Report prepared for the Ministry of Health

Review of third party accreditation of Designated Auditing Agencies

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sapere research group

About Sapere Research Group Limited

Sapere Research Group is one of the largest expert services firms in Australasia and a leader in provision of independent economic, forensic accounting and public policy services. Sapere provides independent expert testimony, strategic advisory services, data analytics and other advice to Australasia's private sector corporate clients, major law firms, government agencies, and regulatory bodies.

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Purpose of this review

Sapere Research Group (Sapere) was commissioned by the Ministry of Health (the Ministry) to undertake an independent review of the system of third party accreditation of Designated Auditing Agencies (DAAs) of aged residential care providers (ARCs) who are subject to the certification requirements of the Health and Disability Services (Safety) Act 2001. There are currently two third party bodies approved by the Ministry: the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) – a government-appointed body established under Treaty between Australia and New Zealand; and the International Society for Quality in Health Care Incorporated (ISQua) – an internationally recognised membership-based organisation headquartered in Ireland. Between them they accredit five DAAs. The evaluation period was 1 January 2012 to 30 June 2014.

The objectives of this review were to:

- determine how effective each third party body is in strengthening the certification process;
- further explore the differences between ISQua and JAS-ANZ in their determinations regarding non-conformities and recommendations, including mitigation of any identified risks and/or issues;
- ensure the Ministry's approach in retaining these two third party bodies can be satisfied; and
- identify to the Ministry other suitable international third party bodies (if any) able to undertake this work.

An unusual regulatory system in a complex environment

While it was outside the project scope to comment on the overall regulatory framework, consideration of the wider context is essential to formulating a meaningful assessment of the accreditation system. The current third party accreditation regime is situated within a complex sector, particularly given the functional inter-relationships with District Health Boards (DHBs). In addition, the population being served is highly vulnerable, and close attention is paid to the ongoing quality and safety of care of the residents of ARCs.

The current regulatory framework appears to be a unique arrangement that is not, as far as we were able to determine, directly comparable to any other jurisdiction. Key distinguishing features are that:

- the role of the Ministry is unusual in that it is responsible for issuing certification to ARCs, and is therefore reliant (inter alia) on audit reports completed by the DAAs;
- the Ministry is responsible for regulatory enforcement, but has a limited spectrum of enforcement tools;
- the role of accreditation in the system is not explicit, and the particular configuration of third party bodies operating as they do in relation to DAAs and the regulator, appears to be an unprecedented arrangement; and

- and there appears to be a lack of mutual clarity and understanding across the sector regarding the respective roles of third party bodies, DAAs and the Ministry.

The Ministry relies, inter alia, on the outcomes of third party accreditation reports to provide it with assurance of the quality of DAAs' audits and on the DAAs' audit reports on the quality of the ARC providers' performance. It therefore appears to be trying to use the system to performance manage DAAs – something the system is not designed to do.

Overall performance of third party accreditation

We found no evidence to suggest that the differing approaches employed by the two third party bodies are associated with differing quality of DAA audits. Both third parties are working to provide assurance around audit processes and to lift the performance of DAAs.

We are unable to say from the available evidence whether the quality of audits has improved over the evaluation period. Moreover, it is not possible to attribute changes to third party accreditation, given the multiple other interventions occurring over the evaluation period, as well as the natural maturity cycles of the DAAs as organisations.

Should the current two third party bodies be retained?

We found no evidence to suggest that either of the two third party bodies should not be retained by the Ministry. The fact that there are two third parties, and that they use different approaches, does not appear to be of concern per se.

Answering the question of whether two is the optimal number of third party bodies would require a first principles analysis of the regulatory framework, based on the regulatory best practice principles and sector policy objectives, which was outside the scope of this review. What we would emphasise is that the costs of change (e.g. to having just one third party body) would be high and there may be little sectorial or political appetite for such change. Any more than two for such a small number of DAAs would seem to be excessive and may not attract any additional third parties in to the market.

Exploring the differences between the two third parties

By design, the two third parties apply different standards and processes. Both have made concessions to their standard procedures to incorporate the Ministry's requirements. For example, ISQua has included on-site mid-point surveillance assessments, and JAS-ANZ has made concessions regarding the frequency of surveillance of ARCs. Both third party bodies have processes for monitoring and managing identified issues, including closure of issues. Both undertake on-site mid-point surveillance assessments. Both have escalation processes, with the ultimate sanction of withdrawal/suspension of the DAA's accreditation award, though to date this sanction has not been employed here (and the Ministry has never cancelled a DAA's designation).

On the basis of the qualitative and quantitative evidence reviewed, we have concluded that, although the two third parties employ different approaches, they are both working to provide an endorsement statement on DAAs' competence, credibility and independence to do the job to the Ministry's requirements.

Performance monitoring and sectorial relationships

In light of feedback from stakeholder interviews, and our review of the data currently used for monitoring, we query whether the Ministry is focusing on the indicators and issues of most importance, and whether an appropriate balance is being struck between administrative performance (such as reporting style) and matters of substance (the quality of audits determining the actual quality and safety of care). In our view, the Ministry's current focus on process-level matters is resource intensive and may be detracting attention from more substantive matters. The Ministry has indicated that it intends to review its set of DAA performance indicators over 2015 and we support this.

We observed that personal relationships between the Ministry and DAAs have at times been strained. We are concerned that the time and effort spent in managing these relationships has the potential to obscure the core focus on patient / resident safety and quality of care.

With respect to the Ministry's relationships with the third party bodies, we observed a need for greater mutual understanding between the Ministry and the third parties regarding their standards and processes, and how these can fit within the existing regime and meet the Ministry's expectations. We envisage that the information garnered through this review may contribute to this understanding.

Overall, we observed a need for greater clarity and understanding between all sector participants – DAAs, third party bodies, ARCs, DHBs and the Ministry – regarding the Ministry's regulatory policy objectives, in particular the role of accreditation of DAAs in the regulatory framework.

1. Introduction

1.1 Purpose of this report

Sapere Research Group (Sapere) was commissioned by the Ministry of Health (the Ministry) to undertake an independent review of third part accreditation of Designated Auditing Agencies (DAAs) of aged residential care providers (ARCs) who are subject to the certification requirements of the Health and Disability Services (Safety) Act 2001 (the Act). This report sets out our approach to this review, and presents our findings and conclusions. The report is structured as follows:

- section 2 provides contextual information on the regulatory system and the DAA market;
- section 3 describes our approach and methodology;
- section 4 explores the accreditation standards and processes employed by the two approved third party bodies;
- section 5 presents the findings of our analysis of documentation and data, literature scan, survey of DAAs and stakeholder interviews; and
- section 6 sets out our conclusions against the research questions and review objectives.

1.2 Background

In April 2009, a project was established in the Ministry to improve the effectiveness and efficiency of auditing by DAAs of ARCs. The project included the re-introduction third party accreditation requirements for DAAs, effective from 31 December 2010.[1]

Third party accreditation aims to provide a mechanism for the independent assessment of the competence, credibility, independence and integrity of DAAs against an agreed set of standards and requirements. The Ministry relies on audit reports submitted by DAAs to inform its decision making regarding certification and monitoring decisions of health and disability services providers subject to the Act.

There are currently two third part bodies approved by the Ministry:

- the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) – a government-appointed body; and

[1] The designation requirement for DAAs to hold accreditation with a third party had been revoked in 2006 after an assessment report by Systems 3 Group found that third party accreditation was not providing any measureable benefit to the standard of auditing. At that time the majority of DAAs were accredited through IANZ which accredited to ISO17020, an inspection standard rather than a quality management standard. In addition, the Ministry had concerns that performance issues were not being identified by the third party accreditation bodies.

- the International Society for Quality in Health Care Incorporated (ISQua) – an internationally recognised membership-based organisation, with its headquarters in Ireland.

1.2.1 Auditor General's reports

In 2009, the Office of the Auditor General (OAG) issued a performance audit report on the arrangements for checking the quality and safety of services provided by ARCs.[2] It raised serious concerns about the system, and concluded that auditing by DAAs had been inconsistent and sometimes of poor quality. The OAG expressed concern that the Ministry has never removed a DAA's designation, despite evidence of sustained poor performance by some DAAs. The report recommended that the effectiveness of third party accreditation and other work to strengthen the certification process begin to be evaluated by the end of 2010, and to reconsider the design of certification arrangements by examining and evaluating alternatives.

A follow-up report in 2011[3] concluded that the consistency and quality of ARC audits had improved since its 2009 review, and that audits were providing better assurance that ARCs were meeting the required standards:

> *Reintroducing third-parry accreditation has allowed the Ministry to better assess and monitor the capability of DAAs to audit rest homes. Updating the DAA Handbook and monitoring DAAs' compliance with the standards and audit practices in the DAA Handbook have also improved the consistency and quality of audits.*[4]

However the report also noted that the quality of audit reports was still variable and concluded that the effect of changes on the quality of care was uncertain. The report included a recommendation that the Ministry consider how it might bring together and use clinical and audit information from newly implemented systems to continuously improve the quality of care provided in ARCs.

1.2.2 2011 evaluation

An evaluation of third party accreditation was completed in 2011.[5] The time period for the evaluation was 1 January 2011-30 June 2011, though three years of annual compliance data were used. The purpose of the evaluation was to examine whether third party accreditation:

- identified areas for improvement that impacts on the standard of auditing conducted by DAAs;
- resulted in DAAs making changes to the way they operate;
- improved the standard and consistency of auditing and audit reporting;

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2 OAG (2009) *Effectiveness of arrangements to check the standard of services provided by rest homes*.

3 Office of the Auditor General (2011) *Effectiveness of arrangements to check the standard of rest home services: follow-up report*.

4 OAG (2011), p.18.

5 *Evaluation of third party accreditation*. Ministry of Health, June 2011.

- could be improved;
- has been effective in performance managing poorly performing DAAs; and
- requires a choice of two third party accreditation bodies.

The evaluation considered the following data and information:

- a comparison of baseline and subsequent audit reporting data (conducted as part of Ministry business as usual processes);
- a comparison of processes between third party bodies;
- audit and progress monitoring results from third party bodies;
- conditions placed on accreditation by third party bodies;
- provider survey results (conducted as part of Ministry business as usual processes);
- a survey of DAAs specific to third party accreditation; and
- Ministry correspondence with third party bodies.

The evaluation examined data from Ministry evaluations of audit reports, which assessed the compliance of audit reports across a suite of criteria. The analysis found that there had been slippage in compliance across all DAAs, compared to the previous year.

The evaluation concluded that areas for improvement in the standard of audit reporting had been identified through the third party accreditation process and that all but one DAA had made changes as a result of their accreditation assessment. Two of the six DAAs reported that third party accreditation had contributed to the improvements in the standard and consistency of auditing but acknowledged other reasons why standards have improved, such as the OAG report, changes to the DAA Handbook, continued implementation of continuous quality management systems within the DAA and providing on-going in-service auditor training.

With respect to whether there should be choice of third party, the evaluation concluded that:

> *There is sufficient information available to support the continued choice of a third party accreditation body where DAAs can choose either JAS-ANZ or ISQua. There is significant philosophical difference between the two bodies however, both are able to demonstrate assessment against relevant standards important to the standard of quality auditing. To introduce a third choice would be unnecessary given the size of the market and differing standard that might need to be accommodated which are not the best fit for accreditation agencies who undertake quality auditing.*[6]

The evaluation identified some areas for improvement in the third party accreditation process, particularly around the sharing of information with the Ministry by DAAs and appraisal of risk by third party bodies.

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6 Evaluation of third party accreditation (2011), p.17.

