



Auditing Regulatory Activities

Insights: Audit Practice

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Introduction

The purpose of Insights: Audit Practice is to explain ANAO methodologies to help entities prepare for an ANAO audit.

Audit Practice: Auditing Regulatory Activities is intended for senior management and those responsible for managing internal audit within Australian Government entities that have a regulatory function.

Regulation is any rule endorsed by government where there is an expectation of compliance. The Department of Finance describes the purpose of regulation is to provide equitable access to public services, promote competitive markets, ensure systems work effectively, and protect Australia and its people from harm. Regulatory functions may include administering (for example, providing approvals, making operational rules about, handling complaints on), monitoring, promoting compliance with and enforcing regulation.

Regulatory functions are exercised across a range of governance arrangements and structures. They may be located within Commonwealth entities that also hold responsibility for other non-regulatory functions, and that are not publicly identifiable in their own right as a regulator.¹

Performance audit topics on regulatory activities

The Auditor-General for Australia is an independent officer of the Parliament, supported by the ANAO, with responsibility under the *Auditor-General Act 1997* (Auditor-General Act) for auditing Commonwealth entities and reporting to the Australian Parliament. The Auditor-General cannot be directed in deciding what to audit², but the Auditor-General is to have regard to the audit priorities of the Parliament.³

The ANAO's performance audit activities involve the independent and objective assessment of all or part of an entity's operations and administrative support systems. This includes auditing regulatory activities. More information on the overall performance audit process is outlined in the Insights publication [Audit Practice: Performance Audit Process](#).

To help explain how the ANAO undertakes performance audits of regulatory activities, this edition of Audit Practice refers to audits from 2023–24. In 2023–24, the ANAO undertook five performance audits specifically focused on regulatory functions and activities.

1 A summary of Australian Government regulators is available from the Department of Finance: Department of Finance, 'Australian Government regulator stocktake', available from <https://www.regulatoryreform.gov.au/priorities/regulator-best-practice-and-performance/regulator-stocktake> [accessed 20 June 2025].

2 Section 8(4) of the *Auditor-General Act 1997*:
the Auditor-General is not subject to direction from anyone in relation to: (a) whether or not a particular audit is to be conducted; or (b) the way in which a particular audit is to be conducted; or (c) the priority to be given to any particular matter.

3 Section 10 of the *Auditor-General Act 1997*:
In performing or exercising his or her functions or powers, the Auditor-General must have regard to (a) the audit priorities of the Parliament determined by the Joint Committee of Public Accounts and Audit ...

- Auditor-General Report No.3 of 2023–24 [*Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods*](#);
- Auditor-General Report No.5 of 2023–24 [*Trade Measurement Compliance Activities*](#);
- Auditor-General Report No.8 of 2023–24 [*Design and Early Implementation of Residential Aged Care Reforms*](#);
- Auditor-General Report No.15 of 2023–24 [*Australian Taxation Office’s Management and Oversight of Fraud Control Arrangements for the Goods and Services Tax*](#); and
- Auditor-General Report No.26 of 2023–24 [*Department of Home Affairs’ Regulation of Migration Agents*](#).

When deciding to undertake a performance audit, the Auditor-General is guided by six key considerations: risk; impact; importance (to the Parliament and to stakeholders); materiality; auditability; and previous coverage.⁴ One of the 2023–24 topics, [*Department of Home Affairs’ Regulation of Migration Agents*](#), was identified as a priority of the Parliament for 2023–24 by the Joint Committee of Public Accounts and Audit.⁵

Specific regulatory considerations and risk areas were also considered by the Auditor-General when deciding to undertake the five performance audits on regulatory activities for 2023–24: risk-based compliance strategies; proportionate responses to non-compliance; monitoring and reporting on compliance activities; and probity in the administration of regulatory functions.

Audit approach for regulatory audits

Audit objective

For each regulatory audit, the Auditor-General decided on an audit objective, which is the ultimate question to be answered by the audit report. Audit objectives can focus on economy; efficiency; effectiveness; ethics; and legislative and policy compliance. All five of the regulatory audits in 2023–24 focused on effectiveness.

