NZS 8181:2007

STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

New Zealand Standard

Fertility Services

NZS 8181:2007

MINISTRY OF HEALTH
MANATŪ HAUORA

Single User PDF Terms & Conditions

You have material which is subject to strict conditions of use. Copyright in this material is owned by the New Zealand Standards Executive. Please read these terms and conditions carefully, as in addition to the usual range of civil remedies available to Standards New Zealand on behalf of the New Zealand Standards Executive for infringement of copyright, under New Zealand law every person who infringes copyright may be liable to a fine of up to $10,000 for every infringing copy or imprisonment of up to 5 years, or a fine of up to $150,000 or imprisonment not exceeding 5 years.

You have access to a single-user licence to read this non-revisable Adobe Acrobat PDF file and print out and retain ONE printed copy only.

We retain title and ownership of the copyright in this PDF file and the corresponding permitted printed copy at all times.

Under this license use of both the PDF file and the single permitted printed copy of this PDF file you may make are restricted to you. Under no circumstances are you permitted to save, sell, transfer, or copy this PDF file, the one permitted printed copy of this PDF file, or any part of either of them.

You undertake that you will not modify, adapt, translate, reverse engineer, decompile, disassemble or create derivative works based on any of the downloaded PDF file, nor will you merge it with any other software or document, even for internal use within your organization.

Under no circumstances may this PDF file be placed on a network of any sort without our express permission.

You are solely responsible for the selection of this PDF file and any advice or recommendation given by us about any aspect of this PDF file is intended for guidance only and is followed or acted upon entirely at your own risk.

We are not aware of any inherent risk of viruses in this PDF file at the time that it is accessed. We have exercised due diligence to ensure, so far as practicable, that this file does not contain such viruses.

No warranty of any form is given by us or by any party associated with us with regard to this PDF file, and you accept and acknowledge that we will not be liable in any way to you or any to other person in respect of any loss or damage however caused which may be suffered or incurred or which may arise directly or indirectly through any use of this PDF file.

Regardless of where you were when you received this PDF file you accept and acknowledge that to the fullest extent possible you submit to New Zealand law with regard to this licence and to your use of this PDF file.

COMMITTEE REPRESENTATION

The Expert Committee P 8181 was responsible for the preparation of this Standard and consisted of representation from the following:

Nominating Organisations

Advisory Committee on Assisted Reproductive Technology (ACART)
Australian and New Zealand Infertility Counsellors' Association (ANZICA)
Designated Audit Agencies of New Zealand
Fertility Associates
Fertility New Zealand Inc. (Men's Advocacy representative)
Fertility New Zealand Inc.
Fertility Plus
Ministry of Health, New Zealand
New Zealand Committee, Royal Australian and New Zealand College of Gynaecologists (RANZCOG) and Fertility Plus
New Zealand Nurses Organisation (NZNO)
The Fertility Centre and Reproductive Technology Accreditation Committee (RTAC) (of the Fertility Society of Australia)
Women's Health Action Trust

Observer Members

District Health Boards New Zealand
New Zealand Resident Doctors' Association
Quality Health New Zealand
The Royal New Zealand College of General Practitioners

COPYRIGHT

Published by Standards New Zealand, the trading arm of the Standards Council, Private Bag 2439, Wellington 6140. Telephone (04) 498 5990, Fax (04) 498 5994. Website **www.standards.co.nz**.

REVIEW OF STANDARDS

Suggestions for improvements of this Standard will be welcomed. They should be sent to the Chief Executive, Standards New Zealand, Private Bag 2439, Wellington 6140.

AMENDMENTS

No.	*Date of issue*	*Description*	*Entered by, and date*

NZS 8181:2007

New Zealand Standard

Fertility services

ISBN 1-86975-058-6

NOTES

Contents

Committee representation . . . . . IFC
Copyright . . . . . IFC
Review of Standards . . . . . IFC
Preface 5
Acknowledgement 6
Review period 6
Disclaimer 6
Referenced documents 7
Latest Revisions 8
Health and Disability Commissioners' Code of Health and Disability Services Consumers' Rights 1996 (The Code) 9
Foreword 10
Background 11
Human Assisted Reproductive Technology Act 2004 11
Health and Disability Services (Safety) Act 2001 13
Scope 14
Exclusions (services not included) 14
Application 14
Definitions 15
Interpretation 15
Rights of children 15
Māori health 15
Audit workbook 16

Part

1 CONSUMER RIGHTS 17
1.1 Consumer rights during service delivery 18
1.2 Tangata whenua 19
1.3 Recognition of individual values and beliefs 20
1.4 Consumer confidentiality 21
1.5 Personal privacy and dignity 22
1.6 Consumer information 23
1.7 Informed consent 24
1.8 Health and well-being of offspring as a result of reproductive technologies . 25
1.9 Right to know one's genetic origins 26
1.10 Donation and information giving 27
1.11 Donor's rights and responsibilities 28

2 ORGANISATIONAL MANAGEMENT 29
2.1 Governance 30
2.2 Quality and risk management systems 31
2.3 Occupational health and safety 32
2.4 Exception reporting 33
2.5 Complaints management 34

2.6 Service management 35
2.7 Design and implementation of services using new ART technology 36
2.8 Human resource management 37
2.9 Service provider availability 38
2.10 Advertising and marketing strategies 39
2.11 Consumer information management system 40
2.12 Recording systems 41

3 CONTINUUM OF SERVICE DELIVERY 42
3.1 Entry to services 43
3.2 Declining entry to services 44
3.3 Donated gametes and embryos are safe and fit for purpose 45
3.4 Identification processes 46
3.5 Treatment provision 47
3.6 Safety of ART treatment 48
3.7 Day-stay procedures 49
3.8 Clinical review 50
3.9 Exit, discharge or transfer 51
3.10 Evaluation 52
3.11 Medicines, therapeutic goods and medical devices management 53
3.12 Infection control management 54
3.13 Management of waste and hazardous substances 56

4 SAFE AND APPROPRIATE ENVIRONMENT 57
4.1 Physical privacy 58
4.2 Facility and equipment specifications and maintenance 59
4.3 Natural light, ventilation and heating 60
4.4 Reception, waiting and other public areas 61
4.5 Cleaning and laundry services 62
4.6 Essential, emergency and security systems 63

Appendix

A The Code of Health and Disability Services Consumers' Rights (Normative) 64
B Glossary of terms (Normative) 70
C Clinic service providers (Normative) 77
D Closure of a fertility service (Informative) 81
E Related documents (Informative) 82

PREFACE

Kia ora koutou

Fertility services are becoming increasingly important to New Zealanders and their families, and able to assist with a wider range of needs.

The purpose of NZS 8181 *Fertility services* and the associated audit workbook (SNZ HB 8181 *Fertility services audit workbook*) is to ensure the safety and quality of fertility services and ultimately to promote and protect the interests of consumers and their families.

Assisted human reproduction is an area surrounded by rapidly changing technology, difficult ethical questions and emotional issues. In this context, this Standard will help consumers to understand their rights and providers their responsibilities.

This document is the result of many months' work by the Expert Committee, a group of dedicated people representing a range of organisations with an interest in fertility issues and the people whose lives they affect. It is also the result of the efforts of many people who took the time to participate in consultation during its development.

For certification purposes, this Standard will take the place of the Reproductive Technology Accreditation Committee's (RTAC) Code of Practice, against which New Zealand's fertility service providers have been measured for the past ten years. RTAC has made a valuable contribution to fertility services and this is reflected in the fact that many aspects of the Code of Practice have been incorporated into the Standard. Fertility service providers will be assessed against the Standard by audit agencies that I, as Director-General of Health, will designate under the Health and Disability Services (Safety) Act 2001.

I would like to thank the many people and organisations involved in the development of this Standard and the associated audit workbook. Your contribution has made this Standard relevant and useful and will continue to contribute to high quality fertility services into the future.

Stephen McKernan
Director-General of Health

Acknowledgement

Standards New Zealand gratefully acknowledges the contribution of time and expertise from all those involved in developing this Standard and the associated audit workbook.

The significant input provided by the Expert Committee whose experience and knowledge have made the development of this work possible, is particularly recognised.

Acknowledgment is also made of the organisations which, for whatever reason, were unable to fully participate in the Expert Committee, but had Observer status for the duration of the project and contributed during the public comment phase.

Special thanks to the Fertility Society of Australia (FSA) Reproductive Technology Accreditation Committee (RTAC) for making available the Code of Practice for Assisted Reproductive Technology Units (revised February 2005).

The Ministry of Health is acknowledged for funding this project.

Review period

It is intended that the Fertility services Standard and the associated audit workbook remain a dynamic document reflecting current accepted good practice.

In order to achieve this, regular review of the Standard will be required to ensure it remains appropriate and applicable. The Ministry of Health will consider the appropriate timing for the next review, taking into account developments in reproductive technology and international best practice.

Disclaimer

Standards New Zealand gratefully acknowledges the contribution of the Fertility Society of Australia ("FSA") for the use of its RTAC Code of Practice 2005 (the "Code") which assisted in the development of this Standard and the associated audit workbook. While of assistance, the Code was not prepared for the purposes or preparation of this Standard and the associated audit workbook; rather it was prepared for FSA's own specific purposes in Australia. FSA does not warrant in any way that the information in the Code is accurate, correct or reliable nor can it be relied upon by any party for any purpose whatsoever. To the extent permitted by law, FSA expressly disclaims any responsibility and all warranties express or implied and excludes all liability and liability for all loss whatsoever (including consequential loss) that may result in any way directly or indirectly from the use or reliance upon the Code.

Referenced documents

Reference is made in this Standard to the following:

New Zealand Standards

NZS 3003.1:2003	Electrical installations – Patient areas of hospitals and medical and dental practices – Testing requirements
NZS 3019:2004	Electrical installations – In-service testing
NZS 4102:1996	Safer house design
NZS 6703:1984	Code of practice for interior lighting design
NZS 8134:2001	Health and disability sector standards
NZS 8141:2001	Restraint minimisation and safe practice
NZS 8142:2000	Infection control
NZS 8143:2001	National mental health sector standard
NZS 8153:2002	Health records
NZS 8164:2005	Day-stay surgery and procedures

New Zealand Handbooks

SNZ HB 221:2004	Business continuity management
SNZ HB 8134.4:2004	Health and disability sector standards (children and young people) audit workbook
SNZ HB 8181:2007	Fertility services audit workbook

Joint Australian/New Zealand Standards and Handbook

AS/NZS 1336:1997	Recommended practices for occupational eye protection
AS/NZS 1337.5:2004	Personal eye-protection – Eye-protectors for adjustment work on lasers and laser systems (laser adjustment eye protectors)
AS/NZS 2211.1:2004	Laser safety – Equipment classification, requirements and user's guide
AS/NZS 2500:2004	Guide to the safe use of electricity in patient care
AS/NZS 3003:2003	Electrical installations – Patient areas of hospitals, medical and dental practices and dialyzing locations
AS/NZS 3551:2004	Technical management programs for medical devices
AS/NZS 3760:2003	In-service safety inspection and testing of electrical equipment
AS/NZS 4146:2000	Laundry practice
AS/NZS 4187:2003	Cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment and maintenance of associated environments in healthcare facilities
AS/NZS 4360:2004	Risk management
AS/NZS 4801:2001	Occupational health and safety management systems – Specification with guidance for use
AS/NZS 4804:2001	Occupational health and safety management systems – General guidelines on principles, systems and supporting techniques
AS/NZS 4815:2006	Office-based healthcare facilities – Reprocessing and reusable medical and surgical instruments and equipment, and maintenance of the associated environment
SAA/SNZ HB 228:2001	Guidelines for managing risk in healthcare

Other Publications

Fertility Society of Australia (2005) Code of Practice for Assisted Reproductive Technology Units.

