

Audit of TGA's COVID-19 Vaccine Safety Monitoring Plan (2021–2025) – ISO 19011

documentation-compliance audit - Independent Audit Process

Framework: ISO 19011:2018 + ANAO Performance Audit Standards + OSINT Methodology | Period: Feb 2021–Dec 2025 (4 years) | Finding: NON-CONFORMING

1. FOI REQUESTS

2. OAIC REVIEWS

3. RESEARCH AND ANALYSIS

4. EXPERT COLLABORATION

5. LEGAL ANALYSIS

6. AUDIT & MONITORING

KEY AUDIT STEPS

- Risk Assessment: 68M doses (94% rollout), provisional approval, expert warnings (Phillips 2021)
- Define Criteria: TGA Plan (20 outputs), ISO 19011, ICH E2E, TGA's own GMP/GCP standards
- Evidence Collection: FOI Act 1982: 531 folders, 2,218 pages
- OAIC Reviews: MR22/00538, FOI 25-0166
- Senate Testimony: Oct 2025
- Public Docs: 150+ safety reports
- 4-Tier Evidence: Tier 1: TGA's own searches (0 implementation docs)
 - Tier 2: Senate testimony (under oath)
 - Tier 3: FOI responses (statutory)
 - Tier 4: Public documentation
- Analysis: Compare 20 Plan outputs vs documented evidence
- Classify: Full/Partial/Not documented
- Findings: 7 major non-conformities
- 15% fully documented, 85% partial/none
- Reporting: GitHub + Zenodo DOI (permanent archive)
- ISO 19011 conformance: 92/100
- Monitoring: Parliamentary oversight (Senate Estimates)
- OAIC reviews ongoing
- OSINT Research Methodology: Systematic collection & verification: 150+ TGA reports, Senate Hansard, performance data - Cross-reference multiple sources to identify contradictions in TGA positions - Transparent documentation: GitHub version control + Zenodo permanent archive + ISO 19011 checklist

ISO 19011 PRINCIPLES APPLIED

- Integrity: Independent, no conflicts of interest, ~30 yrs experience
- Fair Presentation: Evidence-based findings, limitations acknowledged
- Due Professional Care: 4-year systematic investigation, comprehensive evidence
- Confidentiality: FOI framework respected, sensitive info protected
- Independence: No funding from manufacturers/government/advocacy
- Evidence-Based: 4-tier hierarchy, verifiable primary sources
- Risk-Based: High-consequence gaps, materiality focus (68M doses)

ANAO STANDARDS APPLIED

- Proper Use of Resources: Assess effectiveness, economy, efficiency, ethics
- Evidence-Based Approach: Systematic FOI, OAIC validation, Senate testimony
- Parliamentary Importance: National health emergency, largest provisional rollout
- Risk Assessment: Materiality (68M doses), expert warnings, auditability
- Records Management: ANAO guidance applied to assess TGA documentation
- Performance Audit Process: Planning → Fieldwork → Reporting → Monitoring

7 MAJOR NON-CONFORMITIES

- No Systematic Tracking: TGA admits monitoring 'day-to-day processes' never tracked vs Plan
- No Coordination Protocols: OAIC unable to find integration between AusVaxSafety-AEMS
- Data Linkage Gap Persists: Expert warnings (2020) → same gaps exist (2025)
- Contradictory FOI Positions: 'Don't exist' → 'Ample docs' → 'Too complex'
- No Signal Pathways: 6.8M surveys → 148 signals → 57 actions (no documented bridge)
- Communication Contradiction: 'No different' (public) vs 'Enhanced' (policy)
- Expert Warnings Ignored: 5-year gap between identification and response

EVIDENCE HIERARCHY

- ✓ TGA's own OAIC-directed searches (Tier 1 - highest quality)
- ✓ Senate testimony under oath (Tier 2)
- ✓ FOI statutory records (Tier 3)
- ✓ Public documentation (Tier 4)
- ✓ OAIC independent validation
- ✓ External legal review
- ✓ Expert peer-reviewed literature

OUTCOME: NON-CONFORMING

15% outputs fully documented (3/20)
85% partial (5/20)
60% not documented (12/20)
ISO 19011 Score: 92/100

*Scope: documentary evidence only (FOI, OAIC, Senate public docs); no internal system access or interviews

Phases of Audit: 1. Plan the audit 2. Gather evidence 3. Assess conformity 4. Report & archive