment of patients with maximum chance of benefits, with minimum risk of harm and at an acceptable cost.

Clinical Protocol Development

Clinical protocols need to be developed by a multi-disciplinary team and should include consumers. The involvement of a range of multi-disciplinary health care professionals, experts and consumers in the development of the clinical protocols will ensure quality, continuity of care and ownership of the protocol by the health care team. The panel should:

- document the purpose;
- describe the natural history of the disease/condition;
- describe the various treatments that are possible;
- identify situations where any recommendations might not apply;
- detail the probable outcomes;
- ensure clinical protocols are comprehensive and flexible;
- describe the support services that may be required for each potential treatment;
- include information for consumers and clinicians on any special clinical training or equipment needed;
- compare the costs associated with the various options;
- provide a statement of the scientific basis on which the clinical protocols were developed and clearly specify the level, quality, relevance and strength of the evidence;
- document the uncertainty associated with the conclusions; and
- document the economic appraisals used in formulating the protocols.

A plan for disseminating, implementing, evaluating and revising the clinical protocols should be developed. Drafted clinical protocols should be referred for consultation to a wide range of stakeholders.
Evidenced Based Clinical Protocols

Clinical practice should be based on evidence extracted from systematic reviews of research where possible. If this type of information is not available, practice should be supported by expert opinion and recognised best practice. A rating system is required to indicate the level of supporting evidence used throughout the clinical protocol.

<table>
<thead>
<tr>
<th>Level of evidence:</th>
<th>Study design used as an indicator of the degree to which bias has been eliminated by design (systematic review of randomised controlled clinical trials).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of evidence:</td>
<td>The quality of the methods used by the investigators to minimise bias in a study design.</td>
</tr>
<tr>
<td>Relevance of evidence:</td>
<td>A term encompassing the closeness of the study question to the clinical question, which is determined by the relevance of the outcome measures used and the applicability of study results to other treatments, setting and patients.</td>
</tr>
<tr>
<td>Strength of evidence:</td>
<td>The magnitude, precision and reproducibility of the intervention effect; includes the effect size, confidence intervals, P value, and the exclusion of clinically unimportant effects. In the case of non-randomised studies, additional factors such as biological plausibility, biological gradient and temporality of associations may be considered.</td>
</tr>
</tbody>
</table>


There are a number of sources of materials about rating the level of evidence of different types of studies. For example the Joanna Briggs Institute (www.joannabriggs.edu.au), Cochrane Collaboration (www.cochrane.org), Agency for Healthcare Research and Quality (www.ahrpr.gov).

Recommendations contained in clinical protocols should be based on the highest level of evidence that measure relevant outcomes and demonstrate a strong, clinically important beneficial effect of the intervention. If evidence based information is not available to support practice it should be supported by expert opinion and recognised best practice. A rating system is required to indicate the level of supporting evidence used throughout the clinical protocol and the following is an example.

Rating system to identify levels of evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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<tbody>
<tr>
<td>Level I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials.</td>
</tr>
<tr>
<td>Level II</td>
<td>Evidence obtained from at least one properly designed randomised control trial.</td>
</tr>
<tr>
<td>Level III.1</td>
<td>Evidence obtained from well designed pseudo randomised controlled trials (alternative allocation or some other method).</td>
</tr>
<tr>
<td>Level III.2</td>
<td>Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with a control group.</td>
</tr>
<tr>
<td>Level III.3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.</td>
</tr>
<tr>
<td>Level IV</td>
<td>Evidence obtained from case series, either post test and pre-test and post-test.</td>
</tr>
</tbody>
</table>

Dissemination and Implementing the Guidelines

The multi-disciplinary panel should identify any barriers to the implementation of the guidelines and work to overcome potential barriers with the target groups. Clinical protocols should be presented in a format and style that is suitable for their target audience. Suggested strategies for dissemination:

- asking respected clinical leaders to promote the clinical protocols;
- involving potential users to develop the clinical protocols; and
- piloting the draft clinical protocols in order to facilitate their assessment.

Evaluation and Revision

Evaluation should include:

- how well were they disseminated?
- is clinical practice moving towards the clinical protocol?
- has the clinical protocol contributed to any specific changes in clinical practice?
- has the clinical protocol affected consumers’ knowledge and understanding?
- have health outcomes changed?
- what is the cost effectiveness analysis?
- user satisfaction (consumers, medical, nursing, allied health) based on relevance, ease of access, clarity etc.

A date should be set for the revision of the clinical protocols.

Agreement

The health service/organisation must agree to share the clinical protocols developed for the designated area within the health care industry. They must agree to permit the clinical protocols to be held by the Office of the Chief Nursing Officer and made available online at the Department of Health and the Nursing in WA websites.

Summary of the Structure for each Clinical Protocol

State for whom the clinical protocol is designed for, outline the development and the initial review process. Include requirements for clinical protocol review, for example, agreed change in clinical practice or a pre determined review date. Each specific protocol should include but not be limited to:

1. Introduction – overview of illness/injury/condition
   - disease aetiology;
   - population;
   - presentation rates;
   - morbidity and mortality rates; and
   - expected outcome of the protocol.

2. Assessment – include a full list of routine/accepted assessment tools/investigation tools and practices.

3. Management – outline of clinical actions to be taken following assessment. Procedures or medications to be administered as well as referrals to other health care professionals.

4. Discharge – detailed plan of discharge or referral for each protocol and include:
   - criteria of discharge;
   - social supports required;
   - treatment plan; and
   - consumer handout.
5. Evidence base – clinical protocols should be based on the systematic identification and synthesis of the best available scientific evidence which must be included to support the application.
6. Reference list – include references used to develop the protocols.
7. Formulary – detailed information in relation to medications that are likely to be prescribed for the clinical presentation.
8. Review – effective date and review date should be explicitly stated. A review plan needs to be identified and outlined.

Formulary of Drugs - Insert Medications that are likely to be Prescribed for the Clinical Presentation

Drug generic name:

Poisons schedule:

Therapeutic class:

Dosage range:

Route:

Frequency of administration:

Duration of order:

Actions:

Indications for use:

Contraindications to use:

Side effects:

Endorsed by: __________________

Date: _______________  Effective date: __________________

Review date: __________________

NOTE: ANY ALTERATION OR AMENDMENT MUST BE SUBMITTED TO THE DIRECTOR GENERAL OF HEALTH, DEPARTMENT OF HEALTH, WESTERN AUSTRALIA FOR APPROVAL.

THIS DOCUMENT IS INVALID IF ANY ALTERATIONS OR AMENDMENTS ARE MADE WITHOUT THE APPROVAL FROM THE DIRECTOR GENERAL OF HEALTH, DEPARTMENT OF HEALTH, WESTERN AUSTRALIA.
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