- For four audits, the objective was whether the regulator was effective in managing or administering its regulatory functions.
- For one audit, the objective was whether the design and implementation of new regulations had been effective.⁶

Audit criteria

To conclude against the audit objectives set for each audit, the Auditor-General established a set of audit criteria and sub-criteria. The criteria and sub-criteria break down the audit into a series

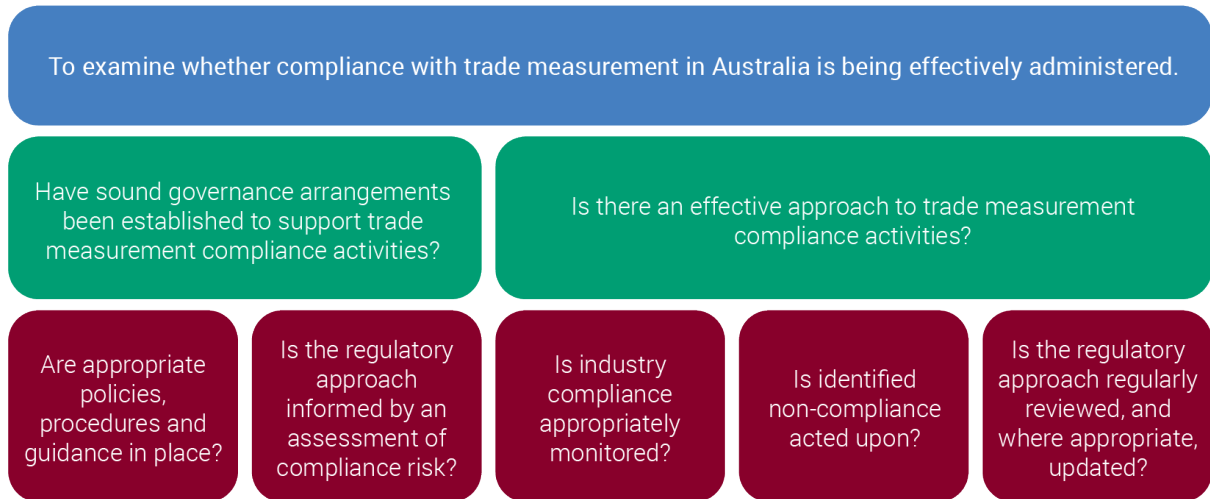
4 To read more, see: *Audit Insights: Performance Audit Process*, available from: <https://www.anao.gov.au/insights>; and the ANAO’s *Annual Audit Work Program*, available from: <https://www.anao.gov.au/work-program>.

5 Auditor-General Report No.26 2023–24, *Department of Home Affairs’ Regulation of Migration Agents*, ANAO, Canberra, paragraph 4, available from <https://www.anao.gov.au/work/performance-audit/department-home-affairs-regulation-migration-agents> [accessed 20 June 2025].

6 [*Auditor-General Report No.8 2023–24 Design and Early Implementation of Residential Aged Care Reforms*](#) was selected to provide early assurance over a new program.

of smaller questions that are mutually exclusive (i.e. do not overlap) and collectively exhaustive (i.e. address the entire audit objective).

Example of audit objective, criteria and sub-criteria for a regulatory audit: *Trade Measurement Compliance Activities*



Source: [Auditor-General Report No.5 2023–24 Trade Measurement Compliance Activities](#)

A section in the background chapter of each ANAO performance audit report titled 'Audit approach' details the audit objective, criteria, and scope. Sub-criteria form the basis of the sub-headings within the report chapters.

Audit scope

The audit scope describes the period being audited and what elements of the activity or program have been included or excluded. The types of regulatory activities within scope across the five regulatory audits are outlined in the table below.