1.3 Review objectives

The objectives of this review were to:

- determine how effective each third party body is in strengthening the certification process;
- further explore the differences between ISQua and JAS-ANZ in their determinations regarding non-conformities and recommendations, including mitigation of any identified risks and/or issues;
- ensure the Ministry's approach in retaining these two third party bodies can be satisfied; and
- identify to the Ministry other suitable international third party bodies (if any) able to undertake this work.

1.4 Research questions

The following table sets out the seven research questions that were developed by the Ministry of Health, and the characteristics/criteria to be considered in each.

Table 1 Research questions

Research question	Characteristic
1. Is the third party body affiliated or a member of the European Cooperation for Accreditation (EA) or the International Accreditation Forum (IAF)?	The third party body accredits against specific schemes of similar processes, and there is consistency of standards between the two third party bodies.
2. Does the third party body accreditation provide an endorsement of a conformity assessment body's competence, credibility, independence and integrity to carry out conformity assessment activities?	Third party body assessment includes: • Management controls • Conformance to relevant NZ legislation and regulation • Auditing practice • Reporting individual auditor competency • Capability to audit health and disability services that need to be certified against the Health and Disability Services Standards NZS8134:2008 • Ability to meet the Ministry's DAA Handbook requirements that specify auditing methods in accordance with ISO/IEC standards • A risk assessment against the requirements of third party accreditation.
3. Are third party body assessment reports available from the third party body to the Ministry (to provide feedback on ongoing performance of	The third party body provides feedback on on-going performance to:

Research question	Characteristic
the DAAs)?	• The conformity assessment body • Scheme owners or organisations reliant upon the third party accreditation that provides eligibility for the conformity assessment body to undertake audits (i.e. the Ministry) • There is information sharing between the Ministry and the third party body • The third party body provides advice on best practice in quality auditing to the Ministry.
4. Does the third party body impose sanctions or consequences where a conformity is not meeting requirements of third party accreditation?	Sanctions or consequences for an underperforming conformity assessment body are managed: • The third party body response to emerging issues identified to them (by any party) and these are made known to the Ministry • The third party body monitors and manages emerging issues • The third party body will undertake an on-site reassessment of the conformity assessment body in response to a serious issue that casts doubt on the conformity assessment body's competence, credibility, independence and integrity to carry out conformity assessment activities • The third party body undertakes on-site mid-point assessments.
5. Have DAAs made changes to the way they operate as a result of third party accreditation?	Changes specifically made to prepare for and maintain third party accreditation: • Audit and progress monitoring results from third party bodies in respect of each DAA • Conditions placed on accreditation • Comparison of other measures including observation audits, performance management activities.
6. How effective are each of the third party bodies in performance managing poorly performing DAAs?	Number and type of issues identified by the Ministry that are forwarded to the third party body. Results of intervention by the third party body.
7. Is it appropriate that there are two third party bodies where there is inconsistency of standards?	Comparison between JAS-ANZ and ISQua processes to accredit and manage process reporting and performance monitoring issues.

1.5 Review scope

The time period for this review was 1 January 2012 to 30 June 2014. The following table sets out the scope of work undertaken by the project team.

Table 2 Review scope

In scope	Out of scope
The two current third party bodies. DAAs responsible for the audit of aged residential care providers. The Ministry of Health. Review of each third party body's systems and processes against the criteria and characteristics set out above. Comparative assessment of the two third party bodies' performance, with a focus on their treatment/responses to non-conformities and issues/risks raised. Development of advice to the Ministry regarding the suitability of retaining the two current third party bodies, including identification of potential overseas alternative providers.	Consideration of whether to retain the overall current third party accreditation and audit system. Auditing the DAAs and/or the auditors. DAAs who do not audit aged residential care providers.

2. Context

This section provides an overview of the regulatory framework governing the aged residential care sector, and explains how third party accreditation of DAAs fits into this broader system. It also summarises the DAA market, including key changes over the review period of 1 January 2012 to 30 June 2014.

2.1 The regulatory system

2.1.1 Legislative framework

The main legislation governing the aged residential care sector is the Health and Disability Services (Standards) Act 2001 (the Act). The Act's purpose is to:

(a) promote the safe provision of health and disability services to the public;

(b) enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely;

(c) encourage providers of health and disability services to take responsibility for providing those services to the public safely; and

(d) encourage providers of health and disability services to the public to improve continuously the quality of those services.

2.1.2 Standards

Providers of aged residential care must provide their residents with care that meets the Health and Disability Services Standards. The Standards are approved by the Minister of Health and published by Standards New Zealand. Standards cover matters such as consumer rights, organisational management, continuum of service delivery, provision of a safe and appropriate environment, restraint minimisation, safe restraint practice, seclusion, infection control management, and infection prevention and control.[7]

2.1.3 Certification for ARC providers

Under s26 of the Act, ARCs must be certified by the Director General of Health. Providers must be audited by a DAA and certification is dependent on the outcomes of the audit. ARCs may choose which DAA conducts their audits, which assess providers' performance against the criteria in the Standards. ARCs engage and pay the DAAs for these audit services.

7 Productivity Commission (2014), *Case study: aged care regulation.* p.4.

Certification can be for varying lengths of time (ranging from six months to five years) depending on the audit results. The Ministry scores providers' performance against a risk matrix, and considers other relevant information, in order to determine the certification period.

Certification may be granted with conditions: under s28 the Director-General may impose any conditions s/he 'thinks necessary or desirable to help achieve the purpose of this Act'. At this point in time, there have been two instances where a cessation order has been issued under section 48 of the Act. DHBs can, and do at times, put in place a contractually-imposed statutory manager if they consider the situation sufficiently risky.

2.1.4 Auditing of ARCs

ARCs are audited by DAAs against the Standards. DAAs are designated by the Director-General under s32 of the Act. Designation occurs by way of notice in the *Gazette*, and may include conditions of designation. The criteria under which an auditing agency may be designated are set out under s33 and are as follows.

> *The Director-General must designate a person who is not an employee of the Ministry to audit the provision of health care services of any kind by certified providers if, and only if,—*
>
> *(a) the person has—*
>
> *(i) applied in writing to the Director-General to be designated to audit the provision of services of that kind by certified providers; and*
>
> *(ii) paid to the Director-General the fee (if any) prescribed for designation to audit the provision of services of that kind; and*
>
> *(b) the Director-General is satisfied that the person—*
>
> *(i) has the technical expertise to audit the provision of services of that kind; and*
>
> *(ii) has in place effective systems for auditing the provision of services of that kind; and*
>
> *(iii) has in place effective arrangements to avoid or manage any conflicts of interest that may arise in auditing the provision of services of that kind; and*
>
> *(iv) will administer those systems and arrangements properly and competently, and in compliance with any conditions subject to which the designation is given; and*
>
> *(v) will comply with this Act.*

Under s36, DAAs are required to provide a copy of their audit reports to the Director-General. Since 2009, summary audit reports have been made available on the Ministry website, and full audit reports began to be published on a trial basis from 2013, and this has been continued from December 2014.

Designation may be cancelled, by notice in the *Gazette*, if the Director-General is no longer satisfied that the DAA has complied with the Act of the conditions of its designation.

2.1.5 Conditions of designation

Conditions of designation (issued by way of *Gazette),*[8] include, but are not limited to, requirements for DAAs to:

- comply with the DAA Handbook which is issued by the Ministry, and which is amended from time to time; and
- hold third party accreditation with a Ministry-approved third party accreditation body.[9]

As noted above, there are two approved third party bodies: ISQua and JAS-ANZ. The government's arrangements with these two third parties is formalised by way of Memoranda of Understanding between the Ministry and each third party organisation.

2.1.6 The DAA Handbook

The DAA Handbook[10] sets out the Ministry of Health's requirements of DAAs for auditing and audit reporting for the certification of health care services under the Act. It also gives providers of health care services a guide to specific requirements for various types of audits.

We understand the formal status of the DAA Handbook to be guidance material;[11] as such it is not subject to the standard Regulatory Impact Analysis requirements that would usually govern the introduction of and changes to government policies that impose mandatory requirements on organisations.

2.1.7 Roles and responsibilities

The Ministry is responsible for administering the Act and has primary responsibility for its enforcement. Where audits identify weaknesses in the provision of care, the Ministry may require the ARC to take corrective action or add conditions to their certification. The Ministry can also require more frequent audits, and can impose fines for offering health services without certification, or for obstructing or misleading an audit or inspection. However unlike some other jurisdictions, such as the US, they cannot impose fines on ARCs for non-compliance.[12]

HealthCERT is the division of the Ministry responsible for ensuring that hospitals, ARCs, residential disability care facilities, mental health facilities, and fertility providers provide safe and reasonable levels of service for consumers, as required under the Act. Its role is to

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8 Advice from the Ministry of Health's legal team to the Minister of Health in 2009 was that legislative change was needed in order to impose a mandatory requirement for third party accreditation (via an amendment to section 33). An amendment was prepared and intended to be progressed via an Amendment Bill, but we understand this Bill never progressed up the legislative agenda. As we discuss later, the current arrangements, whereby designation is mandated by way of conditions issued through the *Gazette*, seems an unusually informal way of regulating.

9 The full list of conditions is available here: https://gazette.govt.nz/notice/id/2011-go5674.

10 Available on the Ministry of Health website: http://www.health.govt.nz/publication/designated-auditing-agency-handbook

11 This is how it is described in the 2009 OAG report (see p.50).

12 Productivity Commission (2014), pp.4, 10.

administer and enforce the legislation, issue certifications, review audit reports and manage legal issues.[13]

District Health Boards (DHBs) contract with ARCs, providing funding for the rest home care of those residents who are entitled to subsidies. DHBs monitor and oversee the provision of services and manage issues arising. They may work with the Ministry following DAA audits if there is a need. DHBs do not have regulatory powers of enforcement but do have a number of levers they can use through their funding contract, such as the ability to appoint a temporary statutory manager or cancel an ARC's funding.[14] DHBs can also advise the referral agencies to halt referrals to an ARC if there is serious quality or safety concern.

DHBs and the Ministry jointly review audit reports: DHBs to review the audit findings specific to the contract; and the Ministry to verify that the audit report is valid and reliable. DHBs work with providers following an audit to develop corrective action plans in response to audit requirements.

2.1.8 Summary of the regulatory system

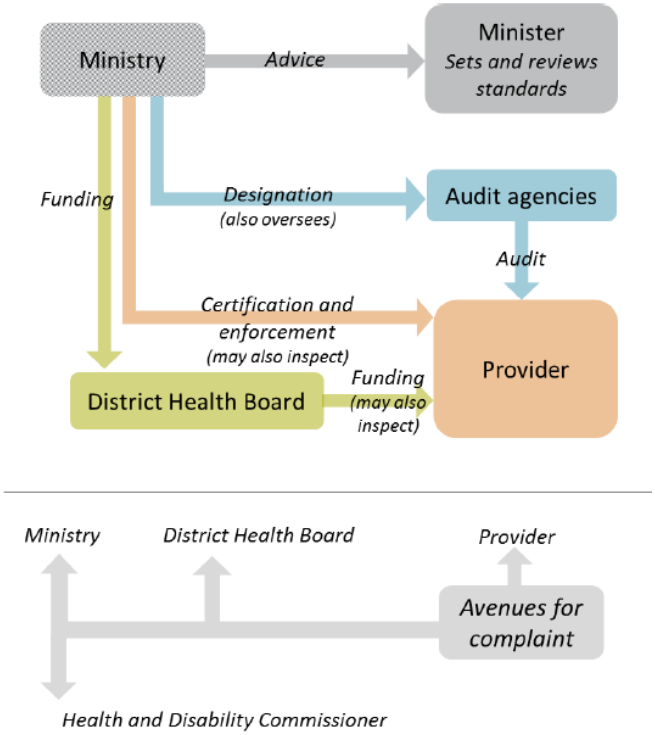
The regulatory system is summarised in the following diagram from the Productivity Commission, in a case study on aged care regulation that was undertaken as part of its 2014 inquiry into regulatory institutions and practices.[15] Third party bodies do not feature in this diagram, but can be considered as sitting between the Ministry and DAAs ('audit agencies').

