

*Joint Accreditation System of Australia and New Zealand*

**POLICY NUMBER 6/09**



**Policy for the application of Procedure 31, Issue 4  
to nominated healthcare standards other than  
the Core Standards for Safety and Quality in Healthcare**

Authority to Issue

Dr James Galloway  
Chief Executive  
With Authority of the Governing Board

---

## 1 OBJECT AND FIELD OF APPLICATION

---

- 1.1 This policy provides for the application of JAS-ANZ Procedure 31 Issue 4, *Requirements for bodies providing audit and certification of healthcare management systems to the Core Standards for Safety and Quality in Healthcare*, to nominated healthcare standards other than *The Core Standards for Safety and Quality in Healthcare*.
- 1.2 This policy applies to all conformity assessment bodies that are DAA applicants for accreditation to JAS-ANZ Procedure 31. This policy also details the transition arrangements from the Draft DAA Handbook published by the New Zealand Ministry of Health to the new DAA Handbook which is scheduled for publication around October 2009.
- 1.3 This policy shall remain valid until JAS-ANZ Procedure 31, Issue 5 is published.

---

## 2 REFERENCES

---

- 2.1 ISO/IEC 17021:2006, Conformity assessment – Requirements for bodies providing audit and certification of management systems.
- 2.2 JAS-ANZ Procedure 31, Issue 4, *Requirements for bodies providing audit and certification of healthcare management systems to the Core Standards for Safety and Quality in Healthcare*.
- 2.3 DAA Handbook, New Zealand Ministry of Health.

---

## 3 BACKGROUND

---

- 3.1 In April 2009 the New Zealand Ministry of Health decided to reintroduce accreditation as a requirement for Designated Audit Agencies (DAA) operating under the Health and Disability Services (Safety) Act 2001.
- 3.2 When JAS-ANZ last offered this programme, the MOH requirements allowed for both accredited and unaccredited DAAs. Accredited DAAs were accredited by both IANZ to IANZ specific requirements and JAS-ANZ to Procedure 32 based on ISO/IEC Guide 62. Rather than reviewing and reissuing Procedure 32, JAS-ANZ and the MOH agreed that it would be more appropriate to develop a DAA Annex to JAS-ANZ Procedure 31 as this is designed specifically for the audit and certification of healthcare management systems.
- 3.3 Procedure 31 Issue 4 calls up the Core Standards for Safety and Quality in Healthcare, but these do not apply to DAAs.
- 3.4 Procedure 31 Issue 4 is to be reviewed to accommodate the healthcare schemes in New Zealand and other healthcare standards.
- 3.5 The amendments to the DAA Handbook will align with the DAA Annex A to this policy and do not contain any particularly significant changes.

---

## 4 POLICY

---

- 4.1 As directed by MOH all existing DAAs, recognised by MOH, shall be compliant with this policy within 6 months of the publication of the amended DAA handbook.

---

## **5 IMPLEMENTATION**

---

- 5.1 Upon the issue of this policy, all applicants for the DAA scheme will be assessed against JAS-ANZ Procedure 31, the DAA Handbook and Annex A to this policy. References in Procedure 31 to the Core Standards for Safety and Quality in Healthcare shall be read as being references to the DAA Annex A to this Policy.
- 5.2 The DAA specific programme requirements documented in the DAA Annex to this Policy do diminish the requirements of Procedure 31 and ISO/IEC 17021 in relation to surveillance frequency – see A 9.3.2.
- 5.3 Other healthcare standards deemed suitable for accredited certification are also recognised in Annex A to this policy. Bodies seeking accreditation for any one of these standards shall be accredited to JAS-ANZ Procedure 31 except that references in Procedure 31 to the Core Standards for Safety and Quality in Healthcare shall be read as being a reference to the relevant healthcare standard where that standard is listed in Annex A to this policy.

---

## Annex A

---

### Designated Audit Agencies – Audits of the provision of health care services under the Health and Disability Services (Safety) Act 2001

---

#### 1 SCOPE

---

- A.1.1 This Annex was developed by JAS-ANZ on behalf of the New Zealand Ministry of Health to set down additional requirements to Procedure 31.
- A.1.2 Where the requirements in the Annex differ to the relevant section of Procedure 31 or the Core Standards then the requirements of this Annex will apply.
- A.1.3 This Annex must be read in conjunction with Procedure 31 and ISO/IEC 17021. The procedure covers the accreditation requirements for the DAA's and not the Ministry of Health requirements for Service Providers.

---

#### 2 REFERENCES

---

- A.2.1 Health and Disability Services (Safety) Act 2001
- A.2.2 [NZS 8134.0:2008 Health and Disability Services \(General\) Standard \(PDF, 731 KB\)](#)
- A.2.3 [NZS 8134.1:2008 Health and Disability Services \(Core\) Standards \(PDF, 988 KB\)](#)
- A.2.4 [NZS 8134.2:2008 Health and Disability Services \(Restraint Minimisation and Safe Practice\) Standards \(PDF, 726 KB\)](#)
- A.2.5 [NZS 8134.3:2008 Health and Disability Services \(Infection Prevention and Control\) Standards. \(PDF, 835 KB\)](#)
- A.2.6 MOH DAA Handbook
- A.2.7 IAF MD2:2007 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

---

#### 3 TERMS AND DEFINITIONS

---

- A.3.1 The following definitions also apply to this Annex;

Designated Audit Agency	Term used by the Minister of Health to identify a Conformity Assessment Body
Service User	The user of the service e.g. client, patient, resident
Service Provider	This is a generic term for any type of healthcare provider offering services under the Health and Disability Services (Safety) Act 2001.