Types of regulatory activities within scope, by audit

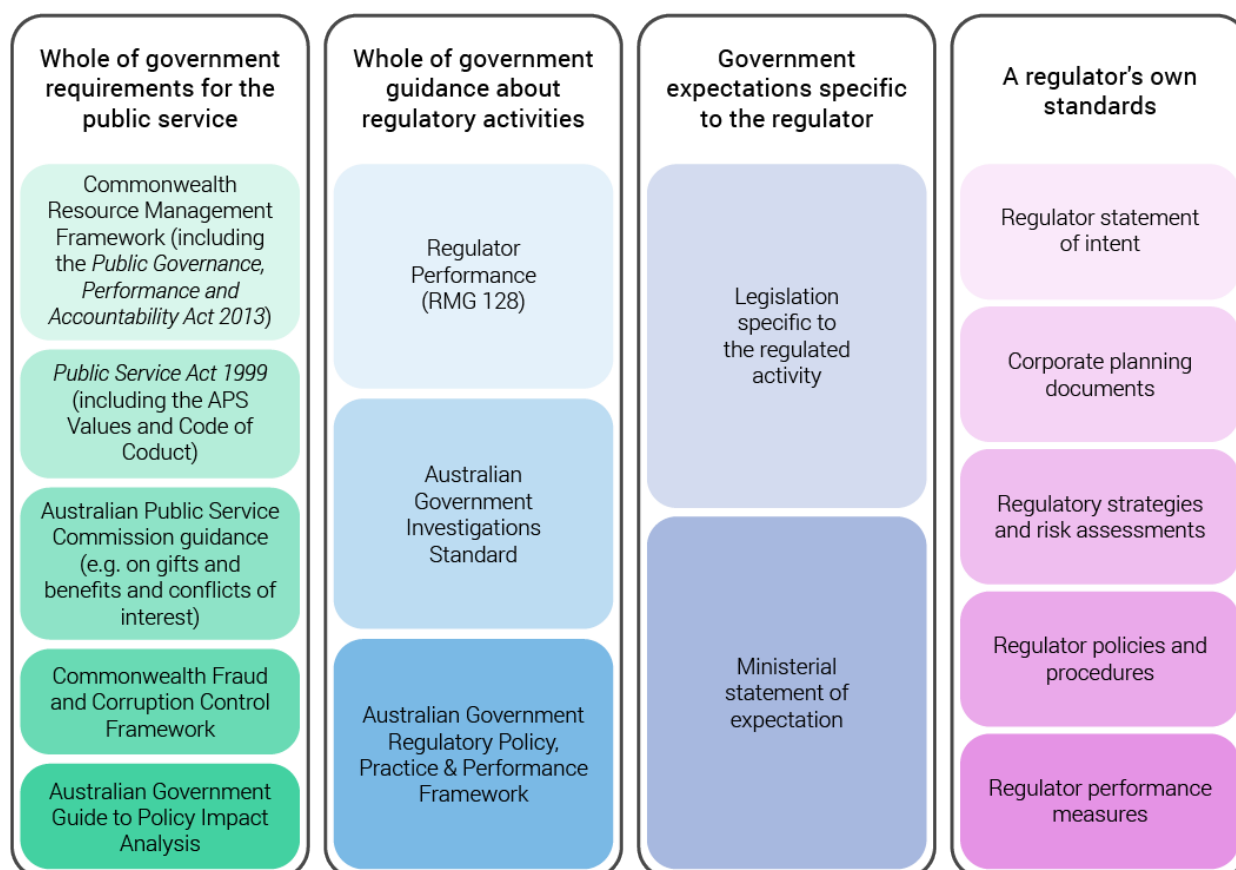
	Preparing to regulate	Risk-based compliance approach	Identifying non-compliance or fraud	Preventing non-compliance or fraud	Responding to non-compliance or fraud	Monitoring and reporting on performance
Design and Early Implementation of Residential Aged Care Reforms	✓	✓	✓	✓		✓
Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods		✓	✓	✓	✓	✓
ATO's Management and Oversight of Fraud Control Arrangements for the Goods and Services Tax		✓	✓	✓	✓	✓
Trade Measurement Compliance Activities	✓	✓	✓		✓	✓
Department of Home Affairs' Regulation of Migration Agents		✓	✓		✓	

Source: ANAO analysis of regulatory audit reports, 2023–24.

Evidence gathering and analysis for regulatory audits

Standards, frameworks and guidance applicable to regulators

The choice of audit criteria and sub-criteria, and the analysis that underpinned answers to these questions, were informed by reference to standards, frameworks and whole of government guidance that apply to regulation and provide an objective basis for assessment. In this way, the ANAO assessed what was being done against a suitable benchmark.



In its 2025 report on the inquiry into the administration of Commonwealth regulations, the Joint Committee of Public Accounts and Audit (JCPAA) noted that Finance had advised the committee that a 'Regulator Maturity Model' was expected to be released in March 2025, which would provide 'a road map for Commonwealth regulators to take steps towards best practice by supporting them to evaluate and improve their capability at the entity level ...'.⁷ Paragraphs 5.19 to 5.24 of the JCPAA inquiry report provide commentary on the whole of government principles-based guidance issued by the Department of Finance.

