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QHFSS DNA laboratory – ISO/IEC 17025 conformance and accreditation

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ABSTRACT

This paper reviews evidence placed before a Commission of Inquiry (CoI) established by the State of Queensland, Australia, to consider the quality and reliability of DNA evidence. It also assesses whether the criticism levied in that report, of ISO/IEC 17025 being insufficient to assure the quality and reliability of DNA evidence, is warranted. The main conclusion drawn is that properly applied and embraced as a means of continuous improvement, conformance with ISO/IEC 17025:2017 alone is sufficient to assure the quality and reliability of the scientific outputs from a forensic science laboratory.

Furthermore, it is clear from the observations and findings of the CoI and those recorded in this paper that the forensic science laboratory in question did not conform to ISO/IEC 17025:2017. Had it done so then the risk of the quality failures that led to the CoI would at least have been reduced and perhaps even avoided.

1. Introduction

In response to a chorus of complaints and concerns about the quality and reliability of scientific evidence and possible miscarriages of justice [1], the government of Queensland, Australia, established a Commission of Inquiry (CoI) in June 2022 [2]. On the 13th of December 2022, the CoI published its 500-plus page report [3]. A principal focus of the CoI was the collection, testing and analysis of DNA by the state forensic science provider, Queensland Health Forensic and Scientific Services (QHFSS) for the Queensland Police Service (QPS). Among the general findings of the CoI was that accreditation to the International Standard ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories' was insufficient in and of itself to assure the quality and reliability of DNA evidence produced by QHFSS. To quote from the report.

> "… accreditation provides only a high-level overview of the scientific processes." [461 p143/157][1]

> "… accreditation does not establish that the systems and processes are best practice or even appropriate." [956 p301/315]

This paper considers evidence[2] placed before the CoI, its observations and findings as recorded in the report and relevant supporting documents and assesses whether the criticism of ISO/IEC 17025 as an insufficient standard is justified.

This paper compares the operation and performance of the QHFSS DNA Laboratory, as recorded in the CoI report, with the requirements of the Standard. It does so in two ways, the first based on the observations and findings of the CoI, and the second by stepping through the operational requirements of the Standard.

The main conclusion drawn is that properly applied and embraced as a means of continuous improvement, conformance with ISO/IEC 17025:2017 in and of itself is sufficient to ensure the quality and reliability of the scientific outputs from a forensic science laboratory.

Furthermore, it is clear from the observations and findings of the CoI and those recorded in this paper that the QHFSS DNA Laboratory did not conform to ISO/IEC 17025:2017. Had it done so then the risk of the quality failures that led to the CoI would at least have been reduced and perhaps even avoided.

2. Relevant quality standards

2.1. ISO and IEC

Before mentioning standards, it is necessary to briefly introduce the two main global standards development organisations (SDO), they are the International Organization for Standardization (ISO) and the

[1] References to the CoI report are in the from [AAA pBBB/CCC] where A is the paragraph number in the report, B is the page number in the report and C the page number in the pdf of the report.

[2] In addition to the CoI report this assessment is based on the report to the CoI of Dr Kirsty Wright 'REVIEW OF BLACKBURN DNA ANALYSIS' version 2, 18th of November 2022, Exhibit 220 https://www.dnainquiry.qld.gov.au/public-hearings/assets/exhibits/module-6/V2%20K.WRIGHT%20Review%20of%20BLACKBURN%20DNA%20Case%20File_Redacted.pdf and the report of Ms Heidi Baker and Dr Rebecca Kogios 'Review of the current operations of the Queensland Health Forensic and Scientific Services DNA Analysis Unit' 28th of October 2022, Exhibit 187 https://www.dnainquiry.qld.gov.au/public-hearings/assets/exhibits/module-5/EXH%20187%20-%20EXP.0007.0001.0001_R.pdf.

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International Electrotechnical Commission (IEC).

ISO is an independent, non-governmental international SDO composed of representatives from the national standards organisations of member countries, for Australia that is Standards Australia (SA), discussed later in §2.6. Through its members, ISO brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges [4].

IEC is an international SDO that prepares and publishes international standards for all electrical, electronic and related technologies. The IEC is a global, not-for-profit membership organization [5].

Many International Standards are developed and published jointly by ISO and IEC. Joint standards are identified by the prefix ISO/IEC, such as ISO/IEC 17025. Standards developed and published solely by ISO have that prefix alone, such as ISO 9001.

2.2. ISO/IEC 17025 general requirements for the competence of testing and calibration laboratories

Since its first publication in 1999, ISO/IEC 17025 has become the *de facto* standard for forensic science laboratories[3]. Most forensic science laboratories worldwide have gained accreditation to this International Standard as a means of demonstrating to forensic science stakeholders, principally criminal justice systems, the competence of the management of the laboratory, its consistent operation, the competence of its staff, the validity of its methods and the reliability of its results.

It is important to note and emphasise that conformance with the Standard does not require 'best' practice and the Standard is not 'the gold standard', merely a standard.

According to ISO, accreditation to ISO/IEC 17025

> "… enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world." [6].

The introduction to the Standard states that it

> "… contains requirements for laboratories to enable them to demonstrate they operate competently and are able to generate valid results."

In addition, laboratories

> "… that conform … will also operate generally in accordance with the principles of ISO 9001."

ISO 9001 is the quality management standard.
And in terms of its scope.

> "… this document specifies the general requirements for the competence, impartiality and consistent operation of laboratories."

According to the Australian accreditation body the National Association of Testing Authorities (NATA) which accredits QHFSS.

> "Overall, ISO/IEC 17025 accreditation supports laboratories in maintaining complex processes of testing and calibration to the highest standards and demonstrates to external clients that the laboratory outputs are valid and reliable."

And

> "ISO/IEC 17025 accreditation benefits organisations by allowing them to demonstrate their competence by satisfying the high level criteria defined in the Standard and hence, the results they generate can be relied upon by end users of their services." [7].

Therefore, based on these claims made by ISO and NATA, conformance to the standard ISO/IEC 17025 as attested to by accreditation should be sufficient to ensure competence, validity and reliability.

2.2.1. ISO/IEC 17025:2005 or 2017?

A potentially complicating factor in assessing the QHFSS DNA Laboratory's conformance with ISO/IEC 17025 is the fact that the third edition of ISO/IEC 17025 was published in 2017 and differs from the second edition in structure and emphasis [8]. Briefly, the scope now covers all laboratory activities, including sampling. The structure was completely revised. A process approach was introduced putting the emphasis on results/outputs of a process rather than a detailed description of its tasks and steps, and a new section on risk-based thinking which aligns with ISO 9001:2015, the quality management standard. ISO 9001 is introduced in §1.3.

Published in November 2017, currently accredited organisations were given three years to transition to the third edition of ISO/IEC 17025. However, many development stages precede final publication by ISO, including the publication of drafts. In addition, NATA and, through representation in NATA governance, QHFSS would have had the opportunity to contribute to the new edition and would certainly have had early notice as to what the new edition required. Therefore, it seems reasonable in conducting this assessment to use the 2017 edition. Another factor in supporting that decision is the fact that the latest edition is generally less prescriptive than the 2005 second edition.

It is of relevance to note that the latest edition of the Standard focuses on a so-called process approach to quality management. A process is defined as a set of activities that uses resources that will transform inputs into outputs. The process approach considers the interaction between these processes and the inputs and outputs that tie these processes together. The output of one process becomes the input of another, and so on [9]. One of the main processes the latest edition examines is the entire Quality Management System (QMS). If the laboratory is considered as a process, principal process inputs would be samples and customer[4] requirements and expected outputs would be results/reports which is covered by Clause 7 of the Standard, 'Process requirements'. Conformance with this approach is best assessed by vertical audits,[5] following a series of input/output operations.

ISO tightly controls copyright so extensive reproduction of the Standard is not possible. However, it might be helpful to know that it has the following clause-based structure.

1 Scope
2 Normative references
3 Terms and definitions
4 General requirements
5 Structural requirements
6 Resource requirements
7 Process requirements

[3] For example, the ANSI National Accreditation Board (ANAB) lists 603 [50], A2LA lists 29 [51] The United Kingdom Accreditation Service (UKAS) accredits all UK and some overseas forensic science laboratories [52], The National Association of Testing Authorities (NATA) lists 92 [53], most of which are accredited to ISO/IEC 17025. In England and Wales, the Forensic Science Regulator requires all providers of laboratory-based forensic science to be accredited to ISO/IEC 17025 [54]. The European Network of Forensic Science Institutes (ENFSI) which has 72 members in 39 countries requires all members to be accredited and those providing laboratory-based testing to be accredited to ISO/IEC 17025 [55].

[4] The term 'customer' must be understood in its broadest sense, particularly in relation to forensic scientific evidence. 'Customer' should be understood to include all justice system stakeholders and not just the agency funding and/or commissioning the laboratory's activities.

[5] An audit is a systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled, ISO9001:2018 §3.13.1. An example of a vertical audit would be to follow the progress of a sample from reception to reporting.

8 Management system requirements

In addition, the graphic shown in Fig. 1 demonstrates how all the requirements of the latest edition are related and, more importantly, how they interact [10]. In terms of assessing QHFSS DNA Laboratory's conformance with ISO/IEC 17025:2017 this graphic will prove useful and, to some extent, will be relied upon.

However, to fully understand this assessment, a copy of ISO/IEC 17025:2017 should be referred to or, failing that, the sight of ISO's Online Browsing Platform for the Standard [11] might suffice.