13 Refer www.moh.govt.nz/certification

14 Productivity Commission (2014), p.4.

15 Refer: http://www.productivity.govt.nz/inquiry-content/1788?stage=4

Figure 1 Overview of the aged care regulatory system



Source: New Zealand Productivity Commission (2014) *Case study: aged care regulation*.

2.2 The current DAA market

At the start of the time period relevant to our review, there were six DAAs in the market:

- Bureau Veritas (New Zealand) Limited;
- Health and Disability Auditing New Zealand Limited (HDANZ);
- Health Audit (NZ) Limited (HANZ);
- The DAA Group Limited;
- Telarc Health Quality; and
- Verification New Zealand.

There are now five:

- Central Region's Technical Advisory Services Limited (CentralTAS);
- HDANZ;
- HANZ;
- HealthShare Limited (HSL); and
- The DAA Group Limited.

The DAA Group and HDANZ are currently accredited with ISQua; the other three DAAs are with JAS-ANZ. The DAA Group and HDANZ between them account for around 80% of the ARC auditing market.

Key changes over the review period have been:

- Verification New Zealand exited the DAA market. Clients of Verification New Zealand were transferred to HDANZ when they exited the market in 2012.
- Bureau Veritas was acquired by HANZ in 2012. Telarc was acquired by The DAA Group in 2011.
- HSL and CentralTAS entered the market (though as yet they maintain relatively small market shares).
- The DAA Group moved from JAS-ANZ to ISQua in 2012.

3. Approach and methodology

In this section, we describe the approach taken and show how the methodologies employed match to the research questions specified by the Ministry. We employed a mixed methods approach comprising:

- a review of documentation provided by the Ministry;
- analysis of data on the standard of audit reporting;
- a rapid literature scan;
- an e-survey of DAAs; and
- semi-structured interviews with the third party bodies, DAAs and key Ministry staff.

3.1 A mixed methods approach

Our review involved a mixed methods approach comprising:

- desk-based gathering and review of documentation and data;
- a rapid literature scan of relevant regulation literature to support answering research question 7;
- interviews with representatives of the two third party bodies and key Ministry staff (the interview topics are set out in Appendix 4); and
- an e-survey of DAAs, supplemented with follow-up interviews. The survey form is included as Appendix 5.

The following table matches the methodologies to the research questions.

Table 3 Review framework

Research question	Methods
1 Is the third party body affiliated or a member of the European Cooperation for Accreditation (EA) or the International Accreditation Forum (IAF)?	• Interview third party bodies • Desk-based review of standards used • View affiliation certificates • Desk-based review of relevant back ground documents
2 Does the third party body accreditation provide an endorsement of a conformity assessment body's competence, credibility, independence and integrity to carry out conformity assessment activities?	• Interview third party bodies • Survey DAAs
3 Are third party body assessment reports available from the third party body to the Ministry (to provide feedback on ongoing performance of the DAAs)?	• Interview third party bodies • Interview Ministry • Survey DAAs
4 Does the third party body impose sanctions or consequences where a conformity is not meeting requirements of third party accreditation?	• Interview third party bodies • Interview Ministry • Survey DAAs (follow up interviews if necessary)
5 Have DAAs made changes to the way they operate as a result of third party accreditation?	• Interview third party bodies • Survey DAAs (follow up interviews if necessary)
6 How effective are each of the third party bodies in performance managing poorly performing DAAs?	• Interview and gather documents from the Ministry • Interview third party bodies
7 Is it appropriate that there are two third party bodies where there is inconsistency of standards?	• Literature scan • Consider Commerce Commission requirements • Scan other international third party accreditation bodies

4. The accreditation process

This section describes and compares the accreditation processes undertaken by the two third party bodies. By design, the two third parties apply different standards and processes, but both have made concessions to their standard procedures to incorporate the Ministry's requirements. Key differences between the two bodies are that:

- ISQua as an organisation has a health sector/ patient safety focus whereas JAS-ANZ services a wide variety of industries;
- both are not-for-profit organisations; JAS-ANZ was established under Treaty between the Australian and New Zealand governments;
- in the DAA market, JAS-ANZ audits against ISO 17021, whereas ISQua applies its own internationally-recognised programme that spans a range of organisational performance dimensions;
- JAS-ANZ applies a strict 'compliance' approach, whereas ISQua adopts a continuous improvement approach.

Our conclusion is that, although the two third parties employ different approaches, they are both working to provide an endorsement statement on DAAs' competence, credibility and independence to do the job.

4.1 Summary comparison

The following table provides a summarised comparison of the different accreditation models of the two third party bodies. It updates the table prepared for the 2011 evaluation.

Table 4 Comparison of third party accreditation systems and processes

	JAS-ANZ	ISQua
Ownership & Governance	Jointly appointed accrediting body by the governments of Australia and New Zealand. Is overseen by a governing board and technical advisory council. Board members are government-appointed (3 from NZ, 6 from Australia). JAS-ANZ is a not-for-profit self-funding organisation and provides services in 29 countries.	A non-profit independent society with members in over 70 countries. It is self-supporting through a number of patient safety programmes including accreditation, education and events. Governed by a Board that is elected every two years by its members. The International Accreditation Programme is led by the Deputy CEO and governed on behalf of the ISQua Board by the Board Accreditation Committee (BAC). Advice is provided by the Accreditation Council which consists of all the CEOs of the major accreditation and regulation programmes.
Accountability	Member of the International Accreditation Forum (IAF), Member of the Pacific Accreditation Co-operation under a MLA, Member of Asia Pacific	Recognised by the World Health Organisation as being in official relations to assist with technical and policy advice on evidence and best practices.

	JAS-ANZ	ISQua
	Laboratory Accreditation Co-operation MRA, Multi Lateral Co-operative Accreditation arrangement.	ISQua has a number of other partners, including IHI, HTAi, EPSO, CEC, IHF. ISQua's International Accreditation Programme (IAP) has members from all the leading health care accreditation programmes in Canada, Australia, US and Europe.
Accreditation Standards	Uses ISO standards and is recognised to accredit against ISO/IEC 17021. Supports accreditation with a range of procedures and reference to IAF policy documents. JAS-ANZ has a Healthcare Technical Advisory Committee covering Australia and New Zealand.	The only global body that develops its own internationally validated Health and social care standards. These standards are revised every four years and informed by relevant recent research, International Standards Organisation (ISO), the Baldrige criteria for performance excellence as contained in the EFQM (European Foundation for Quality Management) Excellence Model, and criteria for organisational excellence from the standards of a number of national and international accreditation bodies.
Process	Pre-application inquiry, followed by application (including Applicant Deed) and payment. Systems assessment (paper-based review) undertaken by JAS-ANZ, including a technical expert. On-site audit of policies and procedures. Witnessed assessment (includes a technical expert) including on-site audit Assessment report including observations and non-conformities with timeframes for addressing. Assessment report reviewed by an accreditation panel (health sector experts including NZ representation). Accreditation issued with progress reporting and surveillance requirements. Accredited agencies required to sign Deed Poll. JAS-ANZ undertakes scheduled surveillance activities with audit agencies on a 6 monthly or annual basis which includes witnessed audits dependent on performance (provision to go up to 2 years but considered unlikely by JAS-ANZ as vulnerable populations). A complete re-assessment occurs every three years for DAAs (usually four years).	ISQua Standards and implementation guidance available publically. Application and payment. Self-assessment tools available to applicants. Distance support (external facilitators) and advice on implementation. On-site support also available, with strict rules to avoid any conflicts. Completion of a self-assessment against the ISQua Health & Social Care Standards. Completion of an external evaluation survey (including witnessed on-site audits of a sample of the DAA's clients) undertaken by three senior peer reviewers (trained surveyors who are members of the ISQua programme). All evidence is triangulated. Assessment report including recommendations for the improvement of systems and organisation together with an action plan of how recommendations will be implemented The reports have several stages of review before the final award is confirmed: • Survey team • Internal ISQua team • Deputy CEO or Head • Validation Panel • BAC. Awards are up to four years and subject to continuous assessment by a minimum of two progress reports are submitted to ISQua (3 months post-accreditation [if indicated] and at

	JAS-ANZ	ISQua
		15 months and 27 months). A mid-point on-site surveillance audit is undertaken for DAA clients by one peer reviewer (against ISQua programme recommendations and current requirements of the DAA Handbook).
Assessors	Audits conducted by an assessment team that includes a technical expert. The technical expert is approved by the Ministry of Health as having the commensurate skills for health services auditing.	ISQua surveyors validate the organisation's self-assessment and independently assess the level of achievement of the ISQua Standards producing a report with expert advice and recommendations (that notes findings, strengths, areas for improvement and excellence). There are 82 surveyors from 20 countries. Surveyors of NZ DAAs are all from overseas in order to avoid conflicts of interest. Surveyors work on a voluntary basis. The Ministry of Health requires that at least one surveyor must have aged residential care experience from Australia.
Relationship to the Ministry of Health	A Memorandum of Understanding is in place to meet specific requirements for agencies to recognise accreditation. JAS-ANZ can amend its assessment process within the requirements of ISO17021 to accommodate Ministry of Health's changing needs. The MoU precludes the accreditation body from sending the report to the Ministry of Health but includes a notification process.	A Memorandum of Understanding is in place to meet specific requirements for agencies to recognise accreditation. Outside of usual ISQua processes, the Ministry of Health has an agreement that specifies: • an on-site surveillance audit occurs at the mid-point of accreditation in addition to progress reporting • annual progress reporting requirements • audit against the DAA handbook as part of the audit process. The MoU precludes the accreditation body from sending the report to the Ministry of Health but includes a notification process.
Fees	New applicant AUD8,000 (NZD8,770), then AUD1,250 for assessment activity until accredited. Thereafter AUD12,000 (NZD13,160) annual body fee plus disbursements.	€1,000 (NZD1,600) per year membership fee for institutions (€200 for individuals). This is not attached to accreditation – assessment activities charges for travel etc only as evaluation services provided on a voluntary basis.

Source: Ministry of Health (2011) *Evaluation of third party accreditation*. Provided to ISQua and JAS-ANZ for review, and further revised by Sapere review team.

4.2 The two third parties: organisations and philosophies

ISQua is a non-profit, independent, health care quality organisation with members in over 70 countries. It is self-supporting through a number of patient safety programmes including accreditation, education and events. It is governed by a Board that is elected every two years by its members.

ISQua provides services to guide health professionals, providers, researchers, agencies, policy makers and consumers to achieve excellence in healthcare delivery and to continuously improve the quality and safety of care. Its mission is: '*inspiring, promoting and supporting continuous improvement in the quality and safety of healthcare worldwide'*.

ISQua launched its International Accreditation Programme in 1999 and is the only healthcare specific body that 'accredits the accreditors'. Its programme is designed to support the improvement of performance and practice of health and social care standards and external evaluation bodies.[16]

JAS-ANZ was established in 1991 by the Australian and New Zealand governments as part of the standards and conformance infrastructure to help markets work better and strengthen the trading relationships between the two countries and with other countries. The *Agreement between Australian and New Zealand establishing the Governing Board, technical Advisory Council and Accreditation Review Board of the Joint Accreditation System of Australian and New Zealand* (the JAS-ANZ Treaty) requires JAS-ANZ to operate a joint accreditation system and to deliver on four goals:

- integrity and confidence – obtain and maintain a joint accreditation system that gives users in Australian and New Zealand confidence that goods and services certified by accredited bodies meets established standards;
- trade support – obtain and maintain acceptance by Australia's and New Zealand's trading partners for domestic management systems and exported goods and services;
- linkages – create links to relevant bodies that establish or recognise standards for goods and services or that provide conformity assessment; and
- international acceptance – obtain mutual recognition and acceptance of conformity assessment with relevant bodies in other countries.[17]

JAS-ANZ is overseen by a governing board and technical advisory council. Board members are government-appointed (three from NZ, six from Australia). It is also a not-for-profit self-funding organisation. It provides services in 29 countries with a focus on the Asia Pacific region. JAS-ANZ provides internationally-recognised accreditation services to Conformity Assessment Bodies (in this case, DAAs). Its activities are structured around five programmes: management systems certification; product certification; personnel certification; inspection; and greenhouse gas validation and verification.