⁷ Joint Committee of Public Accounts and Audit, Australian Parliament, *Report 512 - Report of the inquiry into the administration of Commonwealth regulations* (2025), paragraph 5.26.

Testing and analysis against standards, frameworks and guidance

Whole of government requirements for the public service

Australian government regulators are subject to whole of government requirements that apply across the public sector. This includes the Commonwealth Resource Management Framework, which governs how officials in the Commonwealth public sector use and manage public resources and includes requirements under the:

- *Public Governance, Performance and Accountability Act 2013* (PGPA Act);
- *Public Governance, Performance and Accountability Rule 2014* (PGPA Rule); and
- Department of Finance guidance on performance reporting, governance and risk.

The five 2023–24 performance audits on regulatory activities used whole of government policies and guidelines to inform audit testing.

Whole of government requirements for performance reporting

The PGPA Act and PGPA Rule require accountable authorities to measure their entities' performance.⁸ The PGPA Rule requires that an entity's corporate plan include details of how an entity's performance will be measured and assessed through performance measures and targets.⁹ The PGPA Rule sets out the requirements for performance measures, including, among other things, that they: relate directly to one or more of the entity's purposes or key activities; include measures of the entity's outputs, efficiency and effectiveness; and provide a basis for an assessment of the entity's performance over time.¹⁰

The ANAO applied these requirements in regulatory audits in 2023–24.

- [Auditor-General Report No.3 2023–24 Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods](#) (see paragraphs 2.29 to 2.36) examined whether the Department of Health and Aged Care (Health) had established performance and measures for its compliance activities.
 - The ANAO found that Health published some performance information about its compliance activities for therapeutic goods in annual reports and on its website, but there was no reporting against established targets and little external information on the performance of the department in achieving the expected outcomes of its compliance approach. The ANAO recommended that Health review its performance information for its regulation of therapeutic goods to ensure that the information was appropriate and covered the significant components of its key activities.
- [Auditor-General Report No.5 2023–24 Trade Measurement Compliance Activities](#) (see paragraphs 3.53–56, 3.63–67 and 3.79–83) examined whether there was a performance reporting framework in place.

8 Sections 37 to 40 of the PGPA Act, and sections 16E to 16F of the PGPA Rule.

9 Subsection 16E(2) item 5 of the PGPA Rule.

10 Section 16EA of the PGPA Rule.

- The ANAO found that the Department of Industry, Science and Resources (DISR) had not established performance indicators against which to review or to demonstrate the effectiveness of its regulatory approach to trade measurement.
- The ANAO recommended that DISR, as regulator of Australia’s legal metrology system: apply *Resource Management Guide 128: Regulator Performance*; and establish indicators of, and report on, the effectiveness of its regulatory approach.

Requirements under the *Public Service Act 1999* (including the APS Values and Code of Conduct) and guidance from the Australian Public Service Commission (APSC) on managing gifts and benefits and conflicts of interest also apply to regulators, which may have unique risks stemming from their regulatory function — such as regulatory capture.

Whole of government requirements for managing conflicts of interest

The APS Code of Conduct, which is set out in section 13 of the *Public Service Act 1999*, requires that APS employees take reasonable steps to avoid any real or apparent conflict of interest. Where conflicts cannot be avoided, the APS Code of Conduct, section 29 of the PGPA Act, and section 16 of the PGPA Rule require that employees must disclose details of any material personal interest. The APSC guide *APS Values and Code of Conduct in Practice* states that entities may choose to require written declarations of interest of employees at particular risk of conflict of interest, such as those involved in ‘regulating individual or business activities’.¹¹ Management of conflicts of interest was examined in the following 2023–24 performance audit on regulation.

- [Auditor-General Report No.3 2023–24 Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods](#) (see paragraphs 4.35 to 4.39) examined whether Health had managed conflicts of interest as required by the APS Code of Conduct, the PGPA Act, and the PGPA Rule.
 - The ANAO found that draft policies were place, but declarations of interest had not been completed by those working on regulatory compliance with the *Therapeutic Goods Act 1989*.
 - The ANAO recommended that Health establish an internal control to ensure that officials involved in investigations and compliance activities make and manage declarations of interest and keep appropriate records of declarations of interest.

Management of conflicts of interest has also been the focus of other recent performance audits involving regulators.