2.2.2. ISO/IEC 17025:2017 clause 8 'management system requirements' – options A or B

The Standard offers two options for satisfying the management system requirements; A and B: Option A is documented in the Standard. It lists the minimum requirements for the implementation of a management system. Option B allows the adoption of the requirements of ISO 9001, described below. The conformity of the management system with the requirements of ISO 9001 does not demonstrate the technical competence of the facility. Adoption of only one of the options is required. Facilities that adopt Option A will generally operate in accordance with the principles of ISO 9001. Regardless of the option adopted, the management system must be able to support the consistent fulfilment of the general, structural, resource and process requirements of ISO/IEC 17025. In simple terms, the management system must broadly conform to ISO 9001.

As Option A is given as a minimum and is documented in the Standard, this will be the basis of the assessment of the operation and performance of QHFSS against ISO/IEC 17025.

2.3. ISO 9001 quality management systems – requirements

This is the quality management standard enabling conforming organisations to consistently provide products and services that meet customer (as broadly defined) needs. It employs the process approach which incorporates the plan-do-check-act (PDCA) cycle and risk-based thinking. As stated earlier, the latest edition of ISO/IEC 17025 requires an accredited organisation to broadly conform to ISO 9001.

2.4. ISO/IEC 17011 conformity assessment – requirements for accrediting bodies accrediting conformity assessment bodies

This is the standard with which accrediting bodies, such as NATA, must conform. Conformance is assessed by peer review conducted by other accrediting bodies. Once found to conform, a mutual recognition agreement (MRA) is entered into with the International Laboratory Accreditation Cooperation (ILAC) usually via a regional Cooperation such as the Asia Pacific Accreditation Cooperation (APAC). The MRA is required so that results and outputs from an accredited forensic science laboratory in one jurisdiction might be accepted in another.

A similar complicating factor to that concerning ISO/IEC 17025 affects consideration of this standard in the context of the CoI and the events covered. The latest edition of ISO/IEC 17011 was published in November 2017 and differs to some degree from the earlier 2004 edition.

It is important to note that §8.1.2 of the 2004 edition requires the accredited organisation to inform the accreditation body "without delay" of any significant changes and at §8.1.2 c) "main policies" is specified. This requirement is effectively replaced in the 2017 edition by the requirement for an accreditation agreement (§4.2) between the accrediting body and the accredited organisation. While "main policies" are no longer specified, the requirement to inform the accreditation body "without delay of significant changes" remains.

2.5. ISO 9000 quality management systems – fundamentals and vocabulary

As the title implies, this International Standard describes the fundamental concepts and principles of quality management. In addition, it specifies the terms and definitions that apply to all quality management and quality management system standards.

Perhaps the most important term in the context of this paper is 'quality'. This standard makes clear what ISO and IEC mean by 'quality'. It also emphasises a holistic approach to quality management in which no individual concept or principle is considered more important than any other.

This standard provides a broad definition of 'quality'. It is determined by the ability to satisfy the needs of stakeholders, in this case the criminal justice system, together with the value and benefit to the stakeholders of the organisation's services.

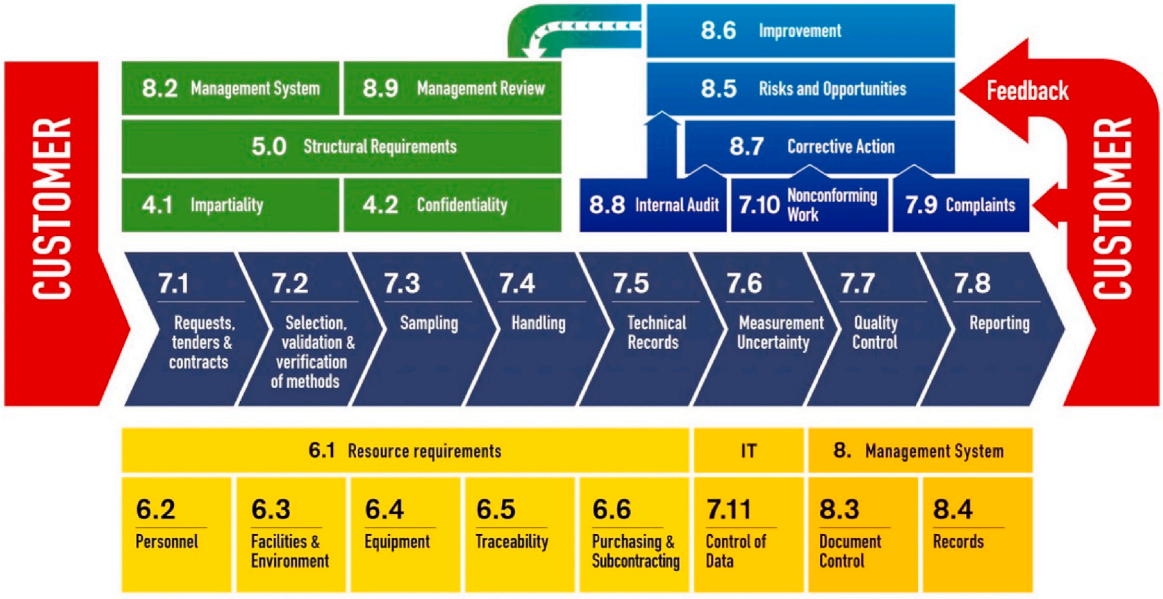

Fig. 1. ISO/IEC17025:2017 'workflow'.

To quote from this standard.

"An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties." (§2.2.1)

Put simply, quality is the degree to which stakeholder requirements are met (§3.6.2).

In the context of the matters at issue in this paper, the requirement is for scientific evidence of sufficient quality as might be relied upon by the criminal justice system to reach a safe decision by a fair process, i.e., minimize the risk of a miscarriage of justice – the guilty going free or the conviction of the innocent.

This Standard also defines 'validation' (§3.8.13) and makes clear that meeting stakeholder needs is part of validation.

2.6. ISO 19011 guidelines for auditing management systems

This document provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits.

It applies to all organisations that need to plan and conduct internal or external audits of management systems or manage an audit programme.

ISO/IEC 17025:2017 at §8.8.2 refers to this document as "providing guidance for internal audits."

There are effectively two layers of documentation, one is the documented QMS of the laboratory and the second is the Standard. So, in auditing the QMS the main audit criterion is; do the laboratory's activities conform to its documented QMS i.e., its Standard Operating Procedures (SOP) secondly does the documented QMS conform to the Standard? These two requirements of the audit process are stated in §8.8.1 of ISO/IEC 17025:2017.

3. The Australian forensic science industry – the ecosystem

3.1. Introduction

In the context of this assessment, it is of relevance to have an understating of the forensic science 'ecosystem', the environment, as it were, in which the loss of confidence and the establishment of the CoI took place.

Australia has a highly interrelated, multi-agency framework which collectively supports the quality of forensic science provision in the jurisdictions of the nation. These agencies are.

- ANZFEC – Australia New Zealand Forensic Executive Committee
- ANZFSS – Australia and New Zealand Forensic Science Society
- ANZPAA/NIFS – Australia and New Zealand Police Advisory Agency/National Institute of Forensic Science and its discipline-specific Specialist Advisory Groups (SAGs)
- NATA – National Association of Testing Authorities
- SA – Standards Australia
- Australian academic institutions

It is the case that many of the same individuals exercise duties and responsibilities or are otherwise engaged in more than one of these organisations. This adds to the degree of interrelatedness; one of the consequences of which is that none of these agencies are fully independent, and, to some degree, this promotes and supports a uniform forensic science culture within Australia.

It should be noted in passing that the secretariat of International Laboratory Accreditation Cooperation (ILAC) a body that, among other things, is responsible for ensuring the consistent operation of accreditation bodies through Mutual Recognition Agreements, as discussed earlier at §1.4, is based in New South Wales, Australia. In addition, Australia currently (June 2023) holds the chair, through Standards Australia of ISO Technical Committee 272 'Forensic Science' developing international standards applicable to forensic science.

3.2. ANZFEC Australia New Zealand forensic executive committee

ANZFEC comprises the ANZPAA Chief Executive Officer, NIFS Director and senior representatives of all forensic science providers and police forces in Australia and New Zealand, including the Queensland Police and Government. ANZFEC oversees and funds ANZPAA/NIFS. According to its promotional material, ANZFEC members

"… share a desire to work across jurisdictions to deliver high quality and operationally relevant forensic science service to police, the criminal justice system, victims of crime and the community." [12].

Ms Lara Keller, acting Executive Director of QHFSS at the time concerns about the DNA Laboratory were being raised, was a recent ANZFEC member [13].

Among its responsibilities is to manage the Specialist Advisory Groups (SAG). According to ANZPAA/NIFS, SAGs provide an important mechanism for ANZFEC and ANZPAA/NIFS to support and promote the continuous improvement of forensic disciplines, encouraging collaboration and innovative thinking.

Among the SAGs is the Biology SAG, which includes the discipline of DNA analysis and interpretation, and another focuses on Quality. The latest edition of the ANZPAA/NIFS Newsletter 'The Forensic Exhibit' (Vol 6 #1) reports a DNA interpretation workshop held in response to the CoI on DNA interpretation. In attendance were representatives of QHFSS (Ms Kylie Rika, QHFSS Host) Forensic Science SA, PathWest Laboratory Medicine WA and Victoria Police Forensic Services. That newsletter also reports a meeting of the Quality SAG which also considered issues raised by the CoI and, among other things, concluded that conformance with ISO/IEC 17025 was a minimum standard.

For reasons given below in the section on NATA at §2.5, most, if not all, ANZFEC members will be members of NATA.