Human Genetics Society of Australasia (2000) ASGC Code of Ethics. Human Genetics Society of Australasia. Australia.

Ministry of Health. (2002) He Korowai Oranga: Māori Health Strategy. Ministry of Health. Wellington.

Ministry of Health. (2006) Operational Standard for Ethics Committees. Ministry of Health. Wellington.

Ministry of Health, Medsafe. 1993-95. New Zealand Code of Good Manufacturing Practice for the Manufacture and Distribution of Therapeutic Goods, Parts 1-5. Wellington.

New Zealand Health and Disability Commissioner Advocacy Guidelines for the National Advocacy Service. (2005). Wellington.

Office of the Privacy Commissioner. (1994). Health Information Privacy Code. Auckland.

United Nations General Assembly (1989). Convention on the Rights of the Child. New York: United Nations Convention on the Rights of Children (1954).

New Zealand Legislation

Births, Deaths and Marriages Registration Act 1995

Children, Young Persons and their Families Act 1989

Fire Service Act 1975

Hazardous Substances and New Organisms Act 1996

Health and Disability Commissioner Act 1994

Health and Disability Services (Safety) (HDSS) Act 2001

Health and Safety in Employment Act 1992

Health Information Privacy Code 1994

Health Practitioners Competence Assurance Act 2003

Health (Retention of Health Information) Regulations 1996

Human Assisted Reproductive Technology (HART) Act 2004

Human Assisted Reproductive Technology Order 2005

Human Rights Act 1993

Privacy Act 1993

Protection of Personal Property Rights Act 1988

Latest Revisions

The users of this Standard should ensure that their copies of the above-mentioned New Zealand Standards and referenced overseas Standards are the latest revisions or include the latest amendments. Amendments to referenced New Zealand and joint Australian/New Zealand Standards can be found on www.standards.co.nz.

Health and Disability Commissioners' Code of Health and Disability Services Consumers' Rights 1996 (The Code)

The Health and disability sector Standards will assist in meeting obligations under the Code of Health and Disability Services Consumers' Rights 1996, a regulation under the Health and Disability Commissioner Act 1994. Therefore, this Standard should be interpreted in a manner that is consistent with consumers' rights and providers' obligations under the Code. Every person or organisation subject to this Standard should be knowledgeable about the Code and comply with its obligations.

Foreword

Reproductive medicine is undergoing constant change. The role of health practitioners providing fertility services is also constantly changing. Advances in technology, ethics and law have an impact on the provision of fertility services, and the activities of the health practitioners providing such services.

NZS 8181 *Fertility services* and its associated audit workbook have been developed to achieve the requirements of the Human Assisted Reproductive Technology (HART) Act 2004, and build on the existing co-operation among specialists and health practitioners in the developing area of fertility services provision.

It is timely that NZS 8181 has been developed. It will assist fertility service providers to meet the requirements of the HART Act and also to meet their obligations resulting from changes to the regulatory frameworks of professional groups with the passing of the Health Practitioners Competence Assurance Act 2003 (HPCA).

Since the passing of the Health and Disability Services (Safety) Act (the HDSS Act) in 2001, there have been a number of initiatives to improve safety and quality in the health and disability sector.

There are currently four key New Zealand Standards that are required by the HDSS Act:

(a) NZS 8134 *Health and disability sector standards*;

(b) NZS 8141 *Restraint minimisation and safe practice*;

(c) NZS 8142 *Infection control*; and

(d) NZS 8143 *National mental health sector standard*.

To promote consistency across the health and disability sector, NZS 8181 *Fertility services* has been developed within the framework set by the HDSS Act 2001.

For the purposes of the HDSS Act, fertility services are deemed to be included in the definition of "specified health or disability services" in section 4(1) of that Act.

Under the HART Act 2004, section 80 deems fertility services to be included in the definition of "specified health or disability services" in section 4(1) of the HDSS Act. This requires a safety Standard to be developed. NZS 8181 *Fertility services* will be gazetted for this purpose and fertility service providers will need to be certified against this Standard.

Under the HART Act, "fertility services" means services performed for the purpose of assisting human reproduction that involve:

(1) The creation of an in vitro human embryo;

(2) The storage, manipulation, or use of an in vitro human gamete or an in vitro human embryo;

(3) The use of cells derived from an in vitro human embryo; or

(4) The implantation in a human being of human gametes or human embryos.

Background

Human Assisted Reproductive Technology Act 2004

In order to strengthen levels of safety for the consumers of fertility services in New Zealand, and to enable the implementation of the requirements of the Human Assisted Reproductive Technology Act 2004 (the HART Act), the Ministry of Health (MoH) contracted Standards New Zealand to work with the sector to develop this Fertility services Standard and the associated audit workbook.

The HART Act sets a new framework for the use and future development of reproductive technologies. The Act, in section 3, lists among its purposes:

(a) To secure the benefits of assisted reproductive procedures and research by protecting the health, safety, dignity and rights of all individuals;

(b) To prohibit unacceptable procedures and research;

(c) To prohibit certain commercial transactions relating to human reproduction;

(d) To provide a framework for the regulation and guidance of procedures and research;

(e) To prohibit the performance of procedures other than established procedures without the approval of the ethics committee;

(f) To establish comprehensive information keeping.

Further, the HART Act sets out a series of principles in section 4 to guide those who perform functions under the Act:

(g) The health and well-being of children born as a result of an assisted reproductive procedure should be an important consideration in all decisions about the procedure;

(h) Human health, safety and dignity of present and future generations should be preserved and promoted;

(i) The health and well-being of women shall be protected in the use of these procedures;

(j) No procedure or research should be conducted on an individual unless that individual has given informed consent;

(k) Donor offspring should be made aware of their genetic origins and have access to information about this;

(l) The needs, values and beliefs of Māori should be considered and treated with respect;

(m) Different ethical, spiritual and cultural perspectives in society should be considered and treated with respect.

The HART Act contains some very specific and detailed requirements on prohibited and regulated activities, and information about donors and donor offspring, which are incorporated into this Standard and the associated audit workbook.

The HART Act (Part 2, subpart 3) establishes, appoints and sets out the functions of the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research (ACART or Advisory Committee). ACART is an advisory committee to the Minister of Health. The primary functions of ACART are to:

(n) Issue guidelines and advice to the Ethics Committee (ECART); and

(o) Provide the Minister with advice on the regulatory issues of assisted reproductive procedures or reproductive research, such as further prohibition, declaration of an established procedure; or modification, whether a moratorium should be imposed and whether regulations of the performance of any kind of procedure or research should be made.[1]

ACART is required to undertake consultation before issuing guidelines to ECART or providing advice to the Minister of Health. Further information can be found on the ACART website: www.newhealth.govt.nz/acart.

The HART Act (Part 2, subpart 2) sets out the framework for ethical review of assisted reproductive procedures and reproductive research by establishing the Ethics Committee (ECART), a committee designated by the Minister of Health under section 27 of the HART Act. The primary functions of ECART are to:

(p) Consider and determine applications for assisted reproductive procedures or human reproductive research; and

(q) Keep under review any approvals previously given, including those applications approved prior to the existence of ECART, and, without limitation, to monitor the progress of any assisted reproductive procedures performed or any human reproductive research conducted under current approvals.

In carrying out its functions, ECART must operate in accordance with any guidelines or advice issued by ACART. Where the kind of activity is not covered in guidelines or the proposed activity is inconsistent with relevant guidelines or advice, ECART must decline the application or refer it to ACART.[2]

Assisted reproductive procedures and reproductive research may only proceed with prior approval from ECART and in accordance with any conditions imposed by ECART and any regulations under section 76 of the HART Act.[3] ECART is not required to review applications for procedures which are declared to be "established procedures" under the Human Assisted Reproductive Technology Order 2005. However, it is important that all healthcare procedures/interventions undertaken within a fertility clinic, whether "established" or not, follow the principles of current accepted good practice.

Further information can be found on the ECART website www.newhealth.govt.nz/ecart.

Research and innovative practice that falls outside the scope of the HART Act 2004 should meet the requirements of the Health and Disability Ethics Committees (refer to the Operational Standard for Ethics Committees, Part 3: Matters Requiring Ethical Review. This document is available on the Ministry of Health website www.moh.govt.nz).

Health and Disability Services (Safety) Act 2001

Over the past ten years, professional oversight of fertility service providers in New Zealand has been provided by the Reproductive Technology Accreditation Committee (RTAC), the accreditation body of the Fertility Society of Australia. Fertility clinics have been audited by RTAC against the RTAC Code of Practice. Clinics have been required to meet RTAC accreditation requirements in order to access public funding. Aspects of the RTAC Code of Practice have been incorporated into NZS 8181.

Under the HART Act, fertility services are deemed to be included in the definition of "specified health and disability services" for the purposes of section 4(1) of the Health and Disability Services (Safety) Act 2001 (HDSS Act) [4] and are also regulated under the HDSS Act. The purpose of the HDSS Act is to promote the safe provision of health and disability services and to establish Standards for providers of health and disability services[5]. This means that all "fertility services"[6] offered by fertility clinics, whether "established procedures"[7] or "assisted reproductive procedures"[8] and "human reproductive research"[9], will need to meet NZS 8181. Interim provisions in the HART Act have allowed time for the New Zealand Fertility services Standard and the associated audit workbook to be developed and for providers to comply with the Standard (as provided for in the HDSS Act).[10]

1. Section 35(1)(b)(i)-(v) HART Act.
2. Section 18(2) and19(2) HART Act.
3. Section 16 and 17 HART Act.
4. Section 80 HART Act.
5. Section 3 HDSS Act.
6. Section 80 HART Act.
7. Section 6 HART Act.
8. Section 5 HART Act
9. Section 5 HART Act.
10. Section 81 HART Act.

Scope

NZS 8181 *Fertility services* defines the quality and safety requirements for the provision of fertility services, with emphasis on the following areas:

(a) Ethical and cultural safety;

(b) Donor information and privacy;

(c) Practices for the storage of reproductive material;

(d) Consumer rights; and

(e) Health and physical safety.

It has been developed by the Expert Committee P 8181 to achieve the requirements of:

(f) NZS 8134 Health and disability sector Standards;

(g) NZS 8164 Day-stay surgery and procedures;

(h) The Human Assisted Reproductive Technology (HART) Act 2004;

(i) Relevant evidenced-based practices, and current accepted good practice (New Zealand and international) and the Code of Practice for Assisted Reproductive Technology Units (Fertility Society of Australia, revised February 2005);

(j) Any contractual service specification for fertility services; and

(k) The Health Practitioners Competence Assurance Act 2003.

The audit workbook will assist providers and auditors in the implementation and review of compliance with this Standard.

Exclusions (services not included)

Processes around the certification or designation of accrediting agencies to audit providers are outside the scope of this Standard.

Application

Since the HART Act deems fertility services to be included within the definition of specified health or disability services in section 4(1) of the Health and Disability Services (Safety) Act, providers of fertility services will be required to comply with this Standard, and be audited by a Designated Audit Agency (DAA), and certified by HealthCert.

NZS 8181 *Fertility services* will apply to health and disability fertility service providers in public and private settings. The settings may range from small units through to services provided by a large District Health Board.

Each organisation is unique. Specific interpretation, application and contextualisation in each environment is required, relative to the setting, consumer acuity and complexity of service provided, and any risks associated with the provision of the service.

This Standard and the associated audit workbook should be interpreted in a manner that is consistent with consumer rights and provider obligations under the Code of Health and Disability Services Consumers' Rights. Compliance with the Standard and the associated audit workbook will assist services to meet their obligations under the Code. Every service or person who implements this Standard should be knowledgeable about the Code of Health and Disability Services Consumers' Rights and comply with the duties set out in it. A copy is attached in Appendix A for reference.