- [Auditor-General Report No.4 2024–25 Management of Conflicts of Interest by the Australian Financial Security Authority](#) assessed the effectiveness of the Australian Financial Security Authority’s (AFSA’s) management of conflicts of interest. This included whether AFSA had: developed appropriate arrangements to manage conflicts

11 Australian Public Service Commission, *APS Values and Code of Conduct in practice*, APSC, 2018, paragraphs 5.2.7–5.2.12, available from <https://www.apsc.gov.au/publication/aps-values-and-code-conduct-practice/section-5-conflict-interest> [accessed 20 June 2025].

of interest (see Chapter 2) and effectively managed conflicts of interest consistent with its own policies (see Chapter 3).

- The ANAO found AFSA’s management of conflicts of interest to be partly effective.
- Shortcomings in the design of AFSA’s processes for declaring, managing and overseeing conflicts of interest resulted in arrangements not being sufficient to manage conflicts of interest in a regulatory operating environment.
- AFSA had not sufficiently articulated conflict of interest risks and controls in its risk management artefacts nor identified regulatory capture as a risk.
- The ANAO made four recommendations to AFSA to strengthen the design and operating effectiveness of its arrangements for managing conflicts of interest.

Another example of whole of government policies and guidance that were used as standards and benchmarks in regulatory audits is the Commonwealth Fraud and Corruption Control Framework.

Commonwealth Fraud and Corruption Control Framework

The requirements for Australian Government entities to have fraud control arrangements in place are contained in the Commonwealth Fraud and Corruption Control Framework (the Framework), developed under the PGPA Act. The Framework comprises three tiered documents, section 10 of the PGPA Rule 2014, the Commonwealth Fraud Control Policy (the fraud policy) and Preventing, detecting and dealing with fraud (RMG 201) (the fraud guidance), with different requirements for corporate and non-corporate Commonwealth entities.

- [Auditor-General Report No.15 2023–24 Australian Taxation Office’s Management and Oversight of Fraud Control Arrangements for the Goods and Services Tax](#) had audit sub-criteria that largely map to the requirements as set out in the sub-rules of Rule 10 of the fraud rule. The analysis of audit evidence against these sub-criteria was informed by the fraud policy and the fraud guidance.

Whole of government guidance about regulatory activities

The 2023–24 performance audits on regulatory activities commonly referenced *Regulator Performance (Resource Management Guide 128)*, as it lists hallmarks of accepted best practice for Australian Government regulators. RMG 128 defines regulatory functions; sets out reporting requirements against the three principles of regulator best practice; and provides information on issuing and refreshing Ministerial Statements of Expectations and responding Regulator Statements of Intent.

The *Australian Government Regulatory Policy, Practice & Performance Framework* was published in August 2024 (after the 2023–24 audits described here), and is another important framework referenced in more recent ANAO audits of regulatory activities. The framework provides regulators and regulatory policymakers with six principles of fit-for-purpose regulation:

1. targeted and risk-based;
2. integrated in existing systems;

3. user-centred;
4. evidence-based and data-driven;
5. reflective of the digital era; and
6. continuously improved and outcomes-focused.

The Department of Finance describes RMG 128 as one resource that supports policy makers and regulators to achieve the *Australian Government Regulatory Policy, Practice & Performance Framework's* purpose and six principles for regulatory systems.

Regulator Performance (Resource Management Guide 128)

Using a risk-based approach in areas such as operational policy development, administration, compliance and enforcement is one of three principles set out in *Regulator Performance (RMG 128)*. This better practice guidance was cited by three of the five 2023–24 performance audits focused on regulation. These contained a specific sub-criterion that examined whether regulators had a regulatory approach informed by risk:

- [Auditor-General Report No.3 2023–24 Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods](#) (see paragraphs 2.1 to 2.20) examined a thematic risk assessment which informed the selection of compliance priorities for the coming financial year.
 - The ANAO found that Health had adopted a risk-based approach whereby the assessment of risk had flowed through to compliance plans and procedures. The ANAO noted that these plans and procedures were largely in draft or out-of-date, and suggested they be finalised.
- [Auditor-General Report No.5 2023–24 Trade Measurement Compliance Activities](#) (see paragraphs 2.29 to 2.62) examined a risk-based approach to targeting industry sectors and individual regulated entities for compliance activity.
 - The ANAO recommended that DISR improve its risk-based approach, because there was not a strong connection between the assessment of industry and trader risks and the targeting of compliance activities.
- [Auditor-General Report No.26 2023–24 Department of Home Affairs' Regulation of Migration Agents](#) (see paragraphs 2.31 to 2.36) found that the department had not undertaken and documented an assessment of risk.