3.3. ANZFSS Australia and New Zealand forensic science society

The Australia and New Zealand Forensic Science Society through its branches, its biennial international symposium (the latest edition was delivered by the Queensland branch of the Society in September 2022 with the aid of QHFSS), and its Code of Professional Practice, is part of the framework supporting the quality of forensic science in Australia as it states.

"Our objectives are to enhance the quality of forensic science through our international symposium and the events and meetings by each branch about forensic science." [14].

The ANZFSS Code of Professional Practice was adopted in September 2014 (updating a previous code) and binds all ANZFSS members. The Code documents the ethical responsibilities of members.

Section 2.1 of the Code is perhaps particularly relevant.

"2.1 Act truthfully, objectively, and not mislead people, nor engage in misrepresentation, including through omission. Forensic practitioners must act truthfully and objectively, and not knowingly provide misleading information, statements, reports, opinions or evidence, nor knowingly misrepresent a situation."

The CoI report makes clear that staff in the QHFSS DNA Laboratory knowingly breached the Code by issuing inaccurate and inadequate reports [1598ff p489/502ff].

The ANZFSS President, or nominee, sits on the forensic science subcommittee of Standards Australia.

According to its promotional material the Queensland branch

> "… are passionate about the continued advancement of forensic science, and encourage the involvement and development of new practitioners and students. We recognise the continued excellence of our branch members …" [15].

3.4. ANZPAA/NIFS Australia and New Zealand police advisory agency/ national institute of forensic science

Operating under a Service Level Agreement, ANZPAA/NIFS is a directorate within ANZPAA and is guided by the Australia New Zealand Forensic Executive Committee (ANZFEC). ANZFEC members help shape the NIFS three-year strategic plan and approve its annual business plan. The ANZPAA Board approve the final strategic plan and program budget, ensuring the work of ANZPAA/NIFS complements the broader policing landscape [16].

ANZPAA/NIFS maintains strategic partnerships with policing and other law enforcement agencies, standards agencies, accreditation organisations, academia, the judiciary, and the international forensic community [17]. It is therefore a labyrinthine organisation with reach into almost every aspect of forensic science within Australia and beyond. Its *raison d'etre* is perhaps best summed as.

> "NIFS was intended and has operated to provide a form of connective tissue, linking the many different components of a multi-jurisdictional system vulnerable to fragmentation and aiding the development and maintenance of proper standards of quality." **The Honourable Frank Vincent AO QC** Independent Review of The National Institute of Forensic Science (July 2014).

The purpose of "aiding the development and maintenance of proper standards of quality." in the context of this assessment is perhaps the most important.

Its stated strategic intent is to.

> "Deliver high quality and innovative products, services, and advice to enhance capability, efficiency, and reliability of the forensic sciences for police, justice, and the community." [18].

According to the CoI Report at 477 p147/161.

> "ANZPAA NIFS is considered the peak[6] body for forensic science in Australia and New Zealand. ANZPAA NIFS has established Specialist Advisory Groups which meet and aim to support and promote the continuous improvement of forensic disciplines, encouraging collaboration and innovative thinking."

3.5. NATA National Association of Testing Authorities

NATA is Australia's main accreditation body. It accredits most, if not all, Australian forensic science providers to the International Standard ISO/IEC 17025. It also offers an appendix to the Standard entitled 'Specific Accreditation Criteria' which provides guidance for forensic science laboratories.

NATA is a not-for-profit organisation owned by its members which are the organisations accredited by NATA. It is governed by a board of directors appointed by the membership [19]. QHFSS will be a member of NATA. Having accredited organisations as members of NATA may call into question its requirement to be a third-party or independent accreditation body.

According to NATA, its accreditation programs are administered, under the board's direction, by Accreditation Advisory Committees (AACs). Each AAC provides support for defined conformity assessment activities, such as forensic science, covered by the various accreditation programs and/or for specific industries which, in the case of forensic science, is 'The Forensic Science Accreditation Advisory Committee.'

The primary role of an AAC is to provide advice and recommendations for the associated area/activity of accreditation [20].

AACs may be asked to:

- Review assessment reports and recommend to NATA's Board the granting, extension or changes to the accreditation status of organisations.
- Approve new technical assessors.
- Develop and review criteria specific to the work carried out by accredited organisations in the particular area of accreditation.
- Provide guidance on the interpretation of the criteria included in the relevant Standard used for accreditation.
- Support assessors and assist in their technical training as necessary.
- Keep NATA abreast of technical developments and strategic issues in industry.
- Act as a liaison between NATA and relevant industry and professional societies
- Identify proficiency testing (PT)[7] needs in order to promote the availability of relevant PT programs.
- Identify potential new areas of accreditation.

ANZPAA/NIFS "partners" NATA through the Forensic Science ACC in developing the "forensic science accreditation program." [21].

Third-party or external audits are conducted by NATA assessment teams. According to NATA, the assessment team is comprised of at least one NATA lead assessor and one or more specialist volunteer technical assessors who are subject matter experts. A review of the management system is essentially conducted by the NATA lead assessor while the technical assessors concentrate on the technical activities performed by the accredited organisation. The size of the assessment team is generally dependent upon the scope of accreditation [22].

It is clear from this description that both the management system and technical activities of the organisation are the subject of external, third-party, independent audit.

3.6. SA standards Australia

Standards Australia is an SDO and is recognised through a Memorandum of Understanding with the Australian government as the primary non-government standards development body in Australia. It is a company limited by guarantee. It is the ISO and IEC representative in Australia and specialises in the development and adoption of internationally aligned standards in Australia [23].

ANZPAA/NIFS has worked with Standards Australia in the development of several national forensic science standards now offered by NATA as a supplement to ISO/IEC 17025, specifically the AS5388 series mentioned later in §6.3 [24,25]. In addition, as stated earlier, the ANZFSS President or nominee sits on the forensic science sub-committee of Standards Australia.

3.7. Academia

Australian academia has taken and continues to take an active role in shaping the future of forensic science [26] and its management [27,28].

3.8. Summary

In summary, there is in Australia a network of interrelated organisations. This network provides a framework supporting the quality and reliability of scientific evidence delivered to the justice system by

[6] 'Peak' is a particularly Australian term which means representing, coordinating, and advocating.

[7] Monitoring laboratory performance using proficiency testing is a requirement of ISO/IEC 17025:2017 §7.7 Ensuring the validity of results.

forensic science laboratories.

With this framework in place, together with such a degree of interrelatedness and a wealth of relevant expertise and experience on offer to assure the quality of forensic science in Australia, it is difficult to understand how an Australian forensic science provider could continuously, over many years, have been so poorly managed and operated and provide sub-optimal outputs and unreliable evidence as detailed at length in the CoI report. However, the very degree of interrelatedness and resulting lack of true independence may have generated conflicts of interest which led to a less rigorous approach to quality management.

4. The causes

4.1. Introduction

There were two main contributors to the loss of confidence in the DNA Laboratory and the establishment of the CoI; concerns about the role of the laboratory in the investigation of the unlawful killing of Shandee Blackburn, which were raised from late 2021 onwards, and the introduction in 2018 of a policy regarding quantitative thresholds for further DNA analysis by the management of the QHFSS DNA Laboratory. This policy resulted in the Queensland Police Service in May 2022 to publicly announce that it had lost confidence in the QHFSS DNA Laboratory.

4.2. The murder of Shandee Blackburn

To quote the CoI report.

> "It is an extraordinary aspect of the work of this Commission that the murder of a young woman on the streets of Mackay in 2013 has played such a pivotal role in the exposure of the failings of the state-run DNA laboratory." [1313 p409/423]

In the state of Queensland in the town of Mackay on the 9th of February 2013, 23-year-old Shandee Blackburn was brutally stabbed to death while on her way home from work shortly after midnight. She was stabbed 23 times by an assailant who, given the brutality of the attack, was thought by investigators to have been under the influence of an amphetamine-type stimulant [29].

On the 4th of September 2014, Shandee's ex-boyfriend John Peros was arrested and charged with her murder. After delays in proceedings and after a trial in the Supreme Court before a judge and jury, Peros was found not guilty of murder on the 7th of April 2017. Despite there being circumstantial evidence linking Peros to the murder there was no physical evidence, including DNA evidence, that linked him directly to the crime.

In August 2020 a coronial inquest found that there was sufficient evidence to conclude that Peros killed Shandee and that no other conclusion was possible. Queensland's double jeopardy law prevents a retrial.

In November 2021 forensic biologist Dr Kirsty Wright who had reviewed files from the investigation of Shandee's murder called the forensic investigation a "train wreck" citing one example in which a sample of "fresh" blood recovered from the murder scene did not return a DNA profile [30]. Dr Wright's findings not only raised doubts about the quality and reliability of DNA evidence in the case of Shandee's murder and how it compromised the police investigation but also about other cases in which a miscarriage of justice might have occurred.

Dr Wright was supporting investigative journalist Hedley Thomas, of The Australian, who was investigating the murder of Shandee as recorded in a podcast 'Shandee's Story'. This podcast, among other things, sought to highlight concerns about the quality and reliability of evidence produced by the QHFSS DNA Laboratory and bring those concerns to the attention of the public and relevant authorities.

4.3. Analysis thresholds

In the late 2010s beyond the gaze of politicians and the public, an issue was developing between the Queensland Police Service and the QHFSS DNA Laboratory. The complexities of this issue and its consequences are discussed in detail in the CoI report which devotes the whole of section 4 to the matter beginning with the "Options Paper" in 4.1. Some of that detail is recorded later in this paper, suffice it to note here that in 2018 the management of the Laboratory wished to introduce a DNA concentration limit below which DNA samples would not be further processed. Such samples would be reported as 'DNA Insufficient for Further Processing' or DIFP. The consequences of this would include reducing the workload and thereby improving some of the performance metrics of the Laboratory.