---

## 4 PRINCIPALS

---

No additional Principles apply

## 5 GENERAL REQUIREMENTS

---

A.5.1 Procedures shall exist to ensure that prior to each audit the DAA audit team completes a freedom of conflict of interest form.

## 6 STRUCTURAL REQUIREMENTS

---

No additional requirements apply

## 7 RESOURCE REQUIREMENTS

---

A.7.1 Designated Audit Agencies shall review the performance of each auditor /Technical Expert on site at least annually ensuring relevant APC (Annual Practising Certificate) scope. Records of these reviews shall be maintained.

A.7.2 The audit team will include a registered practitioner with a current annual practising certificate and expert knowledge in the particular areas being audited. The audit team will also have technical/clinical experience as outlined as per the DAA Handbook.

A.7.3 The Designated Audit Agency shall have procedures in place for determining the ongoing competency of auditors and technical experts relevant to the health discipline being audited as well as audit practice.

A.7.4 Technical Experts/auditors must be competent to make an informed opinion on the appropriateness of the services being offered to the service users.

A.7.5 The Technical Experts/auditors must be able to identify trends in relation to service delivery across the organisation.

## 8 INFORMATION REQUIREMENTS

---

A.8.1 Designated Audit Agencies shall have procedures in place to confirm that service providers have obtained informed consent from service users to participate in the audit process including file reviews and interviews. Participation by service users in the audit is at all times voluntary.

A.8.2 All service user information will be treated in accordance with the Health Information Privacy Code 1994.

---

## 9 PROCESS REQUIREMENTS

---

### 9.1 Audits

---

- A.9.1.1 The audit process shall ensure each element of the NZS 8134.1:2008 (Health and Disability Services (Core) standards 2008) will be audited as identified in the DAA Handbook. Note: Initial and recertification audits require the service provider to be assessed against all the elements.
- A.9.1.2 The audit duration will be determined as per the IAF MD5 for the duration of QMS and EMS audits. The DAA will ensure that at least 50% of the onsite audit time will be spent observing practices within the facility. Audit records will confirm this.
- A.9.1.3 The DAA sampling methodology for file reviews will include stratified sampling as identified in the DAA Handbook. The minimum sample size should consider stratified sample requirements. Calculation of minimum sample size should be based on the following a) b) c)
- a) initial audit & recertification: the square root of the number of service users ( $y = \sqrt{x}$ ), rounded to the upper whole number  
surveillance audits: 0.6 times the square root of the number of service users ( $y = 0.6 \sqrt{x}$ ), rounded to the upper whole number
  - b) where there are less than 5 service users, all service users should be interviewed.
- Note: x is the number of service users  
y is the sample size*

Sample sizes should be widened where nonconformity is found in order to verify systems or process failures rather than a one off anomaly.

A minimum of 10 percent of the sampled files should be reviewed undertaking tracer (or service user pathway) methodology.

- A.9.1.4 The DAA shall ensure that their process ensures that there is a minimum requirement to interview 10 percent of persons receiving care through the service (or representatives of the persons) during the site audit to discuss the audit. This is applicable for both initial and surveillance audits.

**Note:** If the DAA is unable to carry out interviews because the service users or their representatives do not consent to be interviewed, or are not capable of being interviewed, then this must be recorded in the audit report.

There is a minimum requirement to interview staff using the square root rule (see Section A9.1.3). The sample of staff should include staff who work across all shifts on a roster.

- A.9.1.5 For onsite audits a focus group made up of a representative group of service users generally between 2 and 10 may be used however, if used, this must be in conjunction with individual service user interviews. Service provider employees shall not be present during focus groups sessions. Information from the focus group shall be used to validate audit findings.
- A.9.1.6 DAA must have processes in place to assess the appropriateness of the records relating to the service user and their abilities. This requires matching care plans to

observation and/or interview of service users and use of relevant current assessment tools

- A.9.1.7 Procedures shall clearly specify how the DAA determines the correct attainment and risk ratings achieved by the service user.
- A.9.1.8 As well as for initial assessments the DAA shall carry out two stage audit process as per ISO/IEC 17021 for recertification audits.
- A.9.1.9 Transfers of service providers between DAA's shall be managed as per IAF MD 2:2007

## 9.2 Reporting

- A.9.2.1 Audit reports shall clearly specify objective evidence used to support the awarded attainment. Exception reporting alone is not acceptable.

The audit report must clearly differentiate evidence for each clinical area. For example rest home dementia services, hospital services, rest home services in aged residential care and medical services, surgical services, paediatric services, intensive/emergency services, mental health services, women's health services, speciality services (e.g. drug and alcohol, rehabilitation, renal), outpatient and allied health services within District Health Board audits

- A.9.2.2 The DAA shall have procedures in place to comply with the requirements of the MOH for submission of audit reports as outlined in the DAA Handbook
- A.9.2.3 Processes must be documented for the reporting to the M OH within 24 hours of any services where the level of risk is assessed as critical according to the matrix in the standards. This notification may be verbal but must be confirmed in writing within the 24 hours.

## 9.3 Certification

- A.9.3.1 DAA's do not provide certification under this programme. The period of recognition is determined by the MOH.
- A.9.3.2 Surveillance Audits will be as per the DAA Handbook including the review of the annual self declaration and the subsequent reporting to HealthCert.

Note: A.9.3.2 diminishes the surveillance frequency requirement of ISO/IEC 17021. The MOH Handbook allows surveillance frequencies of up to 18 months at the discretion of the Ministry of Health.

## 10 MANAGEMENT SYSTEM REQUIREMENTS FOR CERTIFICATION BODIES

No additional requirements apply