Definitions

See Appendix B for the terms/abbreviations and descriptions used in this Standard and audit workbook. Where possible, and to promote consistency within the health and disability sector, these have been aligned with NZS 8134 *Health and disability sector Standards*, and the definitions and abbreviations suggested by the Fertility Society of Australia.

Interpretation

Where the Standard is implemented the following shall apply:

(a) A "Normative" appendix is an integral part of a Standard, whereas an "Informative" appendix is only for information and guidance. Informative provisions do not form part of the mandatory requirements of this Standard;

(b) The word "shall" refers to practices that are mandatory for compliance with the Standard. It is also used for practices that are already mandated in other documents. The word "should" refers to practices that are advised or recommended.

For information on New Zealand legislation refer to www.legislation.govt.nz.

Rights of children

The rights of children and young people born as a result of fertility treatment need to be considered during the fertility process. The United Nations Convention on the Rights of the Child (UNCROC) states "the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth".

In order to implement UNCROC the emphasis must be holistic and consider the needs of children, young people and their families. Refer to SNZ HB 8134.4 for further information on the rights and needs of children and young people.

Māori health

To achieve Māori health improvement and the reduction of Māori health inequalities, this Standard focuses on:

(a) Ensuring accessible and appropriate services for Māori;

(b) Providing quality improvement systems that focus on Māori receiving health services commensurate with their health needs; and

(c) Enabling Māori and whānau involvement in health decisions.

This document references the framework and principles for the public sector to take into account supporting the health status of Māori as set out in He Korowai Oranga: Māori Health Strategy (2002).

Audit workbook

The purpose of the audit workbook (SNZ HB 8181) associated with this Standard is to:

(a) Establish the degree of attainment against NZS 8181 *Fertility services*;

(b) Identify areas of compliance, and/or areas requiring improvement in order to reduce the risk of serious failure impacting on service delivery.

This will be achieved by:

(c) Focusing on the required outcomes of NZS 8181;

(d) Identifying common acceptable solutions (system, processes, methods etc.) appropriate to the consumer, service and setting that will attain the desired outcomes;

(e) Recognising alternative solutions that achieve the same outcome while providing safe services to consumers;

(f) Evaluating the level of attainment within a continuous quality improvement framework, and in relation to the maturity of the service.

Part 1 Consumer Rights
Ngā Tikanga o te Kiritaki

Outcome: ***Consumers receive safe and reasonable services in a manner that is respectful of their rights, minimises harm, and acknowledges their cultural and individual values and beliefs.***

Guidance: The consumers of fertility services may include any person receiving treatment, or providing gametes in relation to treatment, at a fertility service. This includes prospective parents, those involved in surrogacy, gamete donors and any children born as a result of treatment provided at the fertility service.

Relevant legislation

Refer to rights based legislation and consumer rights legislation.

Consumers are made aware of their rights to access and have present an advocate or support person of their choice at any time during their involvement with the service. Refer to the Health and Disability Commissioner Advocacy Service Guidelines.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.1 Consumer Rights During Service Delivery

Ngā Āhuatanga kia whakawāteatia ki te Kiritaki i a ia e whakaorangia ana

Outcome: ***Consumers receive services in accordance with consumer rights legislation.***

1.1.1 The organisation ensures that the Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights 1996 (the Code) is made known, and/or made available to the consumer using the service.

1.1.2 The organisation ensures that information is provided at the earliest opportunity in languages and formats suited to the needs of persons who use the service.

1.1.3 The organisation ensures that services promote the consumer's freedom of choice balanced with the need for service delivery and are conducted in a manner that is respectful and recognises the consumer's individuality.

1.1.4 The organisation ensures that consumers and service providers are aware of their rights and obligations under the Human Assisted Reproductive Technology Act and the Human Rights Act.

1.1.5 The organisation ensures that consumers are informed verbally, and in writing, or other formats if required, of their right to advocacy or a support person of their choice.

1.1.6 The organisation ensures that the consumer's right to complain is respected by the service.

1.1.7 The organisation ensures that consumers are not subjected to abuse and/or neglect as a result of service delivery.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.2 Tangata Whenua

Outcome: ***Consumers who identify as Māori have their health and disability needs met in a manner that respects and acknowledges their individual values and beliefs.***

1.2.1 The organisation ensures Māori are able to have whānau, hapū and iwi involvement in treatment, support, care plans, and review.

1.2.2 The organisation ensures the service provides access to and/or facilitates culturally appropriate programmes, treatment and support that are respectful of the values and beliefs of Māori.

1.2.3 The organisation ensures that Māori are supported to continue their cultural/traditional practices while receiving fertility services.

1.2.4 The organisation develops necessary links with other Māori organisations such as rūnanga and/or recruits and employs people with links to whānau, hapū and iwi who have relevant Māori cultural knowledge and expertise and experience in health and disability issues.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.3 Recognition of Individual Values and Beliefs
Te aro nui ki ngā Uara Whaiaro me ngā Tikanga a te Kiritaki

Outcome: Consumers receive services in a manner that recognises their cultural and individual values and beliefs.

1.3.1 The organisation ensures service providers identify, and respond sensitively, to the belief and value systems of consumers during service delivery.

1.3.2 The organisation ensures that wherever necessary policies/procedures for interpreter or translation services are developed and implemented.

1.3.3 The organisation ensures that the consumer's cultural or spiritual beliefs regarding the disposal of gametes and embryos are respected.

1.3.4 The organisation supports and facilitates the delivery of culturally safe services.

1.3.5 The organisation ensures that policies/procedures are developed and implemented so that the service provider discusses in advance waste disposal processes with the consumer.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.4 Consumer Confidentiality
Te Noho Matatapu o ngā pānga ki te Kiritaki

Outcome: Consumer confidentiality is maintained at all times.

1.4.1 The organisation ensures that all steps are taken to maintain the confidentiality of the consumer's information in compliance with the requirements of the Privacy Act and the Health Information Privacy Code.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.5 Personal Privacy and Dignity
Te Mana Motuhake me te Noho Matatapu o te Kiritaki

Outcome: ***The personal privacy and dignity of the consumer is respected and met during service provision.***

1.5.1 The organisation ensures that the service provider develops and implements the policies/ procedures that address the protection of personal privacy and respect for the consumer.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.6 Consumer Information
Pārongo Kiritaki

Outcome: ***Consumers receive information that is accurate, timely and in formats appropriate to the consumer.***

1.6.1 The organisation ensures that consumers receive information that is accurate, timely and in formats appropriate to the consumer.

1.6.2 The organisation ensures that consumers receive information covering all important aspects relating to fertility treatment.

1.6.3 The organisation ensures that the service provider informs consumers of the uses to which the consumer's medical information may be put.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.7 Informed Consent
Te Whakaae i runga i te mōhio

Outcome: ***Consumer consent is obtained in line with the requirements of the Code of Health and Disability Services Consumers' Rights and the principles of the Human Assisted Reproductive Technology Act.***

1.7.1 The organisation ensures that the service providers have consent forms appropriate for the procedures performed by the service.

1.7.2 The organisation develops and implements policies/procedures which clearly guide service providers in obtaining informed consent from consumers.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.8 Health and Well-being of Offspring as a Result of Reproductive Technologies

Te Hauora me te oranga o ngā tamariki ka whānau nā runga i ngā hangarau hapūtanga

Outcome: The health and well-being of offspring born as a result of fertility services shall be an important consideration in all decisions about the services.

1.8.1 The organisation ensures the service provider demonstrates during the development and delivery of fertility services that the health and well-being of children have been considered.

1.8.2 The organisation ensures it contributes information about the outcomes of treatments, including the health and well-being of children, to ANZARD, and any other agencies appointed by the Ministry of Health.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.9 Right to Know One's Genetic Origins
Te tika o te mōhio ki ō ira taketake

Outcome: Donor offspring should be made aware of their genetic origins and should be able to access information about their origins.

1.9.1 The organisation develops and implements policies/procedures that support offsprings' knowledge of their genetic origins.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.10 Donation and Information Giving
Te hoatu takoha me te pārongo

Outcome: ***Gamete and embryo donation takes place in a way that protects the interests and health of donors, consumers and offspring.***

1.10.1 The organisation ensures that all donors and recipients of gametes or embryos are informed they are required to meet with an ANZICA approved counsellor.

1.10.2 The organisation ensures the service provider shall not collect or use gametes or embryos for donation from a person who has not given consent.

1.10.3 The organisation ensures that consent for donation shall be obtained from the donor's partner if he or she is married, in a civil union or in a de facto relationship with the donor.

1.10.4 Confidential records about donors shall be retained by the organisation in accordance with sections 47 and 48 of the HART Act.

1.10.5 The organisation ensures donors and recipients are informed of the process for disclosure of identifying information, as required by the HART Act.

1.10.6 The organisation ensures service providers shall explain the provisions, responsibilities and obligations in the HART Act for facilitating linking between donors, consumers and offspring.

1.10.7 The organisation ensures the service provider shall have written policies/procedures which are developed and implemented to cover donor linking.

1 Consumer Rights
Ngā Tikanga o te Kiritaki

1.11 Donor's Rights and Responsibilities
Ngā tika o ngā kaitakoha me ō rātou haepapa

Outcome: ***Donors shall be made aware of their rights and responsibilities, and shall be encouraged to exercise them.***

1.11.1 The organisation shall ensure potential donors are informed of;

(a) The storage and potential use of their gametes or embryos, and the processes involved in donation;

(b) The procedures involved in collecting gametes, the degree of pain and discomfort, and any risks to the person (e.g. from the use of ovarian stimulation drugs);

(c) The screening to be carried out and the practical implications of having an HIV antibody test;

(d) The purposes for which the gametes or embryos might be used;

(e) Legislation defining the legal status of children born as a result of the procedure;

(f) The information that service providers collect and the extent to which that information may be disclosed to people born as a result of the donation;

(g) The possibility that a child born disabled as a result of a donor's failure to disclose defects, is the legal responsibility of the donor;

(h) In the case of oocyte donation, that the woman shall not incur any financial or other penalty if she withdraws her consent after preparation for oocyte recovery has begun;

(i) The donated gametes and embryos created from them shall not be used for treatment after children have been generated for the number of families specified in the relevant legislation or guidelines;

(j) The options of placing boundaries on the use of their gametes and the donor's wishes are carried out by the service provider;

(k) Their right to withdraw or vary the terms of their consent and specify limits, subject to any relevant legislation, at any time until the gametes or embryos are used;

(l) What will happen with their gametes if the donors die.

Part 2 Organisational Management
Ngā Whakahaere a te Umanga

Outcome: ***Consumers receive services that are managed in a safe, efficient and effective manner and that comply with legislation.***

Guidance: ***Relevant legislation***

Services shall comply with the New Zealand Human Assisted Reproductive Technology (HART) Act, and other relevant legislation and ethical guidelines.

Research

Fertility services are encouraged to have an active research programme.

New laboratory techniques shall be scientifically validated before their introduction into clinical practice and shall meet any requirements for ethical review.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.1 Governance
Te Āhua o te Whakahaere Whānui

Outcome: ***Efficient and effective governance ensures services are planned, co-ordinated and appropriate to the needs of the consumer group.***

2.1.1 The organisation ensures that its purpose, scope, strategic direction and goals are clearly identified.

2.1.2 The organisation ensures that monitoring of performance is aligned with the performance, purpose, scope, strategic direction and goals.

2.1.3 The organisation appoints a suitably qualified and/or experienced person to manage the service with authority, accountability and responsibility for service provision.

2.1.4 The organisation supports consumer and community participation in the planning, implementation, monitoring and evaluation of service delivery.