While it is a different standard and as such beyond the scope of the CoI, the potential impact of ISO/IEC 17011 must be considered. As stated earlier in the introduction to ISO/IEC 17011 (§1.4), the accreditation agreement between NATA and the DNA Laboratory required by ISO/IEC 17011:2017 (§4.2), an agreement that must be legally enforceable, requires the accredited organisation to inform the accreditation body "without delay" of any significant changes. It could be argued that the change in thresholds was such a change and should have been reported to NATA at the time.

5. Structure and line management within the QHFSS DNA laboratory

5.1. Introduction

To better understand the non-conformities identified in this assessment based on the CoI report and discussed in this paper, a knowledge of the management structure and complement of the DNA Laboratory is required.

5.2. Hierarchy

This graphic (Fig. 2) is based on one in the CoI report [166 p33/47].

5.3. Complement/roles and responsibilities

According to the CoI graphic the total complement of the QHFSS DNA Laboratory was 71, formed into two teams 'Evidence Recovery and Quality' (total 41) and 'Forensic Reporting and Intelligence' (total 24) plus administrative support. The Laboratory was headed by the Managing Scientist who reported to an Executive Director. QHFSS also had a Quality Manager whose responsibility extended across the entire organisation.

Of particular note in the context of this paper is that one of the teams has responsibility for quality and includes the designated roles of 'Forensic Scientist Advanced Quality …' and one of the team members is designated 'Quality Scientist' [166 p33/47].

5.4. Management

The management team comprised the Managing Scientist, the two Team Leaders and staff immediately below the Team Leaders in the hierarchy. Thus, the management team comprised a total of nine individuals. According to the designated roles, one member of the management team would appear to have some responsibility for quality.

While not the subject of this paper the following are noted in passing. The management structure is hierarchical rather than flat. A flat management structure has many benefits including better communications and faster decision making [31]. Having a management team of nine for a compliment of 71 seems excessive. It dissipates responsibility more widely which weakens the sense of responsibility felt by each member of the team. Trying to reach a consensus is an admirable aim but can result

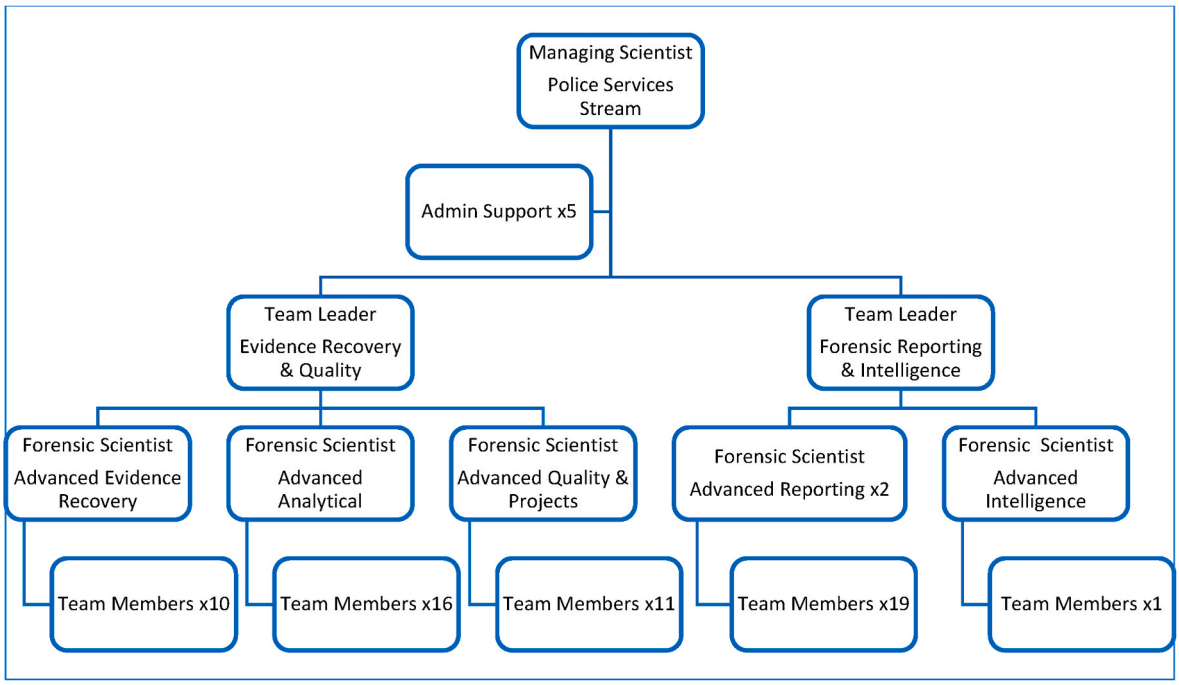

Fig. 2. QHFSS DNA laboratory team chart.

in no action or delay when decisive and timely action is required. These points are made in paragraph 431 p133/147 of the CoI report. Finally, the position of Managing Scientist as described in paragraphs 484 p149/163 to 503 p154/168 of the CoI exposes typical misaligned incentives and misunderstood objectives that often contribute to adverse organisational outcomes [32].

The episodes with the introduction of PowerPlex21 (a more sensitive DNA profiling kit) [1333 p412/428ff] and STRmix™ (probabilistic genotyping software) [1345 p417/431ff] by the deadline of the end of 2012 are good examples of certain performance metrics outweighing the need for quality. Meeting that deadline involved the apparent cutting of corners and implementing a less-than-optimal method resulting in the potential loss of probative evidence to the criminal justice system (CJS) [1355–1356 p419-420/433–434]. Prioritising incorrect metrics is a consequence of misunderstood objectives.

6. Introduction to and initial comments on the COI report

The CoI report is structured in nine sections plus an executive summary and appendices, having a total of 520 pages. To give an idea of the scope of the report the section headings are listed below.

1. The past, present and future of forensic DNA analysis in Queensland
2. Current operations of the laboratory
3. Collection of biological material for forensic DNA testing
4. Testing thresholds and the "options paper"
5. Technical issues at the laboratory and their resolution
6. DNA evidence in the case of Shandee Blackburn
7. Laboratory culture
8. Engagement with stakeholders
9. Governance and future

The CoI identified numerous serious failings revealed by several episodes in the history of the QHFSS DNA Laboratory, the main ones being.

- Setting a high DNA concentration threshold below which samples would not be tested. This reduced the number of samples that would be tested - addressed in section 4.
- Over-long, four-year investigation into an issue with the detection of spermatozoa in semen samples - addressed in 5, and
- Quality issues that arose in the Shandee Blackburn case - addressed in 6.

A paramount requirement identified by the CoI is for 'scientific integrity' this is discussed later in §6.6. In addition, there is the requirement for 'best practice' and 'scientific excellence'.

According to Voltaire (1694–1778), quoting an Italian aphorism, "the best is the enemy of the good" *(il meglio è nemico del bene)*. Striving for the 'best' and 'excellence' risks failing to achieve the 'good'. In addition, an effective quality management system relies on an ethos or culture of continuous improvement. There must be acceptance by an organisation conforming to an International Standard, such as ISO/IEC 17025, that there is always room for improvement. This is the advantage conformance to an International Standard has over somewhat hard-to-define aims like 'best practice' and 'excellence'; conformance assures the competence of the laboratory, the competence of its staff and the validity of the results it generates. Furthermore, conformance requires that stakeholder requirements are accurately captured and properly met. In this case, the main stakeholders are the Queensland Police Service and the justice system.

To state the obvious and for the avoidance of doubt, an organisation that is not competently managed employs personnel in positions of authority that lack the necessary competencies to meet stakeholder needs and does not generate results of sufficient quality to be relied upon by those stakeholders is not conforming with ISO/IEC 17025.

It will be demonstrated in this paper that while QHFSS DNA Laboratory might have been accredited to the standard ISO/IEC 17025:2017 it did not conform to that standard. Had it done so, then the loss of confidence that led to the establishment of the CoI might not have occurred.

7. The main findings of the CoI regarding ISO/IEC 17025:2017 conformance and weaknesses in accreditation

7.1. Non-conformities identified by the CoI

Before detailing the weaknesses in accreditation identified by the CoI and its witnesses, it is first right and proper to record that the CoI identified some non-conformances against NATA's Specific Accreditation Criteria for ISO/IEC 17025 as follows.

> "[T]he laboratory's procedure in relation to extraction negative controls does not comply with ISO 17025 Specific Accreditation Criteria section 7.7.1" [294 p79/93]. §7.7 of the Standard covers ensuring the validity of results.

> "[T]he laboratory has failed to comply with ISO 17025 Specific Accreditation Criteria section 6.3.4 by failing to sufficiently record access to the Forensic DNA Unit or Property Point" [297 p80/94]. Section 6.3 of the standard specifies the requirements for facilities and environmental conditions.

However, the broad conclusion reached by the CoI is that.

> "… the current NATA assessment, against ISO 17025 alone, is not sufficient external review for a forensic service provider and does not guarantee the scientific integrity of the work of an organisation." [464 p144/158]

If the phrase "against ISO 17025 alone" is removed, then that conclusion is supported by this assessment. Interestingly the conclusion suggests "NATA assessment" may contribute to the perceived weakness in ISO/IEC 17025 accreditation. This might hint that the Commission may have realised the distinction between accreditation and conformance.

In addition to appearing here, the requirement for "scientific integrity" occurs elsewhere and often in the CoI report. It seems clear that the need for scientific integrity is considered paramount in the minds of the authors. Unfortunately, the term is not defined in the report.[8] 'Scientific integrity' is discussed later in §6.6 of this paper.