Another whole of government policy that was used as a standard in regulatory audits in 2023–24 is the Australian Government Investigations Standard.

Australian Government Investigations Standard

The Australian Government Investigations Standard (AGIS) is an Australian Government policy that establishes the foundational standard for Australian Government entities conducting administrative, civil, or criminal (type) investigations.

- [Auditor-General Report No.3 2023–24 Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods](#) (see Chapters 3 and 4)

tested a sample of 291 investigations against the requirements of the 2011 edition of the AGIS. The 2011 edition was used as it was the version that was in force for the investigations reviewed. The new version of the AGIS was released in 2022.

- [Auditor-General Report No.15 2023–24 Australian Taxation Office’s Management and Oversight of Fraud Control Arrangements for the Goods and Services Tax](#) (paragraph 3.44 and footnote 87) examined a higher level question of whether the Australian Taxation Office had updated its investigation procedures to align with the 2022 AGIS following its introduction.

Government expectations

As each regulator is established to meet specific regulatory objectives, the audits also needed to use frameworks relevant to the specific circumstances of the regulator. Parliament articulates specific expectations for regulatory activities in the regulator’s enabling legislation or administered legislation; these should be read in the context of general principles of administrative law. The Executive Government sets out its specific expectations in a ministerial statement of expectations.

Statutory requirements

The *Migration Act 1958* and Migration Agents Regulations 1998 set out statutory requirements for the registration of migration agents.

- [Auditor-General Report No.26 2023–24 Department of Home Affairs’ Regulation of Migration Agents](#) (see paragraphs 3.2 to 3.16) examined whether the Department of Home Affairs’ processing of migration agent registrations performed compared to specific timeframes and registration conditions prescribed by the Parliament in legislation.
 - The audit made use of specific deeming provisions (under which an application for registration can be deemed approved in the absence of a decision by the regulator) to test levels of regulatory inactivity.
 - The audit also examined whether the department had lawfully delegated statutory powers to officials responsible for exercising them, by reviewing the specific delegation provisions in migration legislation.