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16 ISQua *Guidelines and standards for external evaluation organisations*, 4th edition version 1.1.

17 *JAS-ANZ Statement of corporate intent for the period 1 July 2014 to 30 June 2017*.

4.3 Standards

The two third parties apply different standards, as set out in the following table.

Table 5 Third party body standards

JAS-ANZ	ISQua
ISO/IEC 17021 • MD 1:2007 – IAF Mandatory Documentation for the Certification of Multiple Sites based on sampling • MD 2:2007 – IAF Mandatory Documentation for the Transfer of Accredited Certification of Management Systems • MD 3:2008 – IAF Mandatory Documentation for Advanced Surveillance and Recertification Procedures • MD 4:2008 – IAF Mandatory Documentation for the use of Computer Assisted Auditing Techniques (CAAT) for Accredited Certification of Management Systems • MD 5:2013 – IAF Mandatory Documentation for Duration of QMS and EMS Audits • MD 11:2013 – IAF Mandatory Documentation for the Application of ISO/IEC 17021 for Audits of Integrated Management Systems 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*	ISQua Accreditation of External Evaluation Organisations Programme Leadership • Standard 1: Governance • Standard 2: Strategic, Operational and Financial Management • Standard 3: Risk management and performance improvement Support services • Standard 4: Human resources management • Standard 5: Information management Service delivery • Standard 6: Surveyor management • Standard 7: Survey and client management • Standard 8: Accreditation of certification awards

Source: ISQua *Guidelines and standards for external evaluation organisations*, 4th edition version 1.1, July 2014; JAS-ANZ *Accreditation manual*, 2014.

4.4 Accreditation and surveillance processes

The diagrams in Appendix 1 map the accreditation and surveillance processes undertaken by ISQua and JAS-ANZ. JAS-ANZ has prescribed processes for the management of non-conformities, which we have mapped in detail. ISQua also has formal processes for escalating matters in the event that they receive a complaint that any accredited organisation is not maintaining their standards.

5. Findings

In this section, we present the findings of each component of our review. Our key findings are:

- we found no evidence to suggest that the differing approaches employed by the two third party bodies are associated with differing quality of DAA audits. Both third parties are working to provide assurance around audit processes and to lift the performance of DAAs;
- on the basis of the available evidence, it is not possible to say whether the quality of audits has improved over the evaluation period, nor to attribute changes to third party accreditation, given the multiple other interventions occurring over the evaluation period, as well as the natural maturity cycles of the DAAs as organisations; and
- we found no evidence to suggest that either of the two third party bodies should not be retained by the Ministry. The fact that there are two third parties, and that they use different approaches, does not appear to be of concern per se.

More broadly, we found that the current regulatory framework appears to be a unique arrangement that is not, as far as we were able to determine, directly comparable to any other jurisdiction. There is a need for greater clarity and understanding between all sector participants regarding the Ministry's regulatory policy objectives, and the role of accreditation in the regulatory framework.

5.1 Document review

5.1.1 Memoranda of Understanding

The Ministry has signed Memoranda of Understanding (MoUs) with the two third party bodies. The MoU with JAS-ANZ was signed in October 2009 and with ISQua in March 2010. The MoUs do not specify end dates, but state that they will be 'reviewed as required'. The Ministry will draft a new MoU for consultation with both third party bodies following this review.

There are a number of differences between the two MoUs; of note:

- the JAS-ANZ MoU references the ISO Standard and Guide and JAS-ANZ procedures; the ISQua MoU references the ISQua Standard. Both MoUs reference the Act and the DAA Handbook;
- in addition to its Standard, ISQua has agreed, at the Ministry's request, to conduct on-site mid-point surveillance audits, to include a surveyor from the Aged Residential Care Sector in its assessment teams and to assemble its assessment teams from overseas to avoid any conflict of interests for the designated audit agencies in New Zealand; and
- the current MoUs are otherwise similar, except that JAS-ANZ is also to participate in the development of Ministry Standards, fulfil reporting requirements and provide feedback to the Ministry on DAA performance.

Notwithstanding the differences between the two third party bodies, we found the variation in the respective MoUs somewhat surprising (we would expect them to be essentially the same).

5.1.2 Accreditation assessment reports and correspondence

We reviewed the assessment reports provided to Sapere by the Ministry, examining out the number of issues identified by the third party body at each assessment. It is hard to draw many conclusions purely on the basis of these measures, but we observed that:

- under both third party bodies, issues identified are subject to review, and may be closed out in subsequent surveillance assessments; and
- the number of issues identified appears to be higher under ISQua than JAS-ANZ, possibly related to the broader scope of ISQua's standards and assessments but more likely related to the volume of DAA work over seen by ISQua (e.g. approximately 80% of all the DAA work is with ISQua).

5.2 Data on the standard of audit reporting

The Ministry employs a set of criteria against which to assess the standard of audit reporting by DAAs. The criteria/indicators reported in the 2011 evaluation and those provided by the Ministry for this evaluation are set out in Table 9 (Appendix 2).

Table 6, below, sets out DAA performance against each criterion, for the most recent year (2013/14). It shows the proportion of audits that were assessed as 'yes' or 'no' (i.e. met or did not meet each criterion). For the purposes of this table, results are based on the total number of yes or no responses – those that were recorded as not applicable are not included in the denominator. However the total number of audits included those that included N/A assessments.

The 2011 evaluation assessed performance against a 95% benchmark; i.e. compliance was judged as being 95% or more for each criterion. The table below uses the same benchmark, and also highlights scores of 80-89%, 70-79% and below 70%. Darker grey cells indicate a higher level of non-compliance. (DAAs undertaking higher volumes will naturally exhibit a higher number of issues, hence the use of proportions rather than levels).

Table 7 shows which criteria are not being complied with. Several relate to the timeliness of reporting to the Ministry, and the need for further information or revisions by the DAA. The Ministry does not apply any weighting to the indicators, to distinguish between those relating to the quality of audits and those that are process-focused. In our view, out of those criteria not being complied with, those of most substantive concern appear to be:

- interviews included at least one medical practitioner (ARC);
- critical risks were reported to the Ministry within 24 hours in writing;
- the advisor did not have to request further information from the DAA to ensure that evidence matched the risk ratings; and
- the content of the audit report was peer reviewed as required by the DAA Handbook.

Table 6 Standard of DAA audit reporting, 2013/14

Proportion of total yes/no assessments (excluding N/A)

Criterion	DAA 1	DAA 2	DAA 3	DAA 4	DAA 5
1.1	100%	100%	100%	100%	94%
1.1.a	100%	98%	98%	100%	88%
1.1.b	100%	100%	100%	100%	100%
1.10	100%	96%	97%	85%	70%
1.2		90%	100%	100%	100%
1.3	100%	79%	91%	97%	90%
1.4		87%	90%	78%	100%
1.5	100%	96%	98%	92%	100%
1.6	100%	92%	95%	86%	94%
1.7	100%	100%	98%	100%	93%
1.8	100%	84%	93%	78%	58%
1.9	100%	92%	96%	87%	70%
2.1	100%	99%	99%	100%	75%
2.2	100%	100%	97%	100%	100%
2.3	100%	99%	100%	100%	100%
2.4	100%	99%	99%	99%	100%
2.5	100%	99%	100%	98%	100%
2.6	100%	97%	99%	98%	100%
2.7	100%	98%	99%	97%	100%
2.8	100%	99%	99%	100%	100%
2.9	100%	100%	100%	100%	100%
2.10	100%	99%	99%	98%	95%
2.11	100%	100%	99%	100%	100%
2.12	100%	100%	100%	100%	89%
3.1	100%	94%	97%	91%	79%
3.2		97%	98%	93%	100%
Total # audits	**<50**	**>200**	**>200**	**<100**	**<50**
Number criteria <95%	**0**	**7**	**3**	**8**	**12**

Source: Ministry of Health data; Sapere analysis. Note: for the purposes of anonymising data, DAA labels do not correspond to those in the chart below, or the tables in Appendix 3.

Table 7 Non-compliance (<95%) by criterion 2013/14

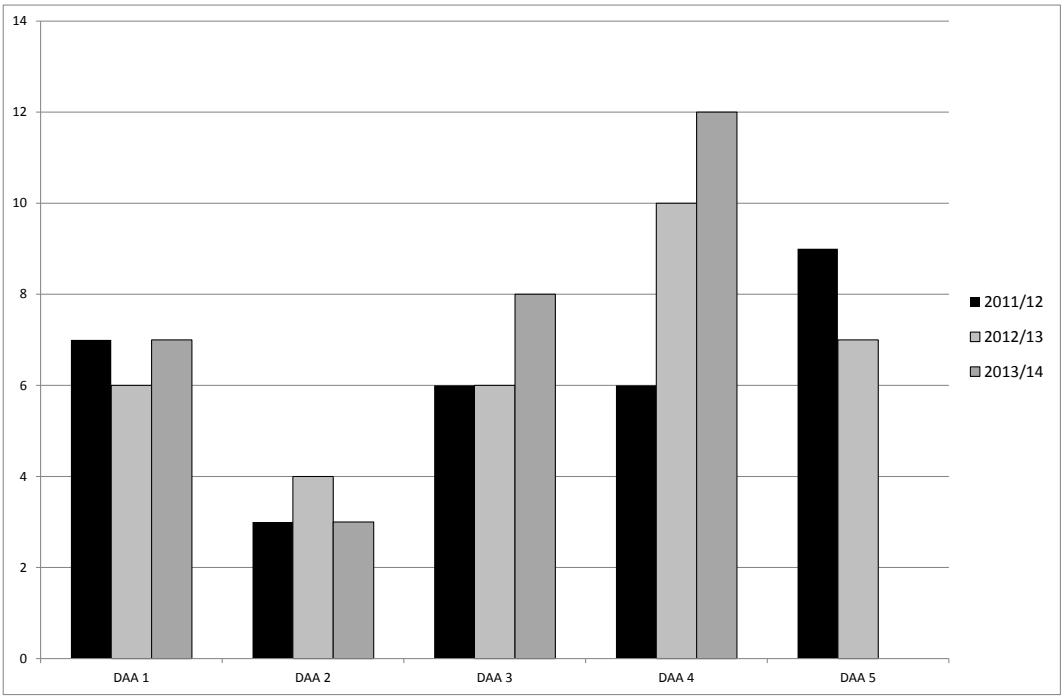
	Criterion	Number of DAAs
1.1	The audit team met the requirements for the audit (audit team membership)	**1**
1.1a	A minimum of 50% of the audit team were NOT involved in previous audit	**1**
1.2	For multi-site sampling, the Ministry agreed the sampling plan	**1**
1.3	Interviews included at least one medical practitioner (ARC)	**3**
1.4	Critical risks were reported to the Ministry within 24 hours in writing	**3**
1.5	The audit summary for publication was accurate and written in plain English	**1**
1.6	The audit summary did not require amendment by the DAA	**3**
1.7	All partial attainments and unattained criteria from the previous certification audit were audited	**1**
1.8	The DAA was not required to re-submit the audit report	**4**
1.9	The audit report was submitted by the earlier of: a) 20 working days of the last day on site OR b) at least 20 working days prior to expiry of the current certificate	**3**
1.10	The content of the audit report was peer reviewed as required by the DAA Handbook	**2**
2.10	Evidence was written in the present tense and without statements of intent	**1**
3.1	The advisor did not have to request further information from the DAA to ensure that evidence matched risk ratings	**3**
3.2	The advisor did not have to request further information from the DAA on more than one occasion	**1**

Source: Ministry of Health data; Sapere analysis

The following diagram shows the change in compliance by each DAA over the evaluation period. Detailed annual results are presented in Appendix 3.