2.1.5 The organisation ensures that policies/procedures and guidelines are developed and implemented and comply with all regulatory requirements and Standards that are relevant to the service.

2.1.6 The organisation provides treatment and support for Māori that is aimed at improving fertility outcomes for Māori and a reduction in Māori health inequalities in this area.

2.1.7 The organisation shall identify suitably qualified and/or experienced people to carry out the functions of:

(a) 'Person responsible for activity', as defined in section 20 of the HART Act;

(b) 'Practice Director', who is responsible and accountable for the activity of the organisation covered by NZS 8181, and for communication with ANZARD.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.2 Quality and Risk Management Systems
Pūnaha Whakahaere Kounga, Tirotiro Whakararu

Outcome: ***The organisation has an established, documented and maintained quality and risk management system that reflects continuous quality improvement principles to better meet the needs of consumers and service providers.***

Guidance: *The quality and risk management system reflects continuous quality improvement principles and may be separate from, or included in, the service's strategic or business plan.*

Sound clinical judgement shall be applied in balancing safety and risk in relation to a consumer's own goals.

The quality management system ensures that all materials and phases of treatment have been evaluated, facilities are suitable, personnel are competent, and all necessary policies/procedures are developed and implemented to assure this quality. Quality management systems ensure fertility services consistently provide services that meet both consumer and regulatory requirements, and maintain consumer satisfaction.

Some aspects of the provision of fertility services require specific risk management protocols that would at least cover: infection control, avoiding the risk of consumer misidentification, reducing the risks of multiple pregnancy, reducing the risks of ovarian hyperstimulation syndrome, compliance with occupational health, environment and safety requirements, and drug administration.

2.2.1 The organisation ensures the quality and risk management system has commitment and participation by management and service providers, and incorporates consumer feedback.

2.2.2 The organisation ensures that relevant Standards are identified and implemented to meet current accepted good practice in the relevant service area or setting.

2.2.3 The organisation ensures that policies/procedures are developed, implemented and documented to a level of detail that enables safe care and these are regularly reviewed.

2.2.4 The organisation ensures that the results of the quality and risk management system are reviewed regularly by the management team or nominated group to ensure monitoring of outcomes and trends are identified.

2.2.5 The organisation ensures the continuous quality improvement process contributes to service improvements, including robust corrective and preventive action.

2.2.6 The organisation has a process to review achievement against the quality and risk management plan.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.3 Occupational Health and Safety
Hauora me te haumanu mahi

Outcome: ***The organisation has a documented and maintained occupational safety and health policy to protect consumers and service providers.***

Guidance: *Refer to SAA/SNZ HB 228* Guidelines for managing risk in healthcare, *AS/NZS 4360* Risk management, *AS/NZS 4801* Occupational health and safety management systems – Specification with guidance for use, *and AS/NZS 4804* Occupational health and safety management systems – General guidelines on principles, systems and supporting techniques *for additional information*.

2.3.1 The organisation shall have a comprehensive health and safety policy including written procedures for health and safety management which complies with the requirements of the health and safety legislation.

2.3.2 The organisation ensures records relating to health and safety are accurate and kept up to date.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.4 Exception Reporting
Pōrongorongo Mate Huhua

Outcome: The organisation systematically collects, reviews and acts on all adverse, unplanned and untoward events to improve its services to consumers.

2.4.1 The organisation ensures that all adverse, unplanned or untoward events are systematically recorded by the service.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.5 Complaints Management
Te Tirotiro Whakapae

Outcome: ***The organisation improves its services by formally acting on complaints from consumers and family/whānau.***

2.5.1 The organisation ensures there is a clear documented process for the identification and management of consumer complaints that complies with legislative requirements and that the process is implemented.

2.5.2 The organisation ensures the complaint management process is clearly communicated to consumers, family/whānau and service providers.

2.5.3 The organisation ensures the complaint management process is sensitive to and respects the values and beliefs of consumers.

2.5.4 The organisation ensures any complainant is informed of the right to have an independent advocate.

2.5.5 The organisation ensures the complaint management process is linked to the quality and risk management system to facilitate feedback and improvements.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.6 Service Management
Te Whakahaere Ratonga

Outcome: ***The day to day operation of the service is managed in an efficient and effective manner which ensures the provision of timely, appropriate and safe services to consumers.***

2.6.1 The organisation ensures the legislation and regulatory requirements that determine the provision of the services are clearly met.

2.6.2 The organisation ensures that the service provision meets the specific needs of the consumer group entering the service.

2.6.3 The organisation shall ensure reporting to relevant agencies is managed in a timely manner.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.7 Design and Implementation of Services Using New Assisted Reproductive Technology

Te hoahoa me te whakatinana i ngā ratonga mā te whakamahi i te hangarau hōu

Outcome: New assisted reproductive techniques are well-designed to maximise the safety and well-being of consumers and their children.

2.7.1 The organisation ensures any new assisted reproductive techniques shall be subject to ECART approval if they are assisted reproductive procedures as defined by the HART Act.

2.7.2 The organisation ensures any new assisted reproductive techniques shall be subject to ECART approval if they are covered under the HART Act.

2.7.3 The organisation ensures consumers shall be informed if a new assisted reproductive technique is being used.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.8 Human Resource Management
Maimoa Pūmanawa Tangata

Outcome: ***The organisation manages its human resources to ensure competent staff deliver a safe and effective service for consumers.***

2.8.1 The organisation ensures the skills and knowledge required of each position are identified and the outcomes, accountability, responsibilities, authority and functions to be achieved in each position are documented.

2.8.2 The organisation ensures professional qualifications are validated, including evidence of registration where applicable prior to employment.

2.8.3 The organisation ensures that appropriate service providers are appointed to safely meet the needs of consumers.

2.8.4 The organisation ensures that new service providers receive an orientation/induction programme that covers the essential components of the service provided.

2.8.5 The organisation has policies/procedures which are developed and implemented in accordance with good employment practice and meet the requirements of legislation.

2.8.6 The organisation ensures a system to identify, plan, facilitate and record training, ongoing education and/or professional supervision for service providers is implemented.

2.8.7 The organisation ensures policies/procedures are developed and implemented for training, supervision and competency recording when service providers work outside the scope of practice normally associated with their discipline. This may happen when nurses perform pregnancy or diagnostic ultrasound, or sperm preparation for insemination.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.9 Service Provider Availability
Te Aro Nui, te Tautōhito o Ngā Taumatua

Outcome: ***Consumers receive timely, appropriate and safe service from suitably qualified/skilled and/or experienced service providers.***

Guidance: *Fertility services shall employ a medical director, a practice director, and an embryology laboratory director. The medical director or laboratory director may act as the overall practice director. There are specific training requirements for medical, nursing, scientific and counselling staff.*

All health practitioners shall be registered and licensed by their relevant registering authority following the requirements of the HPCA Act.

2.9.1 The organisation ensures suitably qualified/skilled and/or experienced service providers are appointed to meet the needs of consumers in a competent, safe and timely manner. See Appendix C.

2.9.2 The organisation ensures there is a clearly documented rationale for determining service provider levels and skill mixes in order to provide safe service delivery. This is effectively implemented to meet the goals and standards of the organisation.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.10 Advertising and Marketing Strategies
Ngā rautaki whakatairanga me te tauhokohoko

Outcome: ***Consumers receive accurate and balanced advertising and marketing information about the service.***

Guidance: *Information about proper and acceptable standards of advertising, provided by the Advertising Standards Authority Inc. can be found at www.asa.co.nz.*

This applies to advertisements and any information prepared for consumers or the public. Such information includes pamphlets, booklets, webpages and other media (e.g. radio and television).

2.10.1 The organisation ensures that all advertising and marketing strategies and information about the service are presented in a consistent and accurate manner, are socially responsible, and do not mislead or deceive the consumer.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.11 Consumer Information Management System
Te Pūnaha Whakahaere Pārongo Kiritaki

Outcome: ***An accurate, accessible, confidential and secure record that promotes efficient and effective delivery of treatment and/or support is maintained for each consumer receiving the service.***

The detail of information required to manage consumer records is identified relevant to the service.

On closure of a fertility service, the integrity of information and stored gametes and embryos are maintained. See Appendix D.

2.11.1 The organisation shall have in place a system to record relevant and appropriate information to safely identify consumers and track records.

2.11.2 The organisation ensures that the information required by the HART Act is collected.

2.11.3 Where organisations are responsible for National Health Index (NHI) registration of consumers, they meet the recording requirements specified by the New Zealand Health Information Service (NZHIS).

2.11.4 Where organisations are not required to meet the data requirements of the New Zealand Health Information Service (NZHIS) they collect adequate consumer detail to safely manage consumer information.

2.11.5 The organisation ensures information is entered into the consumer information management system in an accurate and timely manner appropriate to the service type and setting and in line with the requirements of NZHIS.

2 Organisational Management
Ngā Whakahaere a te Umanga

2.12 Recording Systems
Te Pūnaha Pupuri Kōrero

Outcome: ***Consumer records are accurate, reliable, authorised and comply with current legislative and/or regulatory requirements, and the needs of consumers.***

Guidance: *Record keeping is especially essential in the provision of fertility services; there are specific documentation requirements for clinical and laboratory results, recording of procedures, identifying consumers, gamete or embryo donors and recipients, and outcomes of attempted fertilisation and conceptions. The fate of every embryo shall be able to be readily determined.*

For guidance on appropriate levels of documentation and management of health records providers should refer to relevant legislation and Standards. Refer to NZS 8153 Health records.

Information about the requirements of the New Zealand Health Information Service (NZHIS) can be found at www.nzhis.govt.nz.

2.12.1 The organisation ensures documentation meets the requirements of the Health Information Privacy Code and the Health (Retention of Health Information) Regulations, and complies with other appropriate legislation, relevant professional and sector standards where these exist.

2.12.2 The organisation ensures information of a private or personal nature is maintained in a secure manner that is not publicly accessible or observable.

2.12.3 The organisation ensures service providers use up to date and relevant consumer records.

2.12.4 The organisation ensures all records are legible and the name of the service provider is identifiable.

2.12.5 The organisation ensures documentation pertaining to the individual consumer's service delivery is integrated.

2.12.6 The organisation ensures systems are in place to track and retrieve consumer records when they are removed from the main record management area.

2.12.7 The organisation ensures retained/archived records are maintained in a suitable order and condition so that they may be retrieved when required.

2.12.8 The organisation shall have routine procedures which are established to enable a back-up and disaster recover strategy.

Part 3 Continuum of Service Delivery
He Hātepe Tuku Ratonga

Outcome: ***Consumers participate in and receive timely assessment followed by care that is planned, co-ordinated and delivered in a timely and appropriate manner, within current legislation.***

3 Continuum of Service Delivery
He Hātepe Tuku Ratonga

3.1 Entry to Services
Whakaurunga ki ngā ratonga

Outcome: ***Consumers are considered for entry to ART treatment, including specialist consultation, diagnosis, and scoring for eligibility, in an equitable and timely manner.***

3.1.1 The organisation ensures service providers considering referrals, and undertaking consultation, diagnosis and scoring are suitably qualified, skilled and/or experienced to perform this function competently.

3.1.2 The organisation ensures consultation and diagnosis determines existing and potential risks for each consumer in order to facilitate appropriate and timely entry to the service.

3.1.3 The organisation ensures assessment processes and entry criteria are clearly documented, comply with human rights legislation and are communicated to consumers, local communities and referral agencies in order to promote appropriate referral.

3.1.4 The organisation ensures the service operates at times most appropriate to meet the needs of the consumer group.

3.1.5 The organisation ensures the needs, outcomes and/or goals of consumers are identified during the assessment process and are documented to help defined treatment options.