It must be recognised and accepted that no human-devised system provides complete protection against human error or bad actors. However, embracing an ethos of continuous improvement, a fundamental requirement of quality standards, and not treating accreditation as a mere tick-box exercise can significantly reduce the risks.

7.2. Weaknesses in 17025 accreditation identified by the CoI

Turning now to specific criticism and perceived weakness in ISO/IEC 17025 accreditation. These are mostly found in paragraph 459 p142/156 and following under the heading 'NATA accreditation' and are listed below.

- ISO/IEC 17025 is a generic standard and not specifically written for forensic science laboratories.
- It cannot be applied to the 'non-analytical' phases of DNA analysis [460 p143/156] including.
  - o reporting and interpretation[9] where DNA "technology" such as STRmix™[10] is used
  - o subjective analysis
  - o judgement calls
  - o careful communication
- It does not consider the integrity of the forensic science aspects of the laboratory [461 p143/157]
- NATA is not looking at how decisions are being made. This is particularly so in relation to 'policy decisions' such as setting threshold levels.
- It does not guarantee the scientific integrity of the work of an organisation.

In addition, Dr Wright in her review [33] additionally claims that.

> "… professional conduct, outputs, success rates and the technical suitability of standard operational procedures and internal validation studies are not assessed."

And that there are

> "… growing concerns among the forensic community in Australia that current accreditation standards are not sufficient to ensure quality outputs are being delivered to the police and courts."

And that the gaps provide

> "… an environment for poor quality and corrupt conduct to become entrenched in an organisation's culture."

These criticisms of ISO/IEC 17025 might be summarised as; the standard is insufficient in scope to cover all the activities and processes that contribute to forensic outputs and assure their quality that they might be relied upon by the QPS, and the broader criminal justice system.

7.3. ISO/IEC 17025 is a generic standard and not specifically written for forensic science laboratories

ISO/IEC 17025 is indeed a generic standard for testing and calibration laboratories. As an International Standard, it cannot be anything other. It is for particular sectors/industries to develop and document guidance on conformance. ISO/IEC specifies the requirements or the 'what' and guidance is produced to facilitate conformance or the 'how'. Nevertheless, in the absence of specific guidance and based on conformance with earlier standards [34], forensic science laboratories, from the publication of the first edition in 1999, have been accredited to the Standard as a means of assuring confidence in forensic science provision and its support for justice systems. ILAC, the Secretariat of which is based in NSW, Australia, produced the first guidance document for forensic science laboratories in 2002 [35]. ILAC has published other guides since then, the current edition being ILAC-G19:06/2022 – 'Modules in a Forensic Science Process'. The Australian Standards AS5388 1–4 are procedural standards specifying at length and in detail how a forensic science provider might conform to ISO/IEC 17025, bearing in mind that there would be alternatives. In England & Wales, the Forensic Science Regulator continues to develop and publish guidance for particular evidence types, e.g., DNA analysis [36]. Therefore, while it is true that ISO/IEC 17025 is a generic standard, guidance on how a forensic science laboratory might conform to the Standard has

[8] Scientific integrity may be considered as a condition resulting from adherence to professional values and practices when conducting, reporting, and applying the results of scientific activities that ensures objectivity, clarity, and reproducibility, and that provides insulation from bias, fabrication, falsification, plagiarism, inappropriate influence, political interference, censorship, and inadequate procedural and information security. All requirements of an effective Quality Management System, as echoed by 481 p148/162.

[9] Accreditation is available for interpretation, e.g., Ref. [56].

[10] STRmix™ is expert forensic software that can resolve previously unresolvable complex mixed DNA profiles using probabilistic genotyping. The software generates candidate profiles which might explain the questioned profile and assigns likelihood ratios to find the best fit to a reference profile.

been available for over 20 years and that guidance has continued to develop over that period.

7.4. It cannot be applied to the 'non-analytical' phases of DNA analysis

The probabilistic genotyping software marketed as STRmix™ has been in use by laboratories accredited to ISO/IEC 17025 since 2012 [37]. The STRmix™ 'technology' has been validated to some extent in numerous jurisdictions e.g., Refs. [37,38]. In addition, given the requirement of the Standard, procedures involving STRmix™ would be included in the scope of the accreditation granted. However, the product of STRmix™ is a numerical value and the scope for subjective interpretation of this value is limited, a number is generated and equates to a verbal scale expressing a degree of support for a specified proposition. Nevertheless, recognising those challenges there is no clear or obvious reason why procedures involving STRmix™ would be excluded from the scope of accreditation. It must be possible to document a procedure for interpretation of the STRmix™ results even if that might include "subjective analysis" or "judgement calls".

Communicating the outputs for STRmix™ can be a challenge [39,40]. However, that is a staff training and development issue. The Standard specifically requires staff to be competent. Nevertheless, staff competence is a known area of weakness [41] in that responsibility for the competence of the individual rests with the organisation. According to the Standard, it is for the organisation to deem staff as competent (§6.2.6 and §6.2.5).

7.5. NATA is not looking at how decisions are being made

NATA auditors should be looking at how decisions are made. The record of management reviews required by §8.9 of the Standard will be one of the main sources of evidence for external audits. Section 8.9.2 of the Standard requires a review of changes that are relevant to the laboratory and the suitability of policies.

In addition, as reported earlier in §1.4 and mentioned in §3.3, there is an implicit requirement in ISO/IEC 17011:2017 (§4.2 i) that significant policy changes should be communicated to the accreditation body as part of the accreditation agreement. The CoI report is silent on this issue. If the analysis threshold policy change had been reported to NATA, as it should have been under the accreditation agreement required by ISO/IEC 17011:2017, and had NATA acted then that policy may never have been put into effect.

7.6. It does not consider nor guarantee the scientific integrity of the organisation or the outputs

The requirement for scientific integrity is clearly among the most important for the authors of the report. The term "scientific integrity" is mentioned 18 times in the CoI report without an explanation as to what is meant by the term.

ISO/IEC 17025:2017 ensures the validity of results or outputs by conformance with clause 7 of the Standard. In particular by means of method verification and validation, as defined in ISO9000:2015, and meeting the requirements of §7.7; particularly interlaboratory comparisons (§7.7.1 j), blind testing (k) and proficiency testing (§7.7.2 a). However, for their effectiveness, these measures depend on the integrity (and competence) of the individuals that constitute the organisation.

The normal meaning of 'integrity' is the quality of being honest and having strong moral principles, qualities that more clearly apply to individuals who nevertheless give expression to organisational values. One place that might be looked to provide a relevant definition is the European Code of Conduct for Research Integrity, published in 2011 and revised in 2017. The concept of scientific integrity is developed along four main lines.

- Reliability: concerns the quality and reproducibility of research.
- Honesty: concerns the transparency and objectivity of research.
- Respect: for the human, cultural and ecological environment of research.
- Accountability: concerns the implications of publishing the research.

As ISO/IEC 17025 is a standard for an organisation it says little about the required behaviours of individuals, the main requirement is for staff to be impartial and competent, and this is assured through conformance with §6.2.1 and §6.2.5 by determining the competence requirements; and application through;

- selection,
- training,
- supervision,
- authorization, and
- monitoring competence.

So, it would be up to the organisation to specify the need for honesty and strong moral principles as part of the competency requirements for QHFSS staff members and have effective measures in place to monitor conformance.

The ethical requirements for individual forensic scientists are perhaps best expressed in the ANZFSS Code of Professional Conduct introduced earlier at §2.3. Any forensic scientist at the DNA Laboratory who was a member of the ANZFSS would be bound by that code. As stated earlier, Section 2.1 is of particular relevance.

> "2.1 Act truthfully, objectively, and not mislead people, nor engage in misrepresentation, including through omission. Forensic practitioners must act truthfully and objectively, and not knowingly provide misleading information, statements, reports, opinions or evidence, nor knowingly misrepresent a situation."

Forensic scientists in the USA and UK are bound by similar codes. However, the existence of such codes does not mean that they are effectively policed or enforced with sanctions.

These codes are in addition to any jurisdictional practice direction which would reinforce the need for honesty and transparency, among other ethical requirements, of expert witnesses.

In England & Wales (E&W) in response to several miscarriages of justice and by the will of parliament, the Council for the Registration of Forensic Practice (CRFP) was established in 1999 to restore and maintain public confidence in forensic science. Among its first actions was to draw up a code of conduct for forensic scientists which is closely similar to that of the Forensic Science Regulator's current code [42]. That code includes the following requirements.

- Recognise that your overriding duty is to the court and to the administration of justice.
- Act with honesty, integrity, objectivity and impartiality.
- Declare, at the earliest opportunity, any personal, business, financial and/or other interest that could be perceived as a potential conflict of interest.

A means of policing and enforcing the requirements for these ethical principles was adopted by some UK-based forensic science laboratories. This was achieved by including the code in the documented management system of the forensic science laboratory conforming to ISO/IEC 17025:1999. Thus, adherence to the code was monitored as a part of the external and internal audit plan [43].

Therefore, rather than 'accreditation' to AS5388 (Rec 65 [497 p145/159]), standards which say little about scientific integrity and are procedural which will shift the focus further in the direction of technical competence rather than on management, where most of the non-conformities lie, a higher priority might be to include the ANZFSS Code in the organisation's QMS and leave it to the audit program to monitor conformance. Implementing this measure could be a major step

towards assuring the scientific integrity required by the CoI.