Figure 2 Change in standard of DAA audit reporting, 2011/12-2013/14

Number of criteria scoring <95%



Source: Data provided by HealthCERT; Sapere analysis. Note: for the purposes of anonymising data, DAA labels do not correspond to those in the table above.

5.3 Literature scan

We were unable to identify literature that helps us answer the question of whether it is appropriate that the Ministry retains *two* third party bodies in the current system. The particular configuration of the New Zealand regulatory system – with competing (third party) conformance assessment bodies (the DAAs), plus the layer of competing third party accreditation bodies assessing the DAAs – appears to be unique in the world, from what could be found in the literature.

The most relevant material we could find fell into three categories:

1. research on the value of accreditation and accreditation standards in health care;
2. two recent studies of the New Zealand aged care regulatory system, one by the Productivity Commission and one by a sponsored researcher; and
3. literature and guidance on best practice regulation principles more generally.

A systematic review of empirical research found the evidence base for accreditation to be incomplete and inconsistent. One study reviewed found that improved compliance with accreditation standards had little or no effect on clinical indicator performance; and another

found a weak relationship between accreditation and quality measures.[18] A later review also found a lack of robust evidence on the impact of healthcare accreditation standards.[19] A narrative review of accreditation literature in 2012 came to similar conclusions.[20]

Greenfield, Pawsey and Braithwaite reviewed the lessons learned from the existing evidence base around accreditation in health care, and noted the importance of clarity of regulatory objectives and ensuring a common understanding amongst stakeholders of the purpose of the system:

> *Clarifying and explicitly stating the regulation goals of accreditation is important to enable a consistent and coherent focus on programs and their impacts. For example, which parts of a program are aiming to increase safety and the quality of care, develop organisational capacity and systems, monitor management and clinical practices or provide government and external audit of healthcare organisations?*[21]

In its recent 2013/14 inquiry into regulatory institutions and practices, the New Zealand Productivity Commission undertook a case study of aged care regulation. The Commission identified six main functions involved in operating regulatory regimes, which may be delegated to third parties. In the case of this sector, some quality assurance monitoring has been delegated to DAAs.

The Commission suggested that such delegation may be beneficial where:

- there is a desire or potential to see greater innovation in the achievement of regulatory objectives, such as new measurement or auditing processes, noting that having multiple competing agencies may create dynamic incentives to improve and innovate;
- specialised knowledge is required to carry out monitoring and compliance, and this knowledge resides outside of government; and
- the interests of the external monitoring parties are aligned with the objectives of the regulation.

They noted that delegation of monitoring functions can present challenges – for example innovation may not be desirable in some circumstances such as where the harm from non-compliance is high, and where there is risk of regulatory capture. The Commission's case study did not mention or explore the role of third party bodies in the aged care regulatory system.

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18 David Greenfield and Jeffrey Braithwaite (2008) 'Health sector accreditation research: a systematic review', *International Journal for Quality in Health Care* 2008, 20:3 (172-83).

19 David Greenfield et al (2012) 'The standards of healthcare accreditation research standards: a review of empirical research underpinning their development and impact', *BMC Health Services Research* 2012, 12:329.

20 Reece Hinchcliff et al (2012) 'Narrative synthesis of health service accreditation literature', *BMJ Quality and Safety Online First*, published 4 October 2012.

21 David Greenfield, Marjorie Pawsey and Jeffrey Braithwaite (undated) *The role and impact of accreditation on the healthcare revolution*.

A 2013 research report by April Ferrino compared the New Zealand and US regulatory systems for residential aged care providers.[22] One of the report's observations was that in the New Zealand system, the regulator (the Ministry) has few levers for dealing with providers that continue to provide substandard care or do not address the systemic causes of problems identified during an audit, including a range of financial penalties such as are available to the regulator in the US. The report concludes that the lack of available sanctions reduces the Ministry's effectiveness as a regulator. The Productivity Commission also commented on the lack of enforcement levers.

The Ferrino report also discusses the measurement and monitoring of quality of ARC service provision. It describes the Ministry's definition of quality in the aged residential care sector as too narrow, suggesting that the current focus on audit findings does not assist with supporting on-going quality improvements. Ferrino suggests that indicators to track the progress of quality improvement efforts in the sector should be either created or developed from existing data.

> *Without consistent data reporting and analysis, MOH regulatory staff cannot determine emerging trends or negative patterns of provider compliance, or demonstrate advances in quality improvement. This information gap prevents staff from staying ahead of regulatory issues and supports reactionary responses and short-term solutions.*[23]

5.4 Qualitative information

5.4.1 Themes from semi-structured interviews

Objectives and rationale for current system

Ministry staff we spoke to had mixed views on the objectives of the current system of mandatory third party accreditation, and on the rationale for having two third parties and how the two were selected. Three interviewees stated that third parties (in particular JAS-ANZ) assist the Ministry to manage DAAs in a way they are unable to do due to lack of resources.

Third party processes

The two third parties have different philosophies, apply different standards and have different processes. The Ministry staff we interviews appeared to be unclear on the detail and content of processes undertaken by the two third parties, in particular those of ISQua.

Impact of accreditation on the quality of audits

The Ministry staff we interviewed had mixed views on whether third party accreditation has led to better quality audits. Three Ministry interviewees expressed the view that it is difficult

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[22] April Ferrino (2013) *Improving the quality of age-related residential care through the regulatory process*. Prepared with funding from the Ian Axford (New Zealand) Fellowships in Public Policy and published by Fulbright New Zealand.

[23] Ferrino (2013), p. 49.

to isolate the impact of accreditation as there have been so many other changes implemented over the same time period (in particular the DAA Handbook). Two were of the view that it is not possible to say whether there has been any improvement in the quality of audits under the new system. Two interviewees were of the view that audit reports are no different between the two third parties, stating that it depends on the individual auditor and how the DAA runs its own systems.

One interviewee stated that third parties have been useful in assisting the Ministry to manage poorly performing DAAs out of the market. However, we were also told that DAAs who have exited the market have each had different business reasons for their exit – so it was unclear to us whether it is fair to say that any DAA has actually been 'actively managed out' under the third party accreditation system.

Relationships between the Ministry and third party bodies

Ministry staff described a positive and active relationship with JAS-ANZ that is facilitated by the geographical proximity of JAS-ANZ staff. Interviewees considered JAS-ANZ to be a useful source of advice on audit best practice and support. The Ministry's relationship with ISQua was described as being more difficult due to geographic distance. We were told of one instance in which the Ministry asked ISQua for advice, and that it was provided.

5.4.2 DAA survey and follow-up telephone interviews

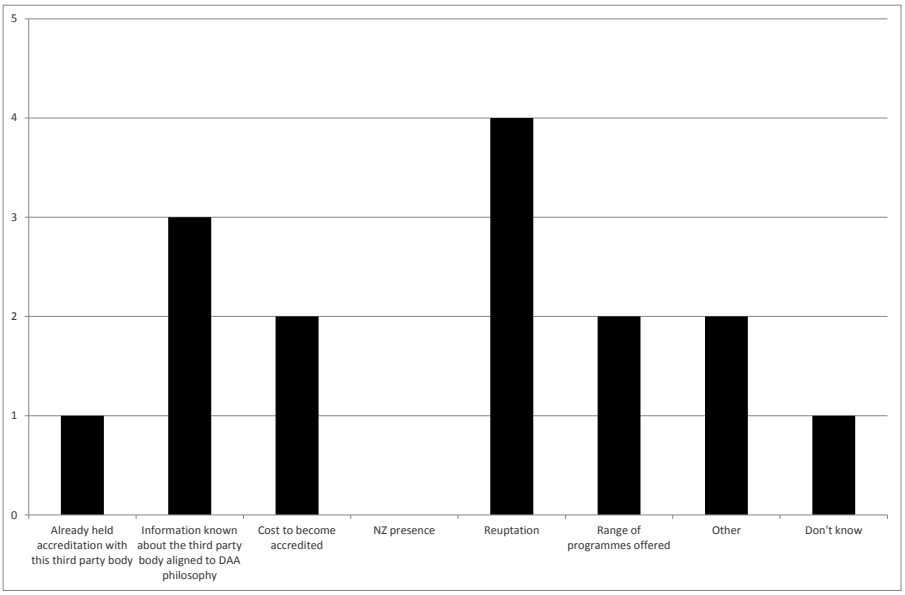
All five DAAs completed the e-survey where they were also given an option of seeking a follow up interview. Follow-up interviews were conducted with the five respondents.

Criteria used by DAAs to select a third party body

The most commonly cited reason for selecting their current third party body was reputation, followed by 'information known about third party body aligned to DAA philosophy'. The 'other' reasons for selection were that the third party was selected by an incumbent and dissatisfaction with previous third party body.

In the 2011 evaluation, the most commonly cited criteria were 'already held accreditation with this body' and 'New Zealand presence'.

Table 8 Reasons for selecting current third party body



Source: Sapere e-survey of DAAs, November/December 2014

The accreditation process

The accreditation processes of both third parties were described by the DAAs as a robust and rigorous assessment of their competence in conducting audits. Both third parties undertake site visits that include interviews (with management staff, auditors and clients) and desk-based review of a sample of reporting. ISQua's accreditation assessment was described as longer (four to five days onsite compared to two for JAS-ANZ). ISQua's accreditation process also involves the additional step of a self-assessment, which is reviewed by ISQua staff prior to the site visit. This enables ISQua to prepare targeted questions for the site visit.

Surveillance assessments and management of issues identified

Both third parties undertake on-site mid-point surveillance assessments and both have processes for monitoring and managing identified issues, including closure of issues. Both have escalation processes, with the ultimate sanction of withdrawal/suspension of the accreditation award, though to date this sanction has not been employed here (and the Ministry has not cancelled a designation).

Cost of accreditation

The direct cost of an accreditation survey with ISQua was estimated by one DAA as $12,000, and of a mid-cycle visit as $1,000-2,000. The preparation time was estimated at 40 hours including report review, and 20 hours of internal discussion, plus four to five days on-site with management fully involved and staff at specific sessions. There is an organisational cost to using this staff time.

The time spent by DAA staff in a JAS-ANZ audit was valued by one DAA as $5,000 per audit (being the opportunity cost of office staff time). It was noted by one DAA that JAS-

ANZ undertakes separate audits for each programme, which entails duplication of effort and additional cost.

Suggestions for improvement

DAAs offered the following suggestions for improvements to the accreditation process:

- smaller self-assessment component, e.g. focusing on key identified criteria (ISQua);
- more online and offsite reviews and assessments; and
- lower cost/review of pricing (JAS-ANZ).

Value from third party accreditation

Four out of five DAAs stated that they had made changes to their auditing processes as a result of third party accreditation and both third parties were described as adding value to DAA organisations and the quality of auditing. Both third parties were described as providing helpful support and guidance.

Relationship with the Ministry of Health

Three DAAs mentioned that they would like a more open dialogue with the Ministry, including more timely, proactive and cooperative engagement on changes (e.g. to the DAA Handbook). It was mentioned that there is an association of DAAs which used to meet regularly with the Ministry at the Ministry's request, but that these meetings have lapsed. It was felt by some interviewees that it would be useful to start these again.

6. Conclusions

In this section, we present our conclusions against each of the original research questions and review objectives.