3.1.6 The organisation ensures adequate and accurate information about the service is made available.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.2 Declining Entry to Services
Te Whakapekapeka o te Urunga Mai

Outcome: ***Where entry to the service is declined, consumers receive adequate support and information regarding the reasons for the service being declined.***

3.2.1 The organisation's consumers for whom entry to the service has been declined are informed of the reason for this.

3.2.2 The organisation ensures consumers are informed of other reasonable options or alternative services that may assist them with respect to their needs and risks.

3.2.3 Where a potential consumer is declined entry to the service the organisation ensures this is recorded and the referrer informed. Where this information is required for statistical purposes it is conveyed to the appropriate authority or agency.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.3 Donated Gametes and Embryos are Safe and Fit for Purpose

He haumaru, he hāngai ki te kaupapa ngā gametes me ngā kikiri kua takohahia

Outcome: Gametes and embryos are safe for donation.

3.3.1 The organisation ensures written policies and procedures are developed and implemented which outline the criteria used for selecting donors.

3.3.2 The organisation shall develop and implement policies/procedures for donor eligibility.

3.3.3 The organisation ensures the risk of transmission of infectious agents between donors of gametes and/or embryos and recipients is minimised.

3.3.4 The organisation ensures there is a documented system for collection and retrieval of gametes, to ensure that the quality of the donation is not compromised.

3.3.5 The organisation has a policy that limits the number of children from one donor.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.4 Identification processes
Te tukunga tautuhi

Outcome: Consumer's gametes, embryos and consumers are correctly identified and matched at all times.

3.4.1 The organisation develops and implements safe policies/procedures in regards to identification of consumers, gametes and other biological samples.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.5 Treatment Provision
Ngā Whakaritenga Maimoatanga

Outcome: Consumers receive timely, competent and appropriate treatment.

3.5.1 The organisation ensures that treatment is undertaken by suitably qualified/skilled service providers.

3.5.2 The organisation ensures that treatment is developed in partnership with the consumer, family/whānau or other representatives as appropriate.

3.5.3 The organisation ensures treatment is provided within time frames in order to safely meet the needs of the consumer.

3.5.4 The organisation ensures treatment plans are recorded to the level of detail required to demonstrate that the needs of the consumer are met.

3.5.5 The organisation develops and implements systems which ensure co-ordination and continuity in service delivery.

3.5.6 The organisation ensures that services develop plans which demonstrate service integration.

3.5.7 The organisation shall ensure counselling is provided which meets the needs of the person for the service they receive, based on current accepted good practice.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.6 Safety of ART Treatment
Te haumaru o te hangarau āwhina hapūtanga

Outcome: ***The well-being of consumers and their children is improved by limiting the risks of ART treatment.***

3.6.1 The organisation has policies/procedures which are developed and implemented to limit risks for consumers to ART.

3.6.2 The organisation has developed and implemented policies/procedures that minimise the risk of multiple pregnancy.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.7 Day-stay Procedures
Ngā Whakahaere mō te noho i te rā

Outcome: ***Consumers receive timely, competent and appropriate service provision in order to meet their assessed needs.***

3.7.1 The organisation ensures consumer preparation for egg collection, testicular biopsy or other day-stay procedure.

3.7.2 The organisation ensures the safe discharge of the consumer after the procedure.

3.7.3 The organisation ensures there is post-procedure support.

3.7.4 The organisation ensures the level of sedation or anaesthesia used is appropriate and safe for:

(a) The consumer;

(b) Any pre-existing medical conditions;

(c) The procedure;

(d) The clinical setting;

(e) The education and competence of the personnel;

(f) The equipment available.

3.7.5 The organisation develops and implements policies and procedures to manage clinical emergencies that may arise.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.8 Clinical Review
Arotake Haumaru

Outcome: ***Service delivery for individuals is evaluated in a comprehensive and timely manner.***

3.8.1 The organisation ensures reviews are documented, consumer focused, and consider progress towards meeting the assessed outcome or goal.

3.8.2 The organisation ensures reviews are conducted at a frequency that enables regular monitoring of progress towards achievement of assessed outcomes or goals.

3.8.3 The organisation ensures where progress is less than expected, the service responds to this and initiates changes to the service delivery plan.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.9 Exit, Discharge or Transfer
Te Putanga, te Tuku, te Whakawhitinga Rānei

Outcome: ***Consumers are appropriately advised of their options to access other health and disability services where indicated or requested. Consumers experience a planned and co-ordinated exit from services.***

3.9.1 The organisation ensures the service provider identifies the needs of individual consumers for referral to other health and/or disability service providers.

3.9.2 The organisation ensures there are current contact and referral details, and established links with other clinical services, support services, and community agencies, including for pregnancy care.

3.9.3 The organisation ensures the safety of the consumer is managed by service providers co-operating during the referral process.

3.9.4 The organisation ensures service providers facilitate a planned exit of consumers that is documented, communicated and effectively implemented.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.10 Evaluation
Arotakenga

Outcome: ***Future consumers benefit from the review and evaluation of service delivery.***

3.10.1 The organisation ensures service delivery is reviewed and changes or additions to the service delivery process are documented.

3.10.2 The organisation ensures documentation which is no longer relevant or current to the service delivery process is indicated as discontinued ensuring the information remains legible for historical/legal purposes.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.11 Medicines, Therapeutic Goods and Medical Devices Management
Ngā Whakahaerenga rongoā, rawa haumanu me ngā taputapu Hauora

Outcome: ***Consumers receive medicines, therapeutic goods and/or medical devices in a safe and timely manner that complies with current legislative and regulatory requirements.***

Guidance: *Information about medicines, therapeutic goods and medical devices can be found at the Medsafe, New Zealand Medicines and Medical Devices Safety Authority (a business unit of the Ministry of Health) website: www.medsafe.govt.nz.*

3.11.1 The organisation ensures a system is implemented to manage the safe and appropriate prescribing, dispensing, administration, review, storage and disposal of medicines and therapeutic devices and/or medical devices, where appropriate. This shall comply with legislation, regulations, guidelines, and the New Zealand Code of Good Manufacturing Practice for the Manufacture and Distribution of Therapeutic Goods.

3.11.2 The organisation ensures policies/procedures are developed and implemented to clearly document the service provider's medicines management responsibilities in relation to each stage of medicine management.

3.11.3 The organisation ensures service providers responsible for medicine management are competent to perform this function.

3.11.4 The organisation ensures that a process is implemented to identify, record and communicate each consumer's medicine related allergies or sensitivities and respond appropriately to adverse reactions or errors.

3.11.5 The organisation ensures the facilitation of safe self-administration of medicines by the consumer where appropriate.

3.11.6 The organisation ensures consumers who are prescribed or administered medicines and/or therapeutic goods are provided with understandable information about safe and effective use, expected outcomes of therapy, any significant risk of side effects, how to recognise side effects, and what to do if these occur.

3.11.7 The organisation ensures medicinal management information is recorded to a level of detail, and at a frequency to comply with legislation, regulations and guidelines.

3.11.8 The organisation ensures service delivery is reviewed and changes or additions to the service delivery process are documented.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.12 Infection Control Management
Te Whakahaere Whakatina Tahumaero

Outcome: ***Consumers, embryos, gametes and service providers are protected from preventable exposure to infection.***

Guidance: *Infection control in ART covers several distinct aspects:*

- *General hygiene as for any health provider*
- *Screening of consumers for infectious agents that may cross-contaminate in vitro culture or storage systems*
- *Screening donors for infectious agents that may be transmitted to recipients*
- *Day-stay surgery procedures.*

3.12.1 The organisation ensures services are provided in facilities that are clean, safe and suitable for the purpose of the surgery/procedure being carried out.

3.12.2 The organisation should identify contributory factors responsible for spread of infection including those from water, air and other environmental factors.

3.12.3 The organisation ensures effective infection control is achieved by developing and implementing policies/procedures that are practical and safe, with the aim of minimising the risk of infection to consumers, visitors, service providers and communities.

3.12.4 The organisation ensures infection control education, training and information is made available to service providers and consumers, where appropriate.

3.12.5 The organisation ensures that responsibility for the infection control policy is designated to a suitably qualified health practitioner.

3.12.6 The organisation ensures the effectiveness of the infection control processes is monitored and outcomes linked to the quality system.

3.12.7 The organisation ensures infection control principles are integrated into the design and delivery of new and existing services.

3.12.8 The organisation ensures service providers and/or consumers suffering from, or exposed to, infectious diseases should be prevented from exposing others while infectious, and vaccination programmes should be available to all service providers.

3.12.9 The organisation develops and implements policies/procedures which ensure the risk of cross-contamination between gametes and/or embryos from one consumer to another is minimised during in vitro culture or storage.

3.12.10 The organisation develops and implements policies/procedures which ensure where the sterilisation of reusable medical and surgical instruments, textiles or linen and equipment is conducted in-house, policies/procedures are implemented to protect consumer safety and minimise the risk of healthcare acquired infection.

3.12.11 The organisation ensures where the sterilisation of reusable medical and surgical instruments and equipment is outsourced, a process is in place to ensure the contracted service complies with the relevant standards.

3 Continuum Of Service Delivery
He Hātepe Tuku Ratonga

3.13 Management of Waste and Hazardous Substances
Te Whakataute Para me ngā mea Pūmate

Outcome: ***Consumers, visitors and service providers are protected from harm as a result of exposure to waste or hazardous substances, generated during service delivery.***

3.13.1 The organisation ensures service providers follow a documented process for the safe and appropriate storage and disposal of waste and hazardous substances that complies with current legislation and local authority requirements.

3.13.2 The organisation ensures service providers involved in the management of waste and hazardous substances receive education and training to ensure safe and appropriate handling of these materials.

3.13.3 The organisation ensures the management and disposal of biological waste considers the cultural practices of Māori and is in line with the requirements of The Code of Health and Disability Services Consumers' Rights (where applicable).

3.13.4 The organisation ensures all incidents involving infectious material, body substances and hazardous substances are reported, recorded, investigated and reviewed.

3.13.5 The organisation ensures all hazardous substances are correctly labelled.

3.13.6 The organisation ensures protective equipment and clothing appropriate to the risks involved when handling waste or hazardous substances is provided and used by service providers.

Part 4 Safe And Appropriate Environment He Taiao Ora, Taiao Pai

Outcome: ***Where service delivery is facility based, services are provided in an environment that ensures physical privacy is maintained, promotes safety, has adequate space and amenities to facilitate independence, is in a setting appropriate to the consumer group and meets the needs of people with disabilities.***

Guidance: Buildings and facilities used by fertility services should be located, designed, constructed, used and maintained to ensure safety of the services offered, to minimise the risk of error and to permit efficient cleaning and maintenance.

4 Safe And Appropriate Environment
He Taiao Ora, Taiao Pai

4.1 Physical Privacy
Te Noho Motuhake a-Tinana

Outcome: The design of the physical environment promotes privacy.

4.1.1 The organisation ensures consumer's privacy is respected during service provision.

4.1.2 The organisation ensures consumers have visual privacy when attending to personal activities and/or treatment interventions or receiving assistance with personal requirements.

4 Safe And Appropriate Environment
He Taiao Ora, Taiao Pai

4.2 Facility and Equipment Specifications and Maintenance
Ngā Whakatakotoranga me ngā whakatikatika taputapu me te rawa

Outcome: ***All buildings, plant and equipment used in the provision of services are maintained in reliable and safe working order.***

4.2.1 The organisation ensures all buildings, plant and equipment are fit for purpose, and comply with legislation, regulation and the appropriate Standard where a Standard exists.

4.2.2 The organisation ensures all buildings, plant and equipment are maintained in reliable and safe working order.

4.2.3 The organisation ensures the facility layout and design is clinically appropriate, contributes to safe service delivery and maintains consumer and service provider safety.