It should be noted in passing that the AS5388 series is lengthy and contains much procedural detail. Conformance would place an additional burden in terms of costs and effort on both first and third-party auditors. In addition, given the findings and observations of the CoI and this paper regarding non-conformities against ISO/IEC 17025:2017, the current implementation of recommendation 65 – to broaden the scope of accreditation to include the AS5388 series - may be a bridge too far!

8. ISO/IEC 17025:2017 non-conformities revealed by the CoI

8.1. Introduction

The CoI report records numerous non-conformities with the Standard. To list and comment on each one would significantly add to the length of this paper and is unnecessary to support the main thesis; that conformance with the Standard is sufficient to ensure the quality and reliability of scientific evidence and consequently to significantly reduce, or even avoid, the risk of the loss of confidence in QHFSS DNA Laboratory that led to the CoI.

Therefore, not every non-conformity is recorded and commented upon only sufficient to demonstrate the depth and the breadth of those non-conformities which clearly establish that the operation and performance of the DNA Laboratory fell well short of the requirements of ISO/IEC 17025:2017.

Many of the non-conformities identified relate to the 'Options Paper' and setting DNA concentration thresholds which are covered in Section 4 and pages 240/254 to 351/366 of the CoI report. In essence, the CoI concluded that the genesis of the 'Options Paper' and the framing of the options presented was deliberately engineered to produce an outcome that permitted a quantitative DNA threshold to be set at such a level as to deny the justice system probative evidence in pursuit of a reduced workload and better performance metrics. The CoI found that the Managing Scientist was primarily responsible for the deception that led to that outcome. Consequently, many of the non-conformities are in the categories of competencies and behaviours.

8.2. Competencies

Under §6.2 'Personnel' the Standard requires the DNA Laboratory (or any Conformity Assessment Body) to document the competence requirements for each function and to ensure all staff have the necessary competencies, including behavioural competencies, to perform the activities for which they are responsible. In addition, according to §6.2.5, the Laboratory must have procedures in place and retain records for determining competence requirements and taking account of those requirements; staff selection, training, supervision, authorising and monitoring competence.

It is important to note that QHFSS has five separate accreditations by NATA under both ISO/IEC 17025 and ISO/IEC 15189 'Medical laboratories – Requirement for quality and competence' for the activity of human pathology. Therefore, most of the activities of QHFSS were accredited by NATA and not just the DNA Laboratory.

The CoI revealed no record of the procedure(s) or retained records required by §6.2.5. Their absence might go some way to explaining why certain staff lacked that which might be considered essential knowledge to fulfil their function as evidenced numerous times; for example in 516 p156/172 to 531 p162/176, 1002 p315/329, 1016 p319/333 to 1019 p321/335, 1025 p323/337, and in 1078–9 p343/357, 1038 p327/341, 1049 p333/347 1476 p450/464 and 1056 p335/349 of the CoI report in terms of line management.

The role of the QHFSS Quality Manager (QM) is recorded in paragraphs 395 p121/135 to 398 p122/136. Based on the CoI report it is hard to discern what in practice the QM's duties and responsibilities were concerning quality management despite giving evidence to the effect that she must " … ensure each laboratory complies with … accreditation …" [396 p121/135]. According to the CoI report the QM was able to do no such thing with regards to the DNA Laboratory. The lack of what might be considered essential knowledge for the role and its consequences are highlighted in the CoI report in paragraphs 399 p122/136 to 401 p123/137. Furthermore, there are examples of when the QM was acting as the Managing Scientist's line manager, at which time the QM's knowledge and experience of quality did not appear to be sufficient, for example, 1056 p335/349, 1060 p337/351, 1062 p338/352 and 1065 p338/352. Finally, even if the QM lacked the necessary technical competencies, she should have been able to determine whether the DNA Laboratory was conforming to the management requirements of the Standard, which apply to all the accredited activities of QHFSS.

It seems clear that the DNA Laboratory does not meet the requirements specified in §6.2 'Personnel' of the Standard.

Having responsibility for maintaining accreditation and with 16 years of experience, the QM would have known that to conform with ISO/IEC 17025 each QHFSS accredited laboratory, including the DNA Laboratory, would need staff who, irrespective of other responsibilities, would have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities (§5.6 a-e of the Standard).

The absence of such staff is a non-conformance against the structural requirements of the Standard set out in §5.0. This non-conformance will be referred to later in §7.5 of this paper. In simple terms then, some named individual or individuals must be assigned the duties a) to e) listed above and must have the resources and authority necessary to discharge those duties effectively.

In her evidence to the CoI, the Managing Scientist claimed that her line managers "… did not necessarily understand the forensic services." [489 p151/165]. In addition, the CoI report acknowledges that as a result of a lack of competence, there was little effective oversight of the work of the DNA Laboratory [516 p158/172]. Had the Managing Scientist's line managers had the competencies to effectively manage, monitor and assess performance then she may not have been able to mislead them and others to such a damaging extent. In addition, had the QM had the competencies to fully understand even the management requirements of the Standard then the quality failures resulting from non-conformance with the Standard might have been avoided.

8.3. Behaviours

Recalling the earlier quote from ISO 9000:2015.

> "An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties." (§2.2.1)

The only behaviours specified in the Standard are §4.1 Impartiality and §4.2 Confidentiality. Confidentiality, or lack of it, does not seem to have been an issue contributing to the events which led to the establishment of the CoI. However, impartiality or the lack it of did.

Among the other terms that convey the meaning of impartiality, the Standard offers "freedom from bias". The peer review process in which scientists selected reviewers was identified by the CoI at 440–441 p136/

151 as a potentially biasing behaviour. In addition, the CoI reported an example of the lack of impartiality of the Managing Scientist at 1242–1244 p386/400. The Managing Scientist had distorted an external review of the DNA Laboratory's microscopic examination of spermatozoa to engineer a particular outcome.

While there is no suggestion of impropriety, the relationship[11] between the Managing Scientist and Acting Inspector, Forensic Technology Coordinator could be seen as potentially conflicting. That police officer was involved in the initial decision to accept the higher DNA analysis threshold to cut down the workload [828–831 p265-266/279–280], and later a managing director of BDNA [44] which provided the DNA laboratory's information system the 'Forensic Register'. A conflicting relationship may be a non-conformance with the general requirement for impartiality in §4.1 of the Standard. The Standard states that "freedom from conflict of interest" is among the terms that convey the element of impartiality.

It might be argued that accreditation and conformance with International Standards cannot provide complete protection against quality failures caused by a bad actor with intent to deceive. While this must be true in some circumstances it is hard to advance that argument in this case where a whole raft of non-conformities and a lack of the required competencies also contributed to the adverse outcomes recorded in the CoI report.

The CoI report also records some general non-conforming behaviour. For example, an absence of the required culture of continuous improvement, evidenced by the response to complaints (§7.9) or nonconforming work (§7.10) which was to do nothing or if something had to be done then delay, e.g., 899 p284/298, 971–972 p306/320, 1022 p322/336, 1050 p333/347, 1087 p345/359, 1171 p368/382, 1182 p384/370, 1195 p374/388, 1341 p416/430, 1545 p468/482 and 1598 p488/502.

8.3.1. *Quality management of the QHFSS DNA laboratory*

The entire section of the CoI report on quality management in the laboratory [390 p120/134 to 414 p127/141] clearly demonstrates nonconformance with the structural requirements of the Standard (Clause 5), particularly §5.6. While not naming the person (or persons) assigned the duties set out in §5.6 of the Standard, as detailed earlier in §7.2, as a 'quality manager' these are nevertheless the duties of a quality manager. Failure to assign these duties and provide the necessary resources and authority to discharge those duties effectively is a non-conformance.

The second edition of the standard ISO/IEC 17025:2005 required the appointment of a quality manager "however named". So, in the years up to the implementation of the third edition of the standard ISO/IEC 17025:2017, which covers most of the period in question, QHFSS DNA Laboratory conforming to that second edition would have had a quality manager (however named) in place. While the third edition no longer required a nominated quality manager, retaining that role and assigning the duties in §5.6 of the third edition may have made quality management easier and more effective.

Since the adoption of quality standards by forensic science providers in the 1990s and given their complexity and conformance requirements, those with responsibility for quality management have required some specialist training to effectively discharge that responsibility. While it is true that all staff of a laboratory conforming to ISO/IEC 17025 have a responsibility for quality in the sense of conforming to the laboratory's quality management system (QMS) (documented procedures, policies, objectives and provisions), effective quality management requires individuals with the specialist knowledge to maintain conformity.

Given this is such a clear non-conformance with the Standard, it is surprising that no one informed the CoI that there should have been individual(s) within the DNA Laboratory assigned the duties of a 'quality manager' in accordance with §5.6 of the Standard.

8.4. *§7.1 and 7.8 and 7.9 relationships with key stakeholders*

There is a whole raft of non-conformities against Clause 7 'Process requirements' arising from the relationship with the Queensland Police Service (QPS) which is covered in the CoI report mainly in Section 8, paragraphs 1527 p464/478 to 1562 p473/487.

The quality issues arising out of the relationship with QPS and that with the wider CJS are better dealt with in the next section, in §8.2. Accurately capturing and meeting stakeholder needs is one of the principal requirements of the Standard.

8.5. *§7.10 nonconforming work*

§7.10 of the Standard concerns nonconforming work, which according to the CoI represents a significant amount of the DNA Laboratory's outputs e.g., Section 5.3 paragraphs 1160 p365/379 to 1230 p382/396 regarding issues with sperm microscopy. In addition, many of the incidents generating Opportunities for Quality Improvement (OQIs)[12] fall into the category of 'nonconforming work'. The Standard requires a documented procedure for implementation when any aspect of the laboratory's work "does not conform to its own procedures or the agreed requirements of the customer." §7.10.1 goes on to specify the requirements for that documented procedure.