6.1 Answering the research questions

Research question 1: Is the third party body affiliated or a member of the European Cooperation for Accreditation (EA) or the International Accreditation Forum (IAF)?

As set out in Table 4, JAS-ANZ is a member of the IAF, as well as the Pacific Accreditation Co-operation and the Asia Pacific Laboratory Accreditation Co-operation Multi Lateral Co-operative Accreditation arrangement. ISQua is recognised by the World Health Organisation as being in official relations to assist with technical and policy advice on evidence and best practices. ISQua's International Accreditation Programme has members from all the leading health care accreditation programmes in Canada, Australia, US and Europe.

By design, the two third party bodies apply different standards, so it is not clear to us that membership of the EA or IAF is a meaningful criterion for assessing the third party accreditation regime. Both have made concessions to their normal processes and standards to accommodate the requirements of the Ministry and the DAA Handbook.

Research question 2: Does the third party body accreditation provide an endorsement of a conformity assessment body's competence, credibility, independence and integrity to carry out conformity assessment activities?

The standards and processes applied by the two third party bodies are summarised in Table 5 and Table 4. JAS-ANZ uses ISO standards and is recognised to accredit against ISO/IEC 17021. ISQua develops its own internationally expert validated health and social care standards.

ISQua's standards have a health sector and patient safety focus, whereas JAS-ANZ services a wide variety of industries. We note that Disability Services Standards, mental health and hospitals are out of scope of our review. We also note that the reference to ISO/IEC standards was reportedly incorporated into the DAA Handbook at the request of JAS-ANZ. An exercise was subsequently undertaken to map ISQua's standards against the ISO standard.

On the basis of the qualitative and quantitative evidence reviewed, we have concluded that, although the two third parties employ different approaches, they are both working to provide an endorsement statement on DAAs' competence, credibility and independence to do the job.

Research question 3: Are third party body assessment reports available from the third party body to the Ministry (to provide feedback on ongoing performance of the DAAs)?

Third party body assessment reports are not provided directly by the third parties to the Ministry, as this is not a requirement on third party bodies and they have no mandate to do so, with the reports being owned by their clients, the DAAs. Third party bodies' contractual relationships are with the DAAs themselves, and the responsibility for providing reports to the Ministry lies with DAAs. Both third parties encourage DAAs to provide the reports as required.

The procedures for the provision of feedback on performance by third party bodies to DAAs are illustrated in the process maps in Figures 2-4. The Ministry will notify third party bodies of any concerns with DAAs prior to an assessment taking place.

Both third party bodies have provided information on best practice to the Ministry on request, but the Ministry typically goes to JAS-ANZ for advice.

Research question 4: Does the third party body impose sanctions or consequences where a conformity is not meeting requirements of third party accreditation?

Both third party bodies have processes for monitoring and managing identified issues, including closure of issues. Both undertake mid-point surveillance assessments. Both have escalation processes, with the ultimate sanction of withdrawal/suspension of the DAA's accreditation award, though to date this sanction has not been employed here. In addition the Ministry has never cancelled a DAA's designation.

Research question 5: Have DAAs made changes to the way they operate as a result of third party accreditation?

Four out of the five DAAs reported that they have made changes to their systems and processes as a result of third party accreditation. However, we note that not all DAAs have yet completed a full assessment cycle with their current third party body (and one is yet to complete a full cycle given that it only entered the market in 2014).

We are unable to say from the available evidence whether the quality of audits has improved over the evaluation period. Moreover, it is not possible to attribute changes to third party accreditation, given the multiple other interventions occurring over the evaluation period, as well as the natural maturity cycles of the DAAs as organisations.

Research question 6: How effective are each of the third party bodies in performance managing poorly performing DAAs?

On the basis of a review of relevant literature and our stakeholder interviews, we conclude that third parties are not set up for, not appropriate for 'performance management' of DAAs. Their role is to endorse the ability of DAAs to perform their role competently, and in this regard we found no evidence of differing results between the two third party bodies. In the current structure, we conclude that it is the role of the Ministry to performance manage DAAs, not of the third party bodies.

Research question 7: Is it appropriate that there are two third party bodies where there is inconsistency of standards?

The question of what is the appropriate regulatory framework, including whether the use of third party bodies is appropriate, and if so, how many is optimal, depends on the objectives and purpose of the regime. There appears to be no international precedent for the current regulatory structure, especially the layer of DAAs and the Ministry being responsible for provider certification. Also, the specific objectives of the current accreditation model appear to be implicit rather than explicit, making it difficult to form a view on its appropriateness.

Reviewing the broader regulatory framework was out of scope of our assignment, but if we were to undertake such as assessment, our starting point would be to apply the New Zealand Treasury's best practice regulation principles,[24] overlaid with a health policy lens.

The principle of proportionality is key to this context – proportionality involves placing an emphasis on a risk-based, cost-benefit regulatory framework and risk-based decision-making by regulators; and includes ensuring the regime is effective and that any change has benefits that outweigh the costs of disruption. Of particular relevance to this risk-based approach is that the population in question is highly vulnerable, and there continues to be a lot of concern regarding the quality and safety of care of the residents of ARCs.

The principle of capable regulators is also pertinent – meaning that the regulator has the people and systems necessary to operate an efficient and effective regulatory regime.

The Ministry of Health's *Statement of Intent 2014 to 2018* identifies outcomes for the health system and the Ministry:

- New Zealanders live longer, healthier and more independent lives; and
- the health system is cost-effective and supports a productive economy.

The Ministry has three high-level outcomes that support the achievement of the above health system outcomes:

- New Zealanders are healthier and more independent;
- high-quality health and disability services are delivered in a timely and accessible manner; and
- the future sustainability of the health and disability system is assured. The Ministry has a focus on ensuring health services are delivered better, sooner and more conveniently.

The current third party accreditation system is situated within a complex sector. This environment is made more complex when the relationships with DHBs are also considered. In spite of this complexity, and the lack of clarity of roles, our review found no evidence to suggest that the differing approaches employed by the two third party bodies are associated with differing quality of DAA audits. In fact, both third parties appear to be working to provide assurance around audit processes and to lift the performance of DAAs.

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24 http://www.treasury.govt.nz/economy/regulation/bestpractice

The fact that there are two third parties, and that they use different approaches, does not appear to be of concern per se. Answering the question of whether two is the optimal number of third party bodies would require a first principles analysis, based on the regulatory principles and sector policy objectives as outlined above. What we would emphasise is that the costs of change (e.g. to having just one third party body) would be high. Any more than two for such a small number of DAAs would seem to be excessive and may not attract any additional third parties in to the market.

Any change from the current structure would impose costs of change on DAAs and could have dynamic market implications (such as potential movement of DAA client bases) including possible competition effects, and may not be well received in the current environment. We would expect any increase in costs to DAAs to be directly passed on to the ARC sector. These costs would need to be taken into consideration in the regulatory impact analysis. Such analysis should also employ the Treasury's best practice regulation principles, to ensure that any resulting systems change represents the minimum necessary to achieve the desired objectives, and that the costs are justified by the expected benefits.[25]

We note that DAAs were unanimous that there should be choice of third party body, and there are examples where choice is provided in other countries such as Canada (though as noted above, not within an equivalent regulatory system).

6.2 Addressing the review objectives

Determine how effective each third party body is in strengthening the certification process

We found no evidence that the different approaches of the two third party bodies is producing differing results. We note that each third party is working with one of their DAA clients more actively than the others.

Further explore the differences between ISQua and JAS-ANZ in their determinations regarding non-conformities and recommendations, including mitigation of any identified risks and/or issues

The standards and processes applied by the two third party bodies, and the procedures for the provision of feedback on performance by third party bodies to DAAs are explored in section 4 of our report. Both third party bodies have processes for monitoring and managing identified issues and risks, and both appear to be working to provide assurance around audit processes and to lift the performance of DAAs.

Ensure the Ministry's approach in retaining these two third party bodies can be satisfied

We found no evidence to suggest that either of the two third party bodies should not be retained by the Ministry. In a more general sense, it is unclear to us whether the current accreditation model represents the most appropriate regulatory framework; however we note

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[25] Any proposed change to the number of approved third party bodies may also need to consider the competition implications to ensure consistency with the requirements of the Commerce Act.

that the costs of change would be high, so advise that any potential changes to the system are explored cautiously and subject to robust regulatory impact analysis. To comment on the framework itself was outside the scope of this review.

Identify to the Ministry other suitable international third party bodies (if any) able to undertake this work

There is a range of other accreditation providers, such as:

- International Accreditation New Zealand (IANZ) (operates in a variety of sectors);
- Joint Commission International (JCI) (patient safety and health care focused); and
- Commission on Accreditation of Rehabilitation Facilities (CARF International) (health and human services, though does not appear to currently cover Australasia).

But the question of how many third party bodies is appropriate and how to select them (what criteria to employ) depends on what the Ministry is seeking from accreditation, in the context of the broader regulatory system. Whether any alternative providers would be interested in supplying the required services to this relatively small market on an international scale, would also need to be determined, e.g. via a competitive procurement process.

6.3 Additional observations

6.3.1 The regulatory framework and the role of accreditation

We observed a need for greater clarity and understanding between all sector participants – DAAs, third party bodies, ARCs and the Ministry – regarding the Ministry's regulatory policy objectives, in particular the role of accreditation in the regulatory framework.

We also note that there is currently no formal, legislative basis for the mandatory requirement for third party accreditation, as the proposed legislative amendment did not progress through the legislative agenda. The DAA Handbook is therefore being used as an unusually informal method of changing the industry rule book. The risk of this approach is that rule changes could lack the transparency, consultation process and analytical rigour (including consideration of the full costs and benefits) that would normally be required of regulatory changes (or indeed policy changes more generally).

While outside the scope of our review, we would encourage the Ministry to meet the standards expected of regulatory impact analysis and processes for amendments to the DAA Handbook and any other requirements on DAAs, in a manner proportionate to the nature and size of the problem being addressed, and to the impacts of the changes.

6.3.2 Managing sector relationships

We observed that personal relationships between the Ministry and DAAs have at times been strained. We are concerned that the time and effort spent in managing these relationships has the potential to obscure the core focus on patient / resident safety and quality of care.