4.2.4 The organisation ensures relevant equipment is calibrated.

4.2.5 The organisation ensures all equipment necessary to provide the service is available when required, and a contingency plan exists in the event that such equipment is unavailable.

4.2.6 The organisation ensures the potential viability of gametes, embryos and reproductive tissue is maintained.

4.2.7 The organisation ensures the environment is suitable for the procedures carried out.

4.2.8 The organisation ensures procedures undertaken in an "open" system have monitoring systems in place to assess the environmental conditions.

4.2.9 The organisation ensures where critical material is being stored (e.g. medication, culture medium), temperatures or other critical parameters shall be monitored and demonstrated to be in accordance with the manufacturers' instructions.

4.2.10 The organisation ensures facilities are secured against entry of unauthorised personnel.

4.2.11 The organisation ensures the service provider shall have a written procedure that defines the specifications for gamete or embryo transport. The specifications shall include:

(a) The integrity of the vessel is tested before shipping, preparation of the vessel is defined, state of the vessel and its sample is checked on arrival;

(b) Times of dispatch and receipt are recorded; and

(c) Informed consent of consumers is required before shipment.

4 Safe And Appropriate Environment He Taiao Ora, Taiao Pai

4.3 Natural Light, Ventilation and Heating

Ngā Whakamārama māori, ngā Whakahauhau me ngā Whakamahana

Outcome: Consumers are provided with adequate natural light, safe ventilation and an environment that is maintained at a safe and comfortable temperature.

4.3.1 The organisation ensures areas used by consumers and service providers are ventilated and heated, appropriately.

4 Safe And Appropriate Environment
He Taiao Ora, Taiao Pai

4.4 Reception, Waiting and Other Public Areas
Kiripaepae, wāhanga tatari me te wāhi mō te iwi whānui

Outcome: Consumers are provided with safe, adequate, appropriate and accessible areas for waiting and are able to move freely within these areas either independently or with the assistance of one or more persons, or mobility aids.

4.4.1 The organisation ensures consumers are provided with safe, adequate, appropriate and accessible areas for waiting and are able to move freely within these areas either independently or with the assistance of one or more persons, or mobility aids.

4 Safe And Appropriate Environment He Taiao Ora, Taiao Pai

4.5 Cleaning and Laundry Services Te Ratonga Horoi Taputapu, Horoi Pūeru

Outcome: ***Consumers have a clean environment and safe and hygienic laundry services. (Where this service is outsourced, a system exists to ensure compliance is achieved.)***

4.5.1 The organisation ensures policies/procedures are developed and implemented for the regular and incidental cleaning of the facility to ensure a clean environment.

4.5.2 The organisation ensures the appropriate use of cleaning agents is adhered to and chemicals used are compatible with the equipment or surface they are being used on in line with the manufacturer's recommendations.

4.5.3 The organisation ensures there is an appropriately designed laundering programme in a safe and sanitary environment which ensures a supply of clean, hygienic laundry.

4 Safe And Appropriate Environment
He Taiao Ora, Taiao Pai

4.6 Essential, Emergency and Security Systems
Ngā Pūnaha Whakamaru, Waiwai me te Mate Whawhati Tata

Outcome: ***Consumers receive an appropriate and timely response during emergency and security situations.***

Guidance: *Clinical emergencies relative to the setting are identified and provision made for a timely response sufficient to fulfil a reasonable duty of care.*

Information about resuscitation and emergency response can be found at the New Zealand Resuscitation Council at www.nzrc.org.nz.

4.6.1 The organisation ensures service providers receive appropriate information, training and equipment to respond to identified emergency and security situations.

4.6.2 The organisation ensures service providers are able to provide a level of first aid and emergency treatment appropriate for the degree of risk associated with the provision of the service.

4.6.3 The organisation ensures where consumers are required to be transported or transferred between rooms or services in beds or wheelchairs, that doorways, thoroughfares, lifts and turning areas can readily accommodate the bed, attached equipment and any escorts.

4.6.4 The organisation ensures there are implemented fire safety and emergency management procedures identifying and minimising related risk.

4.6.5 The organisation ensures service providers receive training in fire safety and emergency management.

4.6.6 Prior to the operation of the service the organisation ensures there is an evacuation scheme approved by the New Zealand Fire Service that meets the requirements of the Fire Service Act; where an evacuation scheme is not required there is a documented and implemented fire evacuation plan.

NOTE – Guidance from the New Zealand Fire Service is needed to determine when a New Zealand Fire Service scheme would not be required.

4.6.7 The organisation ensures there are contingency plans in place to deal with failure of utilities. This shall include remote monitoring of incubators.

4.6.8 The organisation ensures an appropriate "call system" is available to summon assistance when required that is easily identifiable, accessible and appropriate to the needs of the consumer group and the service setting.

4.6.9 Where it is necessary for security purposes, the organisation ensures that service providers, and where applicable, visitors are appropriately identified.

Appendix A
The Code of Health and Disability Services Consumers' Rights

(Normative)

1. Consumers have Rights and Providers have Duties

   (a) Every consumer has the rights in this Code.

   (b) Every provider is subject to the duties in this Code.

   (c) Every provider must take action to -

      (i) inform consumers of their rights; and

      (ii) enable consumers to exercise their rights.

2. Rights of Consumers and Duties of Providers

   The rights of consumers and the duties of providers under this Code are as follows:

RIGHT 1 - Right to be Treated with Respect

(a) Every consumer has the right to be treated with respect.

(b) Every consumer has the right to have his or her privacy respected.

(c) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Māori.

RIGHT 2 - Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation

(a) Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

RIGHT 3 - Right to Dignity and Independence

(a) Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

RIGHT 4 - Right to Services of an Appropriate Standard

(a) Every consumer has the right to have services provided with reasonable care and skill.

(b) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

(c) Every consumer has the right to have services provided in a manner consistent with his or her needs.

(d) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

(e) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 5 - Right to Effective Communication

(a) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

(b) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

RIGHT 6 - Right to be Fully Informed

(a) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including -

(i) An explanation of his or her condition; and

(ii) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

(iii) Advice of the estimated time within which the services will be provided; and

(iv) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and

(v) Any other information required by legal, professional, ethical, and other relevant standards; and

(vi) The results of tests; and

(vii) The results of procedures.

(b) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.

(c) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about -

(i) The identity and qualifications of the provider; and

(ii) The recommendation of the provider; and

(iii) How to obtain an opinion from another provider; and

(iv) The results of research.

(d) Every consumer has the right to receive, on request, a written summary of information provided.

RIGHT 7 - Right to Make an Informed Choice and Give Informed Consent

(a) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

(b) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

(c) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

(d) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -

(i) It is in the best interests of the consumer; and

(ii) Reasonable steps have been taken to ascertain the views of the consumer; and

(iii) Either, -

1. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
2. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

(e) Every consumer may use an advance directive in accordance with the common law.

(f) Where informed consent to a health care procedure is required, it must be in writing if -

(i) The consumer is to participate in any research; or

(ii) The procedure is experimental; or

(iii) The consumer will be under general anaesthetic; or

(iv) There is a significant risk of adverse effects on the consumer.

(g) Every consumer has the right to refuse services and to withdraw consent to services.

(h) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

(i) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

(j) No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved, or used otherwise than with the informed consent of the consumer; or

(i) For the purposes of research that has received the approval of an ethics committee; or

(ii) For the purposes of 1 or more of the following activities, being activities that are each undertaken to assure or improve the quality of services:

1. a professionally recognised quality assurance programme:
2. an external audit of services:
3. an external evaluation of services.

RIGHT 8 - Right to Support

(a) Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

RIGHT 9 - Rights in Respect of Teaching or Research

(a) The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

RIGHT 10 - Right to Complain

(a) Every consumer has the right to complain about a provider in any form appropriate to the consumer.

(b) Every consumer may make a complaint to -

(i) The individual or individuals who provided the services complained of; and

(ii) Any person authorised to receive complaints about that provider; and

(iii) Any other appropriate person, including -

1. An independent advocate provided under the Health and Disability Commissioner Act; and
2. The Health and Disability Commissioner.
3. Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
4. Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.
5. Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
6. Every provider, unless an employee of a provider, must have a complaints procedure that ensures that:

(a) The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and

(b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of -

(i) Independent advocates provided under the Health and Disability Commissioner Act; and

(ii) The Health and Disability Commissioner; and

(iii) The consumer's complaint and the actions of the provider regarding that complaint are documented; and

(iv) The consumer receives all information held by the provider that is or may be relevant to the complaint.

7. Within 10 working days of giving written acknowledgement of a complaint, the provider must -

(a) Decide whether the provider -

(i) Accepts that the complaint is justified; or

(ii) Does not accept that the complaint is justified; or

(b) If it decides that more time is needed to investigate the complaint, -

(i) Determine how much additional time is needed; and

(ii) If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.

(c) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of -

(i) The reasons for the decision; and

(ii) Any actions the provider proposes to take; and

(iii) Any appeal procedure the provider has in place.

8. Provider Compliance:

(a) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.

(b) The onus is on the provider to prove it took reasonable actions.

(c) For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

9. Definitions in this Code:

"Advance directive" means a written or oral directive-

(a) By which a consumer makes a choice about a possible future health care procedure; and

(b) That is intended to be effective only when he or she is not competent.

"Choice" means a decision-

(a) To receive services

(b) To refuse services

(c) To withdraw consent to services.

"Consumer" means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer.

"Discrimination" means discrimination that is unlawful by virtue of Part II of the Human Rights Act.

"Duties" includes duties and obligations corresponding to the rights in this Code.

"Ethics committee" means an ethics committee -

(a) established by, or appointed under, an enactment; or

(b) approved by the Director-General of Health.

"Exploitation" includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence.

"Optimise the quality of life" means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances.

"Privacy" means all matters of privacy in respect of the consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act or matters to which Part X of that Act relates.

"Provider" means a health care provider or disability services provider.

"Research" means health research or disability research.

"Rights" includes rights corresponding to the duties in this Code.

"Services" means health services, or disability services, or both; and includes health care procedures.

"Teaching" includes training of providers.

10. Other Enactments:

(a) Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

11. Other Rights:

(a) An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.

Reproduced in full from the Office of the Health and Disability Commissioner.

Appendix B
Glossary of terms

(Normative)

For the purposes of NZS 8181, the following definitions apply:

Term/abbreviation	Description
Abuse	*Physical abuse*. Infliction of physical pain, injury or force. *Psychological abuse*. Behaviour that causes mental or emotional anguish or fear. *Sexual abuse*. Sexually abusive and exploitative behaviours involving threats, force, or the inability of the person to give consent. *Material abuse*. The illegal or improper exploitation and/or use of funds or other resources. Taken from "*Promoting the Rights and Well-being of Older People and Those Who Care for Them (An Age Concern Resource Kit) 1992*."
ACART	Advisory Committee on Assisted Reproductive Technology
ACC	Accident Compensation Corporation
Accountability	Where an organisation has to account for, or is liable for fulfilling an action whether or not that action is carried out by that organisation.
Agreements/contracts	This documentation should at least include the scope of practice, limitations and responsibilities of all parties concerned.
ANZARD	Australian and New Zealand Assisted Reproduction Database
ANZICA	Australian and New Zealand Infertility Counsellors Association (a subgroup of FSA)
ART	Assisted reproductive technology
Assessment	A systematic and on-going process for the collection and analysis of information that describes the needs of the consumer in order to: (a) Determine eligibility for a service; or (b) Develop an individual service delivery plan when the consumer enters the service. The assessment process shall meet current standards for assessment and shall include input from the consumer, family/whānau or other representatives where appropriate.