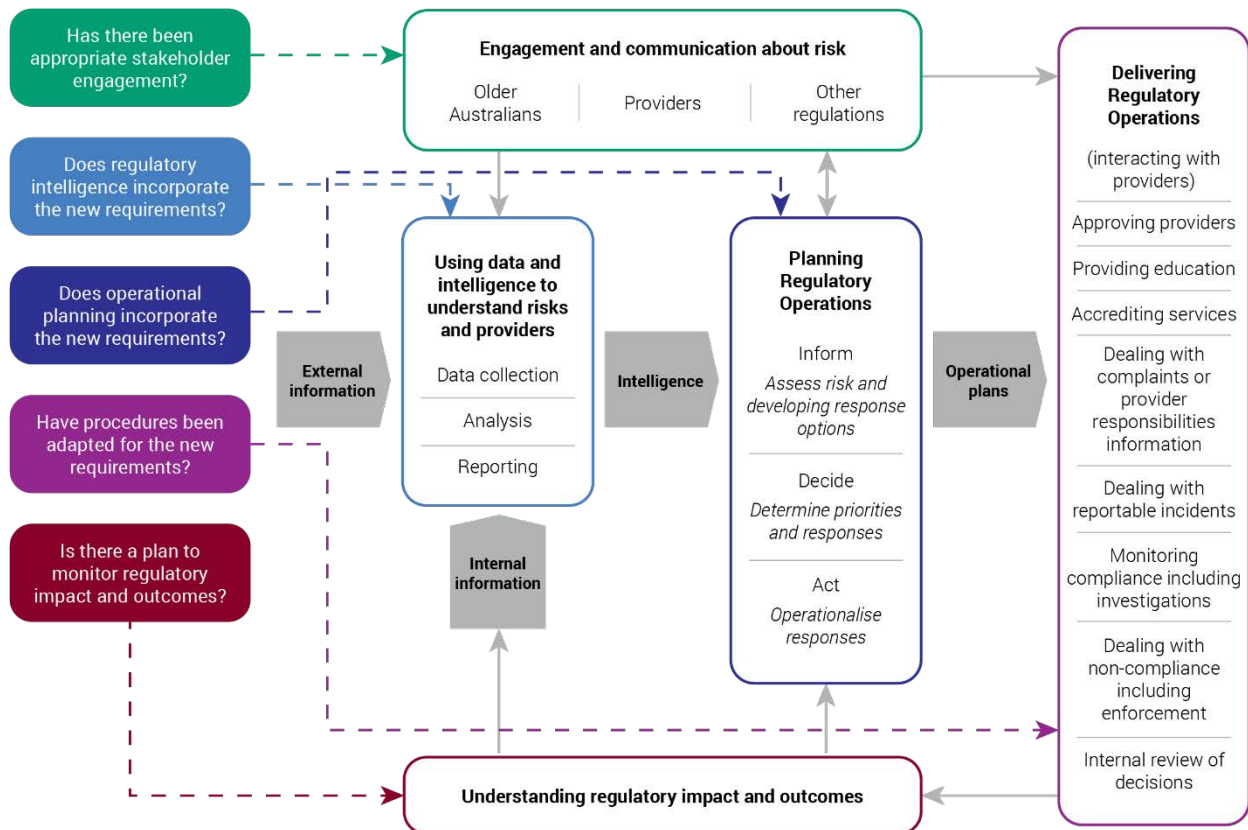
A regulator’s own frameworks

The ANAO also had regard to a regulator’s articulation of its own context, organisation, methods of operating, performance measures and desired regulatory outcomes. These were contained in regulator statements of intent, corporate planning documents, annual reports and published regulatory strategies.

For example, the audit report, [Design and Early Implementation of Residential Aged Care Reforms](#), assessed whether the Aged Care Quality and Safety Commission (ACQSC) had adequately prepared its regulatory operations for the introduction of a new regulatory requirement. Five of the six sub-criteria assessed in Chapter 4 of the audit corresponded to the ACQSC’s regulatory

operating model as it appeared in the ACQSC's 2023–24 Corporate Plan. The audit examined whether ACQSC had made necessary changes to its operations in each of these five areas.

Example of using corporate plan information to inform audit sub-criteria: *Design and Early Implementation of Residential Aged Care Reforms*



Source: ANAO, derived from Auditor-General Report No.8 of 2023–24 *Design and Early Implementation of Residential Aged Care Reforms* and Aged Care Quality and Safety Commission, *Corporate Plan 2023–24*, ACQSC, Canberra, p.29.

The five sub-criteria were also applied to the Department of Health and Aged Care, which was conducting complementary regulatory activities under the same legislation with the same regulated population. A sixth sub-criteria examined whether the department and ACQSC had clearly defined their respective roles and responsibilities.

Assessing a regulator against its own policy and procedure

The ANAO assesses regulators against their own policies and procedures.

- [Auditor-General Report No.5 2023–24 Trade Measurement Compliance Activities](#) contained a sub-criterion which examined the question 'Are appropriate policies, procedures and guidance in place?'
 - Although the ANAO found gaps and weaknesses in DISR's policies and procedures (Appendix 3), the procedures were still used when testing the effectiveness of DISR's regulatory activities (paragraphs 3.33 to 3.37). In other words, these

paragraphs examined DISR's adherence to its own framework as it had articulated them in its policies, procedures and guidance.