Paragraph 419 p129/143 records "There is no formal procedure for which pathway to follow in what circumstances. The ''Procedure for Quality in Forensic DNA Analysis' does not provide a framework for when or how to progress a quality issue." Paragraph 424 p131/145 records that "There is no clear procedure for when to progress a project for a quality issue." The issues are summarised in paragraph 428 p132/146.

The lack of a documented procedure for nonconforming work as required by §7.10 and specified by §7.10.1 or indeed having one and not following it is a non-conformance with the Standard.

Part of the response to nonconforming work required by the Standard is cause analysis (§8.7.1), ideally root cause analysis (RCA), as recommended in paragraph 430 p132/146, followed by corrective action. As the preceding paragraphs demonstrate in its response to nonconforming work, the CoI found little or no evidence of RCA being conducted – the 'unintended human error'[13] often cited seems to be a trite 'get-out' to avoid a proper RCA. The absence of proper cause analysis in response to nonconforming work is a non-conformance with the Standard.

8.6. *§7.11 control of data and information management*

Paragraph 450 p140/154 records a lack of control of data which impacts the ability of the DNA Laboratory to effectively manage its activities and improve performance. Whether this is a non-conformance against §7.11 of the standard is not entirely clear as the requirement is "access to the data". However, as the access arrangements are a hindrance to effective management there must be a non-conformance with the Standard.

The Standard requires the external provider of the information system 'The Forensic Register' [171 p35/49] to conform to §7.11.

[11] See podcast 'Shandee's Legacy' Episode 6: Disney Villain at 1:31 https://www.theaustralian.com.au/nation/shandees-legacy-episode-6-disney-villain/audio/befa367f745f1d337a10ce034789758e.

[12] According to p212 of 1500 EXH 171a OQI's are the Queensland Health's equivalent of non-conformances and corrective actions – this is confusing terminology and not consistent with the Standard. The term 'opportunity' suggests an optional response whereas the Standard mandates a corrective action.

[13] It may be of importance to note the difference between remedial action, an action taken to rectify a mistake, and a corrective action taken to eliminate defined non-conformities. Making necessary changes to a report is a remedial action because correcting a report does not prevent re-occurrence.

According to the Standard at §7.11.4, it is the responsibility of the DNA Laboratory to ensure that the provider, BDNA, complies with the Standard. That provider would need to be the subject of an audit to confirm conformance or otherwise. According to its website the Forensic Register "satisfies all the accreditation requirements of ISO/IEC 17025" [45] which reads like a self-declaration. To be clear, it would be for the DNA Laboratory to assure and declare conformance of the 'Forensic Register' with §7.11 of the Standard.

The differences between the CoI report on the Forensic Register and BDNA's promotion of the product on its website are quite marked [46].

8.7. §8 management system requirements

Paragraph 425 p131/145 records " … that there are no quality specific meetings or committees." And goes on to name some of the agenda items for such meetings.

§8.9 of the Standard concerns management reviews. The purpose of such reviews is to consider the "… continuing suitability, adequacy and effectiveness …" of the management system. §8.9.2 specifies the agenda for such meetings. The absence of such reviews is a non-conformance with the Standard.

Paragraph 429 p130/146 records the absence of time to " … investigate the quality issues". §8.9.2 lists "adequacy of resources" as an agenda item for management review.

Paragraph 431 p133/147 records that management decisions are made by consensus. Quality decisions should be taken according to the requirement set out in §8.9 of the Standard, there is no expectation for consensus in decision-making.

Paragraph 444 p138/152 records details of the DNA Laboratory's internal audit program. What is described here is an example of QHFSS's somewhat *laissez-faire* approach to quality management. The CoI report records that "Audit topics are suggested by management … ". And the plan is "… approved by the Quality Manager" (implying that the QM may not be as detached from the work of the DNA Laboratory as suggested earlier in §7.2). According to the Standard, the purpose of internal audits is to check that the management system conforms to the Laboratory's documented requirements and the requirements of the Standard. The Standard at §8.8.2 requires the audit program to be planned. NATA requires the internal audit schedule to cover all the requirements of the Standard within a twelve-month period [47], which seems ambitious. The standard accreditation cycle is three years with external audits conducted by NATA at 18 and 36 months [48]. Internal or first-party audits should be conducted by staff trained to do so. As described by the CoI report, the DNA Laboratory's internal audit program does not conform to the Standard.

Paragraph 446 p138/152 highlights the absence of vertical audits. Section 8.8.1 of the Standard can only effectively be conformed to by conducting some vertical audits[14] [49].

Paragraph 490 p151/165 records that "The responsibilities of the Management Team do not appear to be documented … ". The responsibilities of the management team must be documented. Their non-documentation is a non-conformance against pretty much the entirety of Clause 8 of the Standard.

As stated earlier in §1.6 of this paper, in auditing the QMS the main audit criteria are; do the DNA Laboratory's activities conform to its documented QMS, i.e., its SOPs, and does the documented QMS conform to the standard? These two requirements of the internal audit process are stated in §8.8.1 of the Standard. The episode with the inaccurate wording of statements about the DIFP reporting [1589–1601 p485/499-489/502] is an example of where activities might conform to the SOP but do not conform to the Standard. This may be indicative of a general pattern where activities conform to the SOPs, but those SOPs do not conform to the Standard.

8.8. Performance and culture of continuous improvement

Monitoring and improving performance are one of the many high-level requirements of the Standard and a contributor to the essential culture of continuous improvement required by the Standard. One of the main changes from the second edition of the Standard was a reduction in prescriptive requirements and replacement by performance-based requirements.

One of the duties that must be assigned is to report to the management of the DNA Laboratory the performance of the management system and any need for improvement (§5.6 d). This report would be considered as part of the management review required by §8.9 of the Standard.

A powerful tool for monitoring and improving performance is key performance indicators (KPIs). Apart from turnaround times (TATs), there do not appear to be any other KPIs mentioned. The CoI report in paragraphs 455 p141/155 notes the lack of KPIs related to the "… quality, accuracy and reliability of validations process or results". The CoI report in paragraphs 538 p163/177 again notes the lack of appropriate KPIs and recommends some that should be adopted to focus on quality.

The absence of relevant and appropriate KPIs is certainly a contributor to the quality failures of the DNA Laboratory and its non-conformance with the Standard.

Key Performance Indicators (KPIs), the minutes of management review meetings, the results of internal audits and opportunities for improvement and/or corrective actions identified should be the main sources of evidence sought by external auditors.

9. ISO/IEC 17025:2017 non-conformities revealed by stepping through the operational requirements of the standard

9.1. Introduction

Having discussed non-conformities against the Standard as they occur in the CoI report, which is effectively a horizontal audit, another approach is to conduct as it were a vertical audit against the operational requirements of the Standard. This approach will generate some repetition. However, such an outcome will lend further weight to the main thesis; that conformance with ISO/IEC 17025:2017 is sufficient to ensure the quality and reliability of scientific evidence.

Before a detailed comparison between the actual operation of the QHFSS DNA Laboratory pre-inquiry and the requirements of the Standard, it is perhaps worth quoting at some length from its introduction. The introduction to the Standard makes clear its objective and the requirements it places on laboratories that aim to conform which, in turn, provides some of the backgrounds to the operational requirements of the Standard.

> "This document has been developed with the objective of promoting confidence in the operation of laboratories. This document contains requirements for laboratories to enable them to demonstrate they operate competently and are able to generate valid results. Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001 [the quality management standard].
>
> This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed."

The stated scope

[14] The International Standard ISO 19011 offers guidance on conducting internal audits as the Standard notes at §8.8.2.

"This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories."

"This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel."

"Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories."

The graphic Fig. 1 is reproduced as it depicts the inputs and outputs and general 'workflow' of a QMS conforming with ISO/IEC 17025:2017.

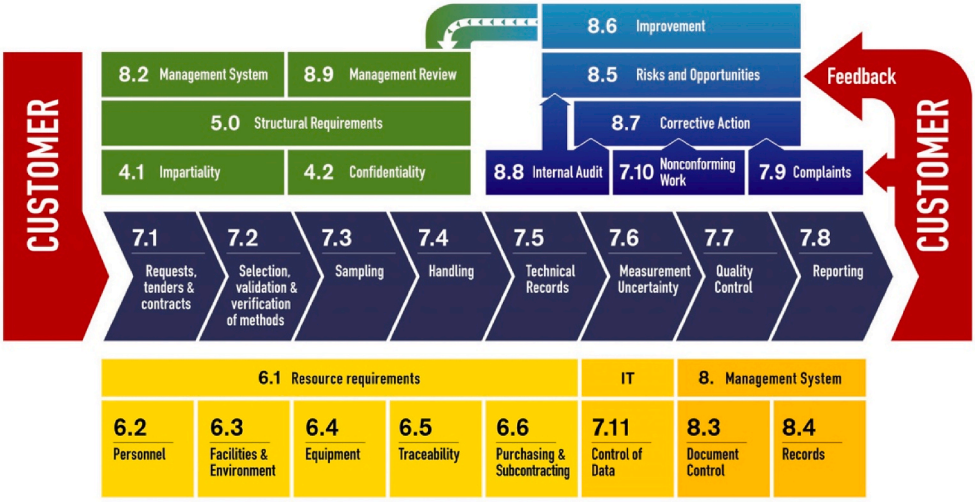

Figure 1

meet those requirements. One of those resources is personnel or staff (§6.2). That section specifies the requirement for staff that are competent. A laboratory accredited to ISO/IEC 17025:2017 requires a management team that is familiar with the Standard and understands management's role in ensuring conformance. Management requirements are set out in Clause 8 of the Standard. The CoI report records little or no evidence of the management reviews required by and specified in §8.9 of the Standard nor conformance with the general management system requirements of §8.1.2. Indeed, in paragraph 425 p131/145, and as stated earlier in §7.8, the CoI reports that no such reviews took place. This is another non-conformance not identified during quality audit.