With respect to the Ministry's relationships with the third party bodies, we observed a need for greater mutual understanding between the Ministry and the third parties regarding their

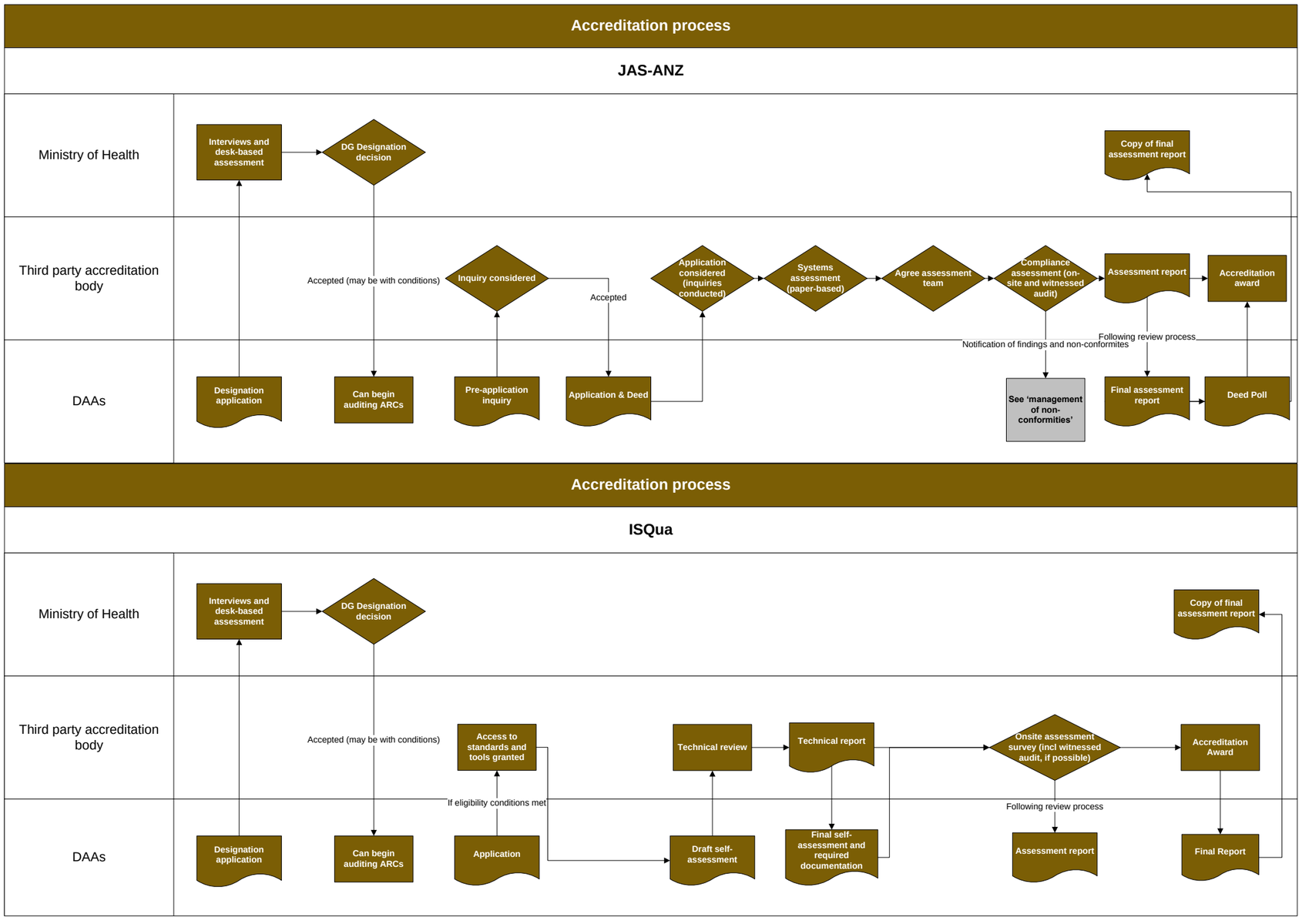
standards and processes, and how these can fit within the existing regime and meet the Ministry's expectations. We envisage that the information garnered through this review may contribute to this understanding.

6.3.3 Measurement and monitoring

In light of feedback from stakeholder interviews, and our review of the data currently used for monitoring, we query whether the Ministry is focusing on the indicators and issues of most importance, and whether an appropriate balance is being struck between administrative performance (such as reporting style) and matters of substance (quality of audits). We note and support that the Ministry intends to review its indicators this year.

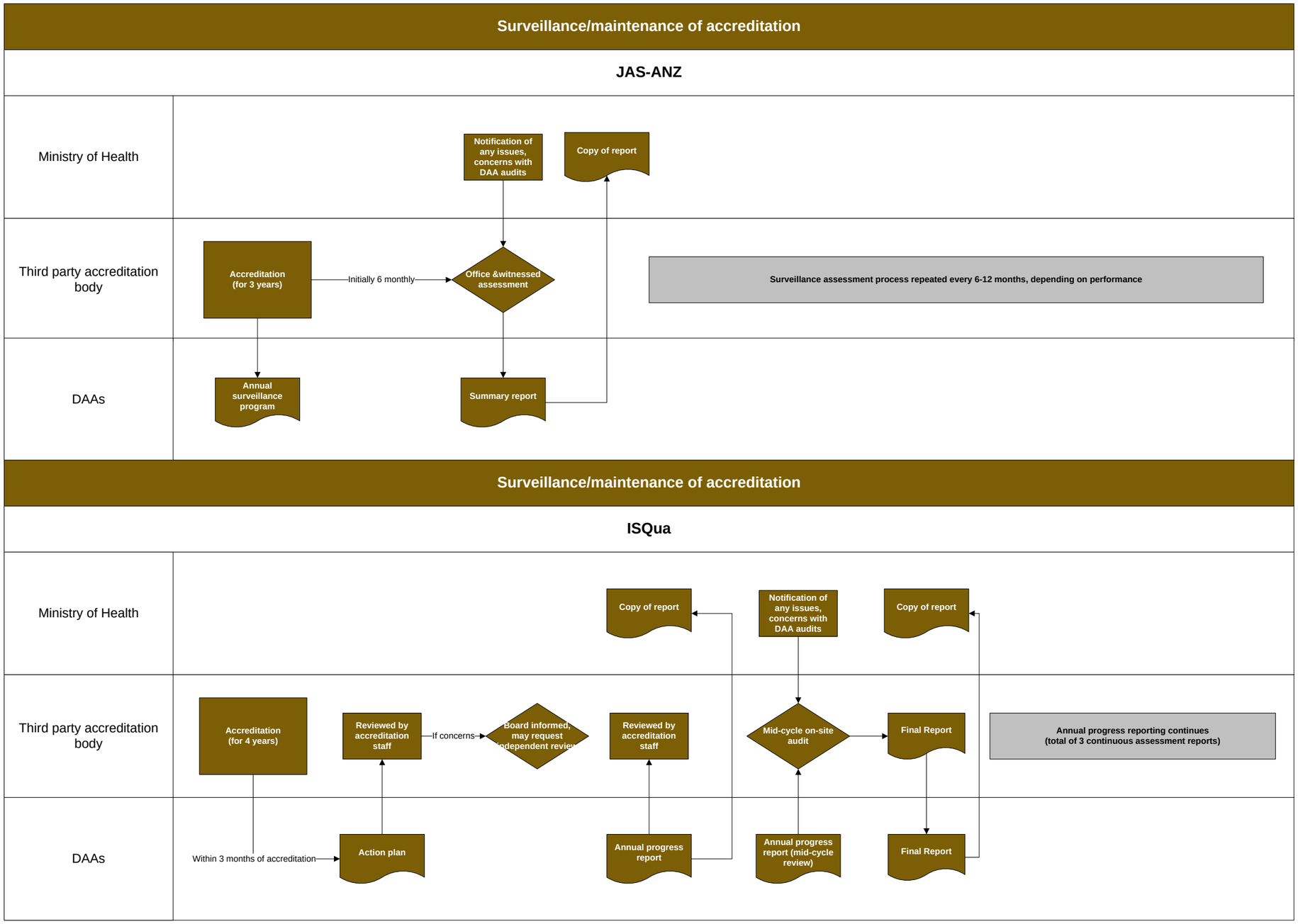
Appendix 1 : Accreditation and surveillance processes

Figure 3 Accreditation processes



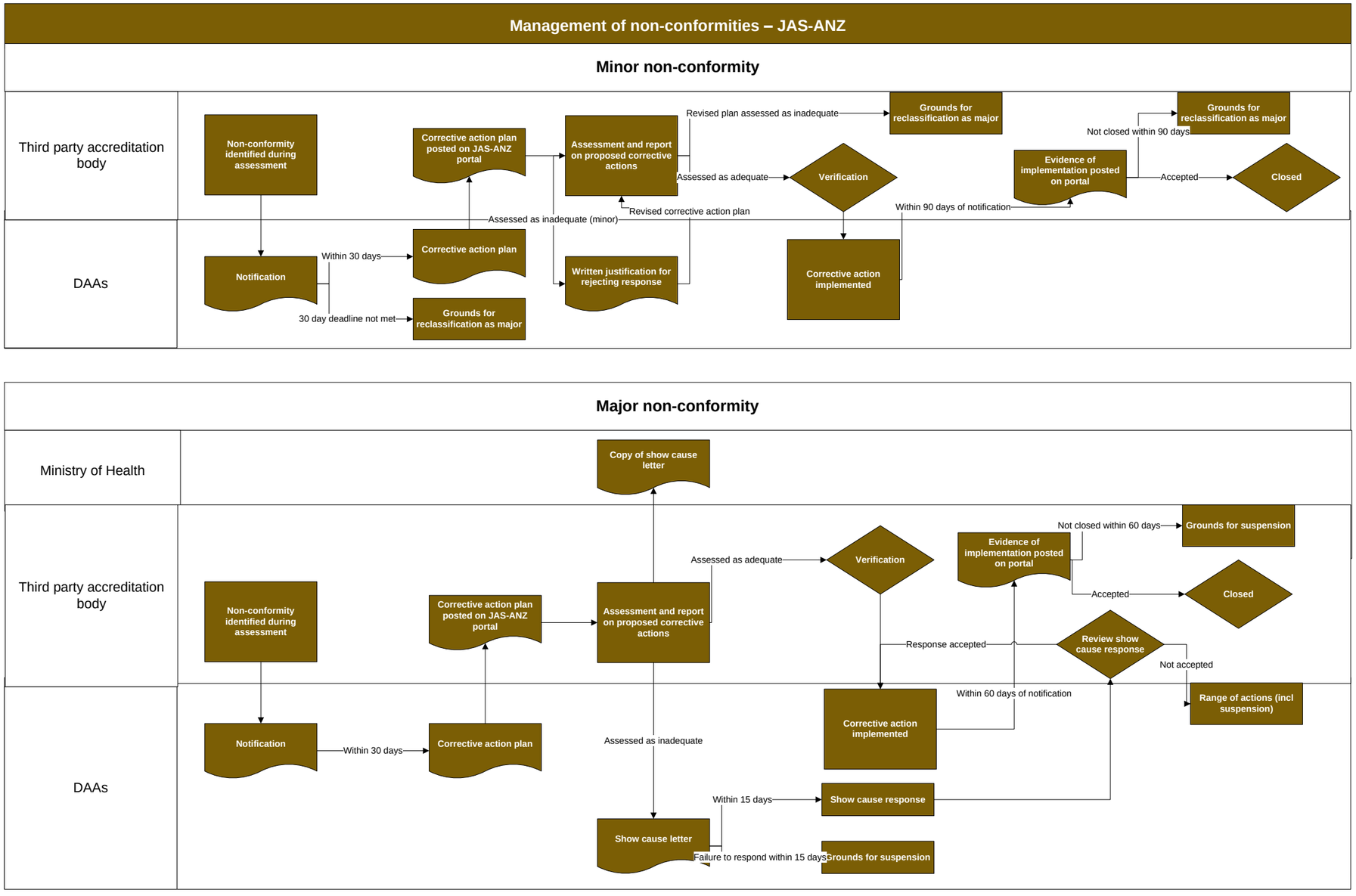
Source: Sapere (based on ISQua *Guidelines and standards for external evaluation organisations*, 4th edition version 1.1, July 2014; JAS-ANZ *Accreditation manual*, 2014; Sapere interviews)

Figure 4 Surveillance processes



Source: Sapere (based on ISQua *Guidelines and standards for external evaluation organisations*, 4th edition version 1.1, July 2014; JAS-ANZ *Accreditation manual*, 2014; Sapere interviews)

Figure 5 Management of non-conformities (JAZ-ANZ)



Source: Sapere (based on JAS-ANZ *Accreditation manual*, 2014; Sapere interviews)

Appendix 2: DAA performance indicators – 2011 and 2014

The following table sets out the DAA performance indicators used in the 2011 evaluation and those provided by the Ministry for 2014 evaluation.