Audit	A systematic independent examination and a review to determine whether actual activities and results comply with planned arrangements.
Authority	The proper powers to carry out an action, whether granted directly or delegated.
Certification	A third party assessment of the quality system of the supplier/ provider with respect to published quality system standards and any supplementary documentation required under the system. (ISO/IEC Guide 62.)
Competent	Having the required ability, knowledge or authority.
Consumer	A user or participant in the service, including client, patient, gamete or embryo donor. Where appropriate this may include the family/whānau or other representatives.
CPR	Cardiopulmonary resuscitation
CPAC	Clinical priority assessment criteria
Current accepted good practice	Current accepted good practice involves the current accepted range of safe and reasonable practice that results in efficient and effective use of available resources to achieve quality outcomes for the consumer. Current accepted good practice should also reflect standards for service delivery where these exist. This may include but is not limited to: (a) Codes of practice; (b) Research/evidence/experience based practice; (c) Professional standards; (d) Evidence based guidelines; (e) Recognised/approved guidelines; (f) Benchmarking.
DHB	District Health Board
ECART	Ethics Committee on Assisted Reproductive Technology
Entry	The point at which the consumer attends the first appointment or consultation or receives the first episode of service delivery that they have been assessed as required.
Evaluation	A formal process for determining the extent to which the planned or desired consequences of an action are attained.
Facility	The physical location, site or building within or from which the service is provided.

Family – in relation to another adult	Family includes a consumer's extended family/whānau, their partners, friends and advocates, guardian/kaitiaki or other representatives nominated by the consumer.
Family – in relation to a Child or Young	A group including an extended family/whānau in which there is least one adult member with whom the child or young person has a biological or legal relationship; or to whom the child or young person has a significant psychological attachment; or the child or young person's whānau or any other culturally recognised family/whānau. (Children, Young Persons and their Families Act.)
FNA	Fertility Nurses Association (a subgroup of FSA)
FSA	Fertility Society of Australia
FNZ	Fertility New Zealand
Governance	Taking responsibility for the overall direction of the organisation, including determination of the purpose and goals of the service.
HART Act	Human Assisted Reproductive Technology Act 2004
Health record	Describes every aspect of the healthcare provided to an identifiable consumer/patient and may be either a single file, multiple files, hard copy (e.g. paper based) or electronic (digital, audio, video etc.) and is held by an organisation, service provider or the consumer/patient themselves. For full details see NZS 8153 *Health records*.
Health Research Council of New Zealand (HRC)	The HRC accredits regional and institutional ethics committees which approve research proposals, and advises the government on the scientific merit of clinical and gene therapy trials. See www.hrc.govt.nz.
HGSA	Human Genetics Society of Australasia
HIV	Human immunodeficiency virus
IVF	*In vitro* fertilisation
IVF-ET	*In vitro* fertilisation and embryo transfer
Iwi	A tribe with a common ancestor, canoe and region(s).
Management	Implementing the policy determined by the governing body and co-ordinating the day-to-day service activities, which achieve the purpose and goals of the organisation.
MoH	Ministry of Health

National Radiation Laboratory	The National Radiation Laboratory (NRL), a specialist business unit within the Ministry of Health is based in Christchurch, New Zealand. It provides a resource of expert advice, service provisions and research capability on matters concerning public, occupational and medical exposure to radiation, the performance of radiation equipment, and the measurement of radiation and radioactivity. For general enquiries, please email: enquiry@nrl.moh.govt.nz
NPSU	National Perinatal Statistics Unit
Neglect	*Active neglect*. Conscious and intentional deprivation by a service worker of basic necessities, resulting in harmful physical, psychological, material and/or social effects. *Passive neglect*. Refusal or failure by service workers, because of inadequate knowledge or disputing the value of the prescribed services, to provide basic necessities, resulting in harmful physical, psychological, material and/or social effects. Definitions taken from "*Promoting the Rights and Well-being of Older People and Those Who Care for Them (An Age Concern Resource Kit) 1992*".
New Zealand Health Information Service	The New Zealand Health Information Service (NZHIS) is a group within the Ministry of Health responsible for the collection and dissemination of health-related data. See www.nzhis.govt.nz for organisation and publication details.
OHSS	Ovarian Hyperstimulation Syndrome
Organisation	Include associations, agencies, groups, independent practitioners and individuals accountable for the delivery of services to the consumer.
OSH	Occupational Safety and Health
Position description	A document describing the purpose of the role/position, the required scope of practice (if relevant), key accountabilities, critical competencies, required education, skills and knowledge, functional relationships, delegated authority (if applicable) and reporting lines.
Representative	Used in this document to refer to the legally appointed representative. A spouse, parent, or next of kin can only make legal decisions on behalf of a person who lacks mental capacity with specific authorisation or an appropriate order from the Family Court. Legal representation is achieved through application of relevant sections of the Protection of Personal Property Rights Act (PPPR) and (where required) information about the provisions in the Act should be made available when needed to family members, friends and relevant service providers.

Responsibility	Where a service provider carries out an action.
Review	A formal process of updating, amending or re-planning based on evaluation outcomes.
Risk	The chance of something happening that will have an adverse impact on objectives (SAA/SNZ HB 436 *Risk management guidelines*).
Risk management	The culture, processes and structures that are directed towards realising potential opportunities whilst managing adverse effects (SAA/SNZ HB 436 *Risk management guidelines*).
RTAC "the code"	Reproductive Technology Accreditation Committee Code of Practice
Safe	Freedom from preventable illness or harm to an individual's physical or non-physical well-being after a consumer has gained entry to a service.
Sedation	Sedation (with or without local anaesthesia), includes the administration by any route or technique of all medication which results in the depression of the central nervous system. The object of these techniques is to produce a degree of sedation of the consumer /patient without loss of consciousness, so that uncomfortable procedures may be facilitated. The medication and techniques used should provide a margin of safety which is wide enough to render loss of consciousness unlikely. Loss of consciousness constitutes general anaesthesia, carries specific risks, and shall be administered by a registered health practitioner appropriately trained in anaesthesia, or a trainee anaesthetist supervised by a vocationally registered specialist anaesthetist.
Service	The provision of teaching, research, assessment, treatment, care, support, promotion of independence and other inputs provided to the consumer by the organisation.
Service delivery	The act of service provision by the organisation or service provider to the consumer or others.
Service delivery plan	The documentation describing the assessment, planning, implementation, evaluation, review and exit processes of service delivery by a service provider.
Service provider	An individual who is responsible for performing the service either independently, or on behalf of an organisation. This includes the provision of direct and indirect care or support service to the consumer.

This includes all staff and management who are:

(a) Employed;

(b) Self-employed;

(c) Visiting;

(d) Honorary;

(e) Session;

(f) Contracted;

(g) Volunteer service providers; or

(h) Responsible or accountable to the organisation when providing a service to the consumer.

For the purpose of this Standard it excludes the informal/unpaid carer and family/whānau network.

Service provision — The act of service provision by the organisation or service provider to the consumer or others.

SET — Single embryo transfer

SIRT — Scientists in Reproductive Technology (a subgroup of FSA).

Suitably Qualified / Skilled

(a) Professionals who provide services (including clinical care or judgement) to consumers and who have qualifications and registration required by statute to practise; or

(b) Individuals with experience in the provision of care or support to the consumers and who are deemed competent to perform this function by a recognised representative body.

Where the above does not apply the organisation will be accountable for ensuring the service provider is competent to provide the service required of them.

Supervision

(a) Definitions appropriate to individual allied health professions will be defined by professional bodies/associations.

(b) An example of a District Health Board definition of Supervision: "Supervision is a formalised, regular, sustained process in which the supervisor enables and facilitates the supervisee in meeting their professional objectives. It takes place within a structured, contractual relationship between the organisation, the supervisor and the supervisee and is protected time for in-depth reflection on practice.

Supervision aims to enable the supervisee to achieve, sustain and develop a high quality of practice through the means of focused support and development."

(Source: Auckland District Health Board. Professional Supervision Policy for Allied Health Practitioners, June 2004).

Tangata whenua	People of the land, people belonging to any particular place.
Well-being	A dimension of health beyond the absence of a disease or infirmity, including emotional and spiritual aspects of health.

Appendix C
Clinic service providers

(Normative)

The organisation shall ensure the fertility service has the following personnel:

ANZICA counsellor

At least one ANZICA counsellor shall be integrated into the clinical service structure of a clinic offering ART.

A person may obtain membership to ANZICA by belonging to an appropriate professional body that meets the educational standards of ANZICA, for example the Aotearoa New Zealand Association of Social Workers, is employed by an ART clinic and has appropriate supervised counselling experience.

Clinical director

The clinical director shall be a specialist medical practitioner, who is accredited by the clinic to undertake assisted reproductive technology (ART) related procedures, and be responsible to the medical director.

Embryology laboratory director

The embryology laboratory director shall have significant experience in the organisation and maintenance of a clinical embryology laboratory and in tissue culture techniques, and shall be an individual with demonstrable knowledge of all laboratory aspects of ART. The laboratory director is responsible for formulating written laboratory policies and protocols and communicating with the medical director about consumer progress and protocols as they affect the laboratory aspects of treatment.

The embryology laboratory director shall fulfill the following requirements:

(a) Hold an earned doctorate degree (PhD) from an accredited institution in a biological science; or

(b) Have served as a laboratory director and have qualified before 1 January 1992, and have expertise in biochemistry, biology and the physiology of reproduction, with experience in experimental design, statistics and problem solving; or

(c) Hold an appropriate university degree demonstrating a broadly based relevant scientific experience in reproductive biology, with expertise and/or specialised training in biochemistry, cell biology and the physiology of reproduction, and experience in experimental design, statistics and problem solving;

(d) Have completed a period of training including performance of a sufficient number of ART procedures to achieve competency; satisfactory completion of this period of training shall be documented by a signed letter from the laboratory director overseeing the training;

(e) Have three years experience in a laboratory performing human in vitro fertilisation (IVF) or ART-related procedures, including familiarity with quality control, quality assurance, inspection, accreditation and licensing procedures; and detailed knowledge of human tissue culture, ART and andrology procedures;

(f) Hold a current annual practising certificate with the Medical Science Laboratory Board;

(g) Have maintained technical competency in the embryology laboratory.

The embryology laboratory director is responsible for:

(h) Providing on-site, telephone or electronic consultation as needed;

(i) Ensuring that the physical plant (space, facilities and equipment) and the environmental conditions of the laboratory are appropriate and safe;

(j) Maintaining aseptic conditions in the laboratory;

(k) Ensuring that consumer confidentiality is maintained throughout the laboratory ART process;

(l) Providing an approved procedural manual to all laboratory personnel;

(m) Establishing and maintaining a laboratory quality assurance programme;

(n) Providing consultation to clinicians and others, as appropriate, regarding laboratory aspects of treatment;

(o) Employing a sufficient number of qualified personnel with the appropriate education and documented experience and training to supervise and perform the work of the laboratory;

(p) All personnel receiving appropriate training for the ART laboratory procedures to be performed;

(q) All personnel obtaining the required number of annual continuing education hours;

(r) All personnel demonstrating continued competence in the ART laboratory procedures performed.

Off-site embryology laboratory director

An 'off-site' laboratory director is one whose primary responsibility is at another physical laboratory that has separate RTAC accreditation/certification and a separate medical director. An off-site director has the same responsibilities as an on-site director.

The off-site director shall:

(a) Physically visit the laboratory frequently to ensure its proper functioning while the laboratory is actively treating consumers;

(b) Be present for any accreditation or certification procedure.

Embryology laboratory supervisor

The embryology laboratory may have one or more qualified laboratory supervisors, who, under the direction of the laboratory director, provide day-to-day supervision of laboratory personnel performing ART procedures. Arrangements shall be put in place if the embryology laboratory director is primarily located off site, or oversees more than one laboratory.