The operational process of a conforming laboratory is covered by Clause 7 (§7.1 to 7.8); for a forensic science laboratory this is the forensic science process. Parts of Clause 8, management system requirements also feed into monitoring and improving operations.

As has been established earlier in §1.3 and 1.5, one of the main requirements of an effective QMS is to accurately capture and meet customer needs. As has been explained in §1.2.1 the term 'customer' is not just the commissioning or the funding party which, as in this case, is often a police service or a law enforcement agency. 'Customer' includes all CJS stakeholders, the accused, complainants, litigators, tribunals, fact finders, regulators and the public.

9.2. Step 1 §7.1 review of requests, tenders and contracts

So, as far as the stakeholder community is concerned step one is §7.1. This requires the QHFSS DNA Laboratory to have a documented procedure which ensures that stakeholder requirements are "adequately defined, documented and understood" and that the DNA Laboratory has the capability and resources to meet those requirements (§7.1.1).

Operating without a Memorandum of Understanding, as recorded by the CoI at 1553 p471/485, or a Service Level Agreement between the QPS and QHFSS is a surprising omission and a non-conformance with both §7.1.1 of the Standard and common business practice.

Given that the DNA Laboratory failed to meet even QPS needs "… to maximise the potential to obtain a [DNA] profile from a sample." [1053 p334/348], this is a non-conformance. The fact that staff in the DNA Laboratory were aware of the broader definition of 'customer' [907 p286/300] calls into question the effectiveness of the internal audit program in not identifying this non-conformance.

In addition to failing to adequately define, document and understand stakeholder requirements, the DNA Laboratory lacked the resources to

Paragraphs 509 to 512 p156/170 describe the "change management procedure" of the DNA Laboratory. This is a procedure with a high risk of delaying change which contrarily aims to be "timely". Further evidence of inaction or delay, some of which lies beyond the DNA Laboratory, is recorded by the CoI report e.g., 1087 p345/359, 1341 p416/430, 1545 p468/482, 1565 p474/488 and 1598 p488/502.

Therefore, there is evidence to support the contention that the management of the DNA Laboratory lacked the necessary competencies to manage the laboratory in conformance with the Standard, which in turn amounted to a lack of resources to conform to §7.1.1 of the Standard.

9.3. Step 2 §7.2–7.7 sampling, validation, analysis and interpretation

The selection, validation and operation of analytical/measurement methods or SOPs are usually matters for the forensic science provider rather than other stakeholders. However, to be validated according to the standard ISO 9000:2015 'Quality management systems - Fundamentals and vocabulary' §3.8.13 the method would have to be approved by stakeholders, particularly the QPS, as meeting their needs. In addition, the performance of the method should be independently assessed by proficiency testing or participating in interlaboratory comparisons as required by §7.7.2 of the Standard. Methods referred to in the CoI report include the quantitation of DNA [236 p58/72], thermal cycling of samples [250 p64/78], the extraction of DNA [256 p66/80], and genetic analysis by electrophoresis [266 p69/83]; all found to be insufficiently validated. Later in the report sperm microscopy is mentioned [1208 p377/391ff] with more fundamental quality issues. At this juncture, the important point to note is that analytical or measurement SOPs form just one part of the documented QMS. Had the management of the DNA Laboratory conformed more closely with the Standard, e.g., in audit

planning and execution, then the risk of quality failures would have been reduced and perhaps avoided.

9.4. Step 3 §7.8 reporting of results

According to the graphic, the next engagement with other stakeholders is in the reporting of results §7.8. Having failed to adequately capture stakeholder requirements it is not possible for the results to meet their needs. Nevertheless, in terms of assessing conformance with the Standard, it would be useful to consider the DNA Laboratory's reporting of results.

The Standard requires results to be reviewed prior to release §7.8.1.1. The CoI uncovered evidence of selective review; reporting scientists targeting particular reviewers and avoiding others [440 p136/150]. In addition to revealing differences of opinion within the DNA Laboratory regarding reporting standards – a quality issue requiring an urgent response, this situation risks introducing bias contrary to the requirement for impartiality §4.1. At §3.1 of the Standard "freedom from bias" is included as a term conveying the element of impartiality. Permitting selective review risked introducing bias, a non-conformance against the Standard which should have been identified at audit.

Unsurprisingly, the Standard's requirements for reports are quite extensive. At §7.8.1.2 the Standard specifies the following.

> "The results shall be provided accurately, clearly, unambiguously and objectively, …and shall include all the information agreed with the customer and necessary for the interpretation of the results …."

The inaccuracy of DNA Laboratory reports was a major issue for the CoI. In addition, the reports were found to be unclear, ambiguous and certainly omitted information necessary for the interpretation of results [1579–1583 p480/494-p482/496] and used misleading wording regarding the meaning of DIFP [1590–1593 p486/500].

The reports issued by the DNA Laboratory clearly did not conform to the Standard. Given that concerns were raised about the accuracy of reports from late 2012 onwards [1592 p486/500] it is again hard to understand why this non-conformance was not identified at audit and corrective actions raised.

9.5. Step 4 §7.9 stakeholder complaints §7.9 and feedback §8.5

The Standard required the DNA Laboratory to have a documented process to receive, evaluate, and decide on complaints. The Standard defines a complaint as an "… expression of dissatisfaction … ". The complaints procedure must be available to any interested party upon request. A complaints procedure is a fundamental quality management requirement. All organisations aiming to conform to any quality standard must have a documented complaints procedure. It is clear from the CoI report that the DNA Laboratory did not operate a complaints procedure in accordance with the Standard. The lack of or, if one did exist, not following such a procedure is a non-conformance with the Standard which should have been easily identified at audit.

Stakeholder feedback must be actively sought (§8.6.2). Such feedback can confirm or otherwise that the management system is fit for purpose, identify opportunities for improvement and reduce the risk of quality failures. These requirements and others are documented in §8.5 of the Standard 'Actions to address risks and opportunities'. In response to stakeholder feedback, the DNA Laboratory is required to plan actions to address the risks and opportunities identified. A review of complaints, stakeholder feedback and any actions arising must be reviewed by management "at planned intervals" according to §8.9. The CoI reports little or no evidence of conformance with §7.9, §8.5 and §8.9 of the Standard. Such non-conformities are clear and should have been identified at audit.

9.6. Step 5 §8.6 improvement

In addition to stakeholder feedback (§8.6.2) and complaints (§7.9), other contributors to improvement are nonconforming work (§7.10) and internal audits (§8.8) both of which might generate corrective actions (§8.7). Identifying and recording opportunities for improvement (OFIs), and seeking and analysing stakeholder feedback, all considered at management review (§8.9), are fundamental to establishing and maintaining the culture of continuous improvement required by ISO/IEC 17025 and other quality standards.

9.7. Step 6 §8.9 management review

The Standard requires the management of the DNA Laboratory to review its management system at "planned intervals". This can be annual but would be determined by the workload created in following the agenda set out in §8.9.2 of the Standard. As stated earlier in §8.2, there is little or no evidence of such a review in the CoI report, quite the opposite. It is only by conducting the management review that the DNA Laboratory can ensure it conforms to the Standard and has the necessary structural (Clause 5) and resource requirements (Clause 6) to do so.

10. Concluding remarks

It is clear from the observations and findings of the CoI and those recorded in this paper that the QHFSS DNA Laboratory did not conform to ISO/IEC 17025:2017 during the period in question. Had it done so then the risk of the quality failures that led to the CoI would at least have been reduced and perhaps even avoided.

There is much evidence in the CoI report of a *Laissez-faire* approach to quality management, both in the DNA Laboratory and more widely within QHFSS. This is counter to the culture of continuous improvement required which in turn depends on proactively seeking opportunities for improvement and, if found, their implementation. A culture of continuous improvement significantly reduces the risk of non-conformities occurring.

How an organisation operating significantly below the standard required by ISO/IEC 17025 gains and maintains accreditation to that standard is difficult to understand. One possible and partial explanation for the continuing accreditation of QHFSS DNA Laboratory is that both the first-party and third-party quality audits were horizontal, focussed on the same procedure or SOP across a number of the same inputs rather than a vertical audit where the interaction of inputs and outputs between procedures is the focus. As stated earlier in §1.2, vertical audit is the optimal means of revealing opportunities for improvement. However, given all the quality issues regarding analytical/measurement procedures in the CoI report, particularly in Sections 2.3 and 5, even this possible and partial explanation seems unlikely.

Another possible explanation may be the relationship between NATA and the other parties involved in the process which are part of Australia's forensic science ecosystem referred to earlier in §2.5. Accreditation is a third-party, or independent, attestation of conformance. It may be that NATA is too closely related to Australian forensic science providers to be truly independent.

Properly applied, competently audited, both internally and externally, and enthusiastically embraced as a means of continuously improving performance and not a mere tick-box exercise, conformance to ISO/IEC 17025 alone can and should be enough to assure the delivery of scientific evidence of sufficient quality to be relied upon by justice systems to help deliver a safe decision by a fair process, as has been the case for over two decades.

CRediT authorship contribution statement

Sean Doyle: Conceptualization, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review &

editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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