Table 9 DAA performance indicators

	2011 evaluation Years provided: 2009, 2010, 2011		Provided for 2014 evaluation Year provided 2013/14	Equivalent 2011 indicator
1	The audit team meets the requirements for the audit	1.1	The audit team met the requirements for the audit (audit team membership)	1
2	The required fields of the audit report are completed	1.1a	A minimum of 50% of the audit team were NOT involved in previous audit	
3	The audit report did not require re-submission	1.1b	The peer reviewer was independent of the audit team	
4	Evidence was triangulated	1.2	For multi-site sampling, the Ministry agreed the sampling plan	
5	Evidence included a consumer interview and/or relative interview	1.3	Interviews included at least one medical practitioner (ARC)	
6	Terminology was explicit	1.4	Critical risks were reported to the Ministry within 24 hours in writing	
7	Standards statements match criterion	1.5	The audit summary for publication was accurate and written in plain English	
8	Evidence matched level of attainment awarded	1.6	The audit summary did not require amendment by the DAA	
9	Evidence matched risk ratings	1.7	All partial attainments and unattained criteria from the	

	2011 evaluation Years provided: 2009, 2010, 2011		Provided for 2014 evaluation Year provided 2013/14	Equivalent 2011 indicator
			previous certification audit were audited	
10	There was quantification of evidence	1.8	The DAA was not required to re-submit the audit report	3
11	Evidence was stratified	1.9	The audit report was submitted by the earlier of: a) 20 working days of the last day on site OR b) at least 20 working days prior to expiry of the current certificate	18
12	Evidence written in the present tense	1.10	The content of the audit report was peer reviewed as required by the DAA Handbook	
13	No further information from the DAA to ensure evidence was triangulated	2.1	Tracer(s) were summarised and anonymised	
14	No information from the DAA to ensure evidence matched risk ratings	2.2	Where issues arose in the tracers, a wider sample specific to the particular issue was taken to verify that the finding was either a single incidence or a systemic issue	
15	Information was requested from the DAA no more than once	2.3	The evidence included a consumer interview and/or relative interview or questionnaire	5
16	When information was requested from the DAA a response was received within 48 hours	2.4	Streamlined approach (SLA) criteria are explicit in the standard evidence	
17	Sampling methodology included tracer methods (added 1 October 2010)	2.5	The risk ratings for SLA standards and criteria are accurate	9?
18	The audit report was submitted 20 working days prior to the certification expiry (added 1 October 2010)	2.6	The evidence matched the level of attainment awarded at criterion and standard level	8

	2011 evaluation Years provided: 2009, 2010, 2011		Provided for 2014 evaluation Year provided 2013/14	Equivalent 2011 indicator
		2.7	The appropriate SLA standards and criteria evidence matched with the risk ratings	9
		2.8	The appropriate SLA standards and criteria were used for the service type	
		2.9	The combined audit evidence has been stratified (e.g. differentiated and referenced to the audit type)	11
		2.10	Evidence was written in the present tense and without statements of intent	12
		2.11	Staff education and training evidence was collated into 1.2.7 with shortfalls identified in 1.2.7.5	
		2.12	Policy and procedure evidence was collated into 1.2.3 with shortfalls identified in 1.2.3.3	
		3.1	The advisor did not have to request further information from the DAA to ensure that evidence matched risk ratings	14
		3.2	The advisor did not have to request further information from the DAA on more than one occasion	15

Appendix 3 : Standard of DAA reporting, 2011/12 and 2012/13

Table 10 Standard of DAA audit reporting, 2011/12

Proportion of total yes/no assessments (excluding N/A)

Criterion	DAA 1	DAA 2	DAA 3	DAA 4	DAA 5	DAA 6
1.1	100%	99%	100%	100%	100%	97%
1.1.a	97%	98%	99%	96%	100%	98%
1.1.b	100%	99%	100%	100%	100%	97%
1.10						
1.2	67%	95%	78%	100%	100%	83%
1.3	82%	70%	83%	70%	60%	53%
1.4	90%	100%	91%	100%	100%	100%
1.5	96%	94%	95%	96%	100%	90%
1.6	91%	91%	95%	92%	83%	81%
1.7	99%	97%	99%	100%	100%	93%
1.8	96%	91%	99%	82%	100%	92%
1.9						
2.1						
2.2	100%	100%	99%	100%	86%	100%
2.3						
2.4						
2.5						
2.6	97%	98%	99%	100%	100%	100%
2.7	99%	98%	98%	100%	100%	97%
2.8						
2.9	100%	98%	98%	93%	86%	97%
2.10	97%	98%	100%	100%	100%	97%
2.11						
2.12	99%	98%	100%	89%	100%	85%
3.1	97%	93%	96%	93%	57%	86%
3.2	100%	93%	98%	96%	57%	94%
Total # audits	**>100**	**>200**	**>200**	**<50**	**<50**	**<50**
Number criteria <95%	**4**	**7**	**3**	**6**	**6**	**9**

Source: Ministry of Health data; Sapere analysis. Note: for the purposes of anonymising data, DAA labels to not correspond to other tables.

Table 11 Standard of DAA audit reporting, 2012/13

Proportion of total yes/no assessments (excluding N/A)

Criterion	DAA 1	DAA 2	DAA 3	DAA 4	DAA 5
1.1	100%	100%	100%	100%	94%
1.1.a	98%	98%	100%	89%	100%
1.1.b	100%	100%	98%	89%	100%
1.10		100%	100%		
1.2	100%	100%	100%		100%
1.3	80%	87%	87%	80%	60%
1.4	95%	98%	96%	100%	100%
1.5	87%	92%	87%	89%	59%
1.6	86%	89%	83%	89%	50%
1.7	100%	98%	97%	83%	100%
1.8	89%	98%	89%	78%	78%
1.9		100%	100%		
2.1		100%	100%		
2.2	99%	99%	100%	100%	100%
2.3		100%	100%		
2.4			100%		
2.5		100%			
2.6	100%	99%	98%	100%	100%
2.7	98%	99%	98%	100%	100%
2.8		100%	100%		
2.9	96%	98%	98%	88%	100%
2.10	97%	98%	98%	100%	94%
2.11		100%	100%		
2.12	100%	100%	100%	100%	91%
3.1	89%	95%	94%	78%	94%
3.2	89%	97%	90%	78%	78%
Total # audits	**>200**	**>200**	**>100**	**<50**	**<50**
Number criteria <95%	**6**	**4**	**6**	**10**	**7**

Source: Ministry of Health data; Sapere analysis. Note: for the purposes of anonymising data, DAA labels to not correspond to other tables.

Appendix 4 Interview questions

Questions for Ministry of Health staff

Objectives

4. What was the Ministry seeking to achieve from the current system of third part accreditation of DAAs?

    (a) What was the rationale for having two TPAs (compared to one or more than two)?

    (b) What were the expected/desired outcomes from having two TPAs with philosophically different approaches to accreditation?

Third Party Agency Selection

5. How were the current two TPAs selected?

    (a) Was it a contestable process?

    (b) What were the selection criteria?

    (c) Did any DAAs have input in to the selection criteria?

Current Processes

6. Describe how the process and relationships works between:

    (a) MoH and TPAs?

    (b) MoH and DAAs?

    (c) MoH and DHBs?

    (d) TPAs and DAAs?

7. How do you monitor / enforce the MoUs? (e.g. regular meetings, feedback loops etc)

8. Have there been any changes in your approach since the reintroduction of third party accreditation?

9. What works well with the current processes? Why is that?

10. What doesn't work well with the current processes? Why is that?

The Future

11. What do you think could change to improve things for the future? Why is that? What might prevent that change, are the risks and enablers?

12. If there was only one TPA, or more than two, what would be the benefits or risks of that?

13. Is there anything else you wish to comment on?

Questions for third party bodies

Current

1. As an introduction, please describe your organisation's general philosophy and overall approach, and in a general sense how this meets the Ministry's requirements including of the DAA handbook, and the MoU between you and the Ministry?

2. Please also describe your activity and practice in relation to the DAA accreditation model.

3. Please include a description of the processes and cycles you use, e.g. observation audits, managing of any non-conformities, mid-point surveillance audits etc.

4. Could you please check and update the summary information in Table 1, below, that describes various aspects of your organisation.

5. What do you see as the strengths of your approach compared to alternative approaches to accreditation, if you are aware of any? What are the weaknesses?

6. What are the communication processes and information flows between your organisation and the Ministry, including any reports you supply to the Ministry and any notifications you provide regarding non-conformity of DAAs?

Quality

7. What is your process for responding to any emerging issues with the DAAs (including managing corrective actions, on-going monitoring and follow ups)?

8. Do you think that DAAs have made changes to the way they operate as a result of your approach to accreditation? Please explain your response. Did these changes go as far as you would have expected?

9. In summary, have you seen any quality changes in auditing since the Ministry reintroduced third part accreditation in 2010?

Future

10. What challenges do you face in performing your role? How could these be addressed?

11. Overall, are there opportunities for change or improvement in the processes? If so, what are the barriers and enablers to change?

12. Is there anything else you wish to comment on?

Appendix 5 Survey form for DAAs

Respondent information

Please provide the following information about your organisation, to assist our analysis.

1. Your name

2. Your designation (job title/role)

3. Name of your DAA
    a. Central Region's Technical Advisory Services Limited
    b. Health and Disability Auditing New Zealand Limited
    c. HealthShare Limited
    d. Health Audit (NZ) Limited
    e. The DAA Group Limited
    f. Other (please clarify)

Comment/clarification (optional)

4. How long have you been accredited as a DAA?
    a. Less than 1 year
    b. 1-2 years
    c. More than 2 years

Choosing your current third party accreditation body

5. Which Third Party Accreditation body (TPA) are you currently with?

    a. JAS-ANZ

    b. ISQua

6. What criteria did your DAA use to select a third party accreditation body? You may select more than one answer.

    a. Already held accreditation with this third party body

    b. Information known about the third party accreditation body aligned to DAA philosophy

    c. Cost to become accredited

    d. New Zealand presence

    e. Reputation

    f. Range of programmes offered

    g. Other

    h. Don't know

7. If you selected 'other', please specify.

8. Have you changed third party body since being a DAA?

    a. Yes

    b. No

9. If yes, when did you change (what year) and what were the business reasons for your change?

Becoming accredited

The following questions are about the process of becoming accredited by your current third party body.

10. Please explain the process you are required to undertake when applying for and being accredited by your current third party body.

11. How do you perceive that your third party body assesses the competency of your auditors and the quality of your audits?

12. Can you estimate the time and cost involved with accreditation?

13. What could be improved or changed to make the accreditation process better, e.g. more efficient?

Quality management and improvement

This section seeks your views on the impact of the accreditation regime on the quality of audits.

14. What kinds of areas for improvement have been identified by your third party body either at an accreditation assessment or surveillance assessment?

15. How has your third party body managed any non-conformities/performance issues it has identified with you?

16. Have you ever made any changes to your processes, auditing practice or other actions based on the third party body's assessment and feedback to you?

    a. Yes

    b. No

    c. Don't know

If 'yes', what type of changes have you made?

17. Are there are ways in which the performance monitoring and management processed used by third part bodies could be enhanced?

18. Do you think being accredited by a third party body adds value to your business and the quality of your audits?

    a. Yes

    b. No

Please explain the reasons for your answer.

19. Does your DAA believe there should be a choice of third party body?

    a. Yes

    b. No

    c. Don't know

    d. No comment

If 'yes' or 'no' please explain the reasoning behind your answer.

Relationships and engagement

20. How does your third party body work with you – what are the communication processes and frequency of contact?

21. With regards to the third party accreditation processes, what are your functional relationships with the Ministry of Health?

    a. Reports

    b. Dialogue

    c. Other

If 'other', please specify.

22. Are there any ways in which your relationship with the Ministry of Health could be improved?

Anything else?

23. Is there anything else you wish to add or comment on?

24. We are also keen to speak with a representative from each DAA (either in person or by telephone), so please indicate whether you are happy to be contacted for a confidential interview, and if so, provide your contact details.

    a. Yes, I am happy to participate in an interview with a Sapere team member.

    b. No, I do not wish to participate in an interview with a Sapere team member.

If 'yes', please provide your contact details.