The embryology laboratory supervisor shall fulfil the following requirements:

(a) Hold a masters degree in science, clinical laboratory science or medical technology; or

(b) Hold a bachelors degree in science or medical technology; or

(c) Have served as a laboratory supervisor since before 1 January 1992;

(d) Have a documented minimum period of training of at least 12 months in an accredited human ART programme and have performed at least 100 ART procedures of each stage of routine in vitro fertilisation and embryo transfer (IVF-ET) under supervision. This training should be documented by a signed letter from the laboratory director of the training laboratory;

(e) Hold a current annual practising certificate with the Medical Science Laboratory Board;

(f) Do at least 20 ART procedures per year.

The embryology laboratory supervisor is responsible for:

(g) Technical supervision for each of the procedures performed in the laboratory;

(h) Monitoring of all quality control procedures and quality assurance protocols;

(i) Being available as needed and also accessible to provide on site, telephone or electronic consultation.

Manager of nursing

The manager of the nursing service shall be suitably experienced.

The manager of nursing services shall be a registered nurse who will normally fulfil the following requirements:

(a) Have a documented minimum of 5 years experience in ART;

(b) Hold a qualification in midwifery or have nursing experience in women's health or reproduction; and

(c) Have management experience or qualifications.

Medical director

The medical director is the person with responsibility for the clinical affairs of the fertility service.

The medical director shall:

(a) Be a recognised specialist gynaecologist or physician who has extensive experience in the management of consumers with infertility and who can demonstrate significant continuing education in the speciality or reproductive endocrinology and gynaecology; and

(b) Be responsible for training, competency, supervision and documentation of all clinicians involved in ART in the clinic, and ensure clinicians are fully competent in the management of OHSS.

Practice director

The practice director is responsible and accountable for the activity of the practice relating to ART, and any communications with RTAC, and ANZARD.

Appendix D
Closure of a fertility service

(Informative)

D1

On closure of a fertility service, the integrity of information and stored gametes and embryos must be maintained.

D2

Polices and procedures should be in place to ensure gametes and embryos can be transferred to another certified fertility service. Records shall be transferred to the Registrar-General of Births, Deaths and Marriages on closure.

1. On-going storage of gametes and embryos

The following shall be provided:

(a) Policies and procedures detailing the arrangements for the ongoing storage of frozen embryos, gametes or ovarian tissue.

(b) Information detailing the number of consumers with frozen embryos, gametes or ovarian tissue in storage and details of the location of the material.

(c) The name and address of the organisation agreeing to accept storage of the frozen gametes, embryos and ovarian tissue, the name of the medical director responsible for the storage of the material if it is being transferred to another organisation, and a letter from the medical director accepting responsibility for storage.

(d) Copies of the communication to consumers who have material in storage, outlining their options and costs for future storage.

(e) A copy of procedures for consenting to the transfer of embryos/gametes to another organisation, including the consent forms.

(f) Details of provision for the on-going storage of medical records.

2. Transfer of medical records

A copy of procedures for consenting for the transfer of medical records to another doctor, including the consent forms.

3. Notification of relevant authorities

Confirmation that a representative from the organisation has notified the Director-General of Health under section 81 of the HART Act within the required time after closure of the organisation.

Appendix E
Related documents

(Informative)

Related Standards/Handbooks

When interpreting this Standard and the associated audit workbook, it may be helpful to refer to the following:

New Zealand Standards

NZS 4121:2001	Design for access and mobility – Buildings and associated facilities
NZS 4304:2002	Management of healthcare waste
NZS 8165:2005	Rooms/office-based surgery and procedures

New Zealand Handbook

SNZ HB 8169:2002	Health network code of practice

Australian Standards

AS 2828 -1999	Paper-based health care records
AS 3789.2 -1991	Textiles for health care facilities and institutions – Theatre linen and pre-packs

Other publications

Fertility Society of Australia (2002). Reproductive technology accreditation committee – Code of practice for centres using assisted reproductive technology (revised).

New Zealand legislation

For information on New Zealand Statutes (Public, Local and Private Acts) and Regulations refer to www.legislation.govt.nz

Building Act 2004

Charitable Trusts Act 1957

Companies Act 1993

Consumer Guarantees Act 1993

Crimes Act 1961

Criminal Justice Act 1985

Crown Entities Act 2004

Employment Relations Act 2000

Fair Trading Act 1986

Fire Safety and Evacuation of Buildings Regulations 2006

Food Act 1981

Food Hygiene Regulations 1974

Hazardous Substance and New Organisms Act 1996

Health Act 1956

Incorporated Societies Act 1908

Injury Prevention, Rehabilitation and Compensation Act 2001

Local Government Act 2002

Medicines Regulations 1984

Medicines Act 1981

Misuse of Drugs Act 1975

Misuse of Drugs Regulations 1977

New Zealand Bill of Rights Act 1990

New Zealand Public Health and Disability Act 2000

Official Information Act 1982

Public Finance Act 1989

Public Records Act 2005

Resource Management Act 1991

Smoke-free Environments Act 1990

State Sector Act 1988

Transport Act 1962

Treaty of Waitangi Act 1975

Tuberculosis Act 1948

Guidelines, related documents and websites

Advertising Standards Authority. (2002) Therapeutic Advertising Pre-Vetting System (TAPS). Advertising Standards Authority. Wellington. www.asa.co.nz/taps.htm.

ISO/IEC Guide 62 (1996) (E) General requirements for bodies operating assessment and certification/registration of quality systems. Switzerland. ISO/IEC.

New Zealand Association of Counsellors (date unknown). Code of Ethics. Retrieved 20 December, 2004 from the World Wide Web: http://www.nzac.org.nz/downloads/ethics.pdf.

New Zealand Psychologists Board (2002) Code of ethics for psychologists working in Aotearoa/ New Zealand. http://www. psychologistsboard.org.nz/publications/index.html

Quality Standards for Pharmacy in New Zealand. Pharmaceutical Society of New Zealand 2004.

Te Puni Kokiri, Ministry of Māori Development. (1999) Hauora o te Tinana me ōna Tikanga – A guide for the removal, retention, return and disposal of Māori body parts and organ donation, Te Puni Kokiri, Wellington. Ministry of Māori Development. www.tpk.govt.nz/publications/docs

Ministry of Health guidelines

An Introduction to HACCP – Food safety information for New Zealand businesses. (Revised edition). Wellington. 2003.

Communicable Disease Control Manual. Wellington. 1998.

Consent in Child and Youth Health: Information for Practitioners. Wellington. 1998.

Drinking Water Standards for New Zealand. Wellington. 2000.

Guidelines for the Control of Legionellosis. (Public Health Commission.) Wellington. 1995.

Guidelines for the Control of Methicillin Resistant Staphyloccus Aureus in New Zealand. Wellington. 2002.

Guidelines for the Management of Norovirus Outbreaks in Hospitals and Elderly Care Institutions. Wellington. 2005.

Guidelines for Tuberculosis Control in New Zealand. Wellington. 2003.

He Korowai Oranga/Māori Health Strategy. Wellington. 2002.

He Taura Tieke Measuring Effective Health Services for Māori. Wellington. 1995.

Immunisation Handbook. Wellington. 2006

Information for Audit Agencies Applying for Designation to Audit Services under the Health and Disability Services (Safety) Act 2001. Wellington. 2002.

Laundry Guidelines for Rest Homes and Small Hospitals. 1997.

National Radiation Laboratory Code of Safe Practice. Wellington. 2001.

Operational Standard for Ethics Committees. Wellington. 2006.

Safe Management of Medicines. A Guide for Managers of Old People's Homes and Residential Care Facilities. 1997.

Standards for Traditional Māori Healing. Wellington. 1999.

Toward Clinical Excellence: A Framework for Credentialling of Senior Medical Officers in New Zealand. Wellington. 2001.

Toward Clinical Excellence: An Introduction of Clinical Audit, Peer Review and Other Clinical Practice Improvement Activities. Wellington. 2002.

Useful New Zealand websites and resources

ACART	www.newhealth.govt.nz/acart/
Access to current legislation and regulations is available at	www.legislation.govt.nz
ACC (Accident Compensation Corporation)	www.acc.co.nz
Advertising Standards Authority Inc	www.asa.co.nz
Allied Health Professional Associations' Forum (AHPAF)	www.ahpaf.wellington.net.nz/
ANZICA (Australia and New Zealand Infertility Counsellors Association)	www.anzica.org
Aotearoa New Zealand Association of Social Workers	www.anzasw.org.nz
Biotech Regulatory Wayfinder	www.morst.govt.nz/wayfinder
District Health Boards New Zealand	www.dhbnz.org.nz
ECART	www.newhealth.govt.nz/ecart/
Enable New Zealand	www.enable.co.nz
Fertility NZ	www.fertilitynz.org.nz
Guide to Health Law – The University of Waikato	www.waikato.ac.nz/law
Health & Disability Commissioner	www.hdc.org.nz
Health Directory	www.healthpages.co.nz
Health Research Council of New Zealand	www.hrc.govt.nz/
Ministry of Health	www.moh.govt.nz
Ministry of Health Communicable Diseases	www.moh.govt.nz/cd
Ministry of Research Science and Technology (MORST)	www.morst.govt.nz
National Ethics Advisory Committee (NEAC)	www.newhealth.govt.nz/neac
National Heart Foundation of New Zealand	www.heartfoundation.org.nz
National Radiation Laboratory	www.nrl.moh.govt.nz
New Zealand Health Information Service	www.nzhis.govt.nz/
New Zealand Medicines and Medical Devices Safety Authority	www.medsafe.govt.nz/
New Zealand Resuscitation Council Inc.	www.nzrc.org.nz
Occupational Safety & Health magazine	www.safeguard.co.nz
National Library of New Zealand database, with links to a wide variety of sites	www.natlib.govt.nz
The Centre for Adverse Reactions Monitoring (CARM)	www.carm.otago.ac.nz
The Immunisation Awareness Society Inc.	www.ias.org.nz
Toi Te Taiao: The Bioethics Council	www.bioethics.org.nz

Useful international websites and resources

American Society for Reproductive Medicine	www.asrmgc.org
Australia and New Zealand Infertility Counsellors' Association	www.anzica.org
BioEdge (Australia)	www.australasianbioethics.org/
BioNews (UK)	www.bionews.org.uk/
British Medical Journal	www.bmj.com/
Canadian Institutes of Health Research	www.cihr-irsc.gc.ca/
European Society for Human Reproduction & Embryology	www.eshre.com/emc.asp
Fertility Society of Australia	www.fsa.au.com/
Human Fertilisation and Embryology Authority (UK)	www.hfea.gov.uk
Human Reproduction (UK)	http://humrep.oxfordjournals.org/
Infertility Treatment Authority (Victoria, Australia)	www.ita.org.au/
National Health Medical Research Council (Australia)	www.health.gov.au/nhmrc/
Nuffield Council on Bioethics (UK)	www.nuffieldbioethics.org/
Reproduction Technology Accreditation Committee (Australia)	www.fsa.au.com/rtac/
Royal Australasian College of Surgeons	www.surgeons.org/
Society for Assisted Reproductive Technology (US)	www.sart.org/
Society for Male Reproduction and Urology (US)	www.smru.org/
Society for Reproductive Endocrinology and Infertility (US)	www.socrei.org/
Society of Reproductive Surgeons (US)	www.reprodsurgery.org/
The President's Council on Bioethics (US)	www.bioethics.gov/
World Health Organization	www.who.int/en/

NOTES

NOTES

Approved by the Standards Council on 16 January 2007 to be a New Zealand Standard pursuant to the provisions of section 10 of the Standards Act 1988.

First published: 31 January 2007

The following SNZ references relate to this Standard:

Project No. P 8181
Draft for comment No. DZ 8181
Typeset by: Standards New Zealand
Printed by: The Colour Guy