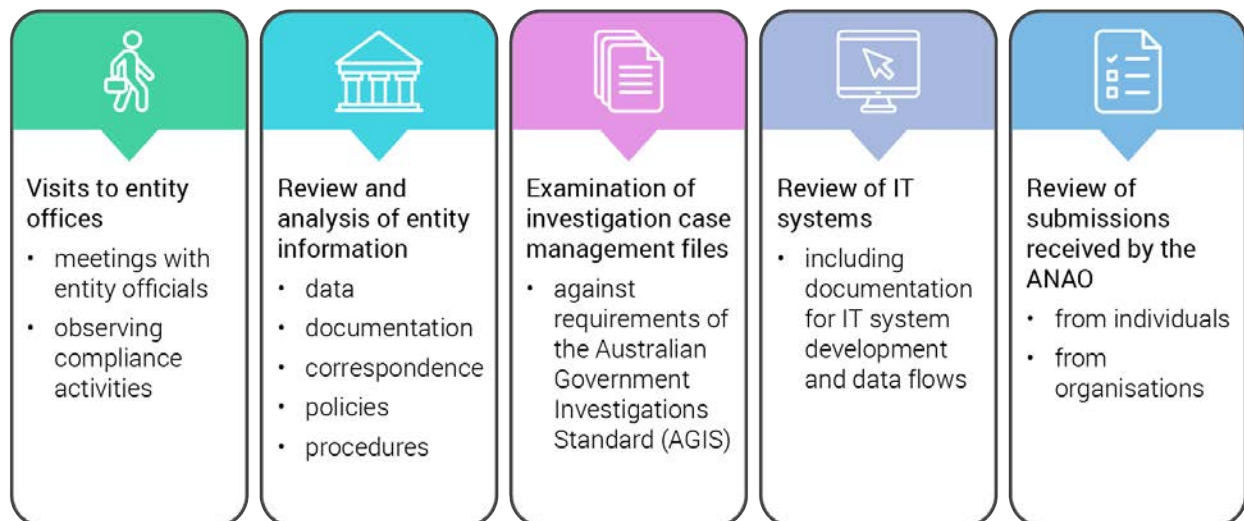
Test program

For each of the regulatory audits, the audit team prepared an audit test program that outlined for each criterion and sub-criterion:

- the standards, frameworks and guidance that applied to regulators;
- the audit methodologies to be used and the evidence to be gathered;
- the testing needed to analyse the evidence and any samples to be undertaken;
- how the evidence and analysis would be used to answer the sub-criteria and conclude against the audit objective.

Audit methodologies and evidence gathering

The ANAO collects, reviews and analyses evidence in a number of different ways. The audit methodologies used and types of evidence collected across the five regulatory audits included:



Concluding against the audit objective and reporting

Once documentation and evidence had been gathered and analysed, the ANAO outlined the preliminary audit findings, preliminary conclusions and potential audit recommendations in a report preparation paper (RPP). The RPP was provided to the audited entities for review and feedback. The purpose of the RPP is to inform auditees of issues and assist the ANAO to clarify its audit findings and conclusions. The RPP is also produced to verify the accuracy and completeness of the information the ANAO has gathered and analysed. The RPP is a working paper that is used in the development of a proposed report, which will take into account entity feedback on the RPP and other information. By its nature, the RPP will always include more detail than the final report.

After considering the entity's response to the RPP and any further information or evidence, the proposed report was drafted, including the Auditor-General's overall conclusion against the audit objective. The conclusion was given one of four classifications, as outlined below.

Conclusion classifications and 2023–24 regulatory audits

Classification	Number of regulatory audits in 2023–24
Fully effective	0
Largely effective	2
Partly effective	2
Not effective	1

Source: ANAO analysis of regulatory audit reports.

For the five regulatory audits in 2023–24, the number of recommendations in each report ranged from four to 11 recommendations. Entities were asked to respond whether they agreed or disagreed with the recommendations. Overall, in 2023–24, 94 per cent of Auditor-General recommendations were fully agreed, 5 per cent were agreed with qualification and less than 1 per cent were not agreed.¹² For the regulatory audits, all recommendations, except for one, were fully agreed by the entity, as outlined below.

Number of recommendations for 2023–24 regulatory audits

Regulatory audit	Number of recommendations	Fully agreed to by the entity (%)
Design and Early Implementation of Residential Aged Care Reforms	4	100
Management of Non-Compliance with the Therapeutic Goods Act 1989 for Unapproved Therapeutic Goods	6	100
ATO's Management and Oversight of Fraud Control Arrangements for the Goods and Services Tax	5	100
Trade Measurement Compliance Activities	6	83 ^a
Department of Home Affairs' Regulation of Migration Agents	11	100

Note a: The entity agreed with five recommendations and 'partially agreed' with one recommendation.

Source: ANAO analysis of regulatory audit reports.

After each of the proposed reports were finalised by the Auditor-General, the Auditor-General sent the report to the accountable authority of the audited entity, as required by section 19 of the *Auditor-General Act 1997*. The accountable authority had 28 calendar days to provide a formal response to the proposed report. In response to formal comments, the Auditor-General may choose to make amendments to the report. The entity's formal response was included as an appendix in the final audit reports presented for tabling in the Parliament.

¹² ANAO, *Annual Report 2023–24*, Canberra, 2024, 'Part 3 – Report on performance', available from <https://www.anao.gov.au/work/annual-report/anao-annual-report-2023-24>.