



*Phase Two Submission to the
Australian Commission on Safety and Quality in Healthcare*

**An Alternative Model For
Safety and Quality
Accreditation of Health Care
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SUBMITTER DETAILS

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Alternative Model For Safety and Quality Accreditation of Health Care

Introduction

NATA wishes to thank the Commission for the opportunity to comment on the second phase of the development of a national system for accreditation of health care facilities in Australia. The alternative model that has been developed in response to the significant stakeholder discussions and submissions to date is, on the whole, a very workable framework from which a national set of safety standards and quality improvement processes can evolve.

This submission will provide comments on the proposed key elements of the alternative model from an accrediting body's point of view. We will also provide some suggestions from our extensive experience in the areas of implementing standards, supporting quality improvement, surveyor training and general accreditation issues in the health care sector.

NATA supports in principle the establishment of a national set of minimum safety standards and quality improvement processes into the current health care sector. This should be viewed as a progressive step for Australia's health care system and provide a mechanism for continual improvement to maintain and advance our standing not only nationally but internationally as well.

NATA is pleased to note that the Commission recognizes our unique role in accrediting diagnostic healthcare services eg. pathology, and the overwhelming positive contributions our programs have had on such services and the support from the affected stakeholders. It is also noted that the Commission anticipates NATA to continue as the primary provider of accreditation for such 'technical' healthcare services under the Alternative Model, dependent however, on NATA's recognition by the 'National Entity' to be established under the model. We look forward to further close involvement in the consultation process on the model.

Key Elements of the Alternative Model

1. Separation of safety assurance and quality improvement assessment process

NATA is in a fortunate position to be able to assess both quality improvement and technical competence within its accreditation format because of the evolution over years of the standards which are applied to testing facilities including pathology laboratories. Historically this came about with defining minimum technical requirements and then imbedding continuous quality improvement frameworks as the standards were reviewed and updated. It may therefore be an appropriate decision to separate the two issues in the initial phases particularly when it is clear from the stakeholder submissions that the two issues are at different stages in their implementation. From the submissions it would seem that safety and the delivery of safe care are well established in terms of the facilities dealing with this and the accreditation of such, but the same cannot be said for quality improvement. This is surprising to note as many of the certifying bodies indeed place emphasis on quality improvement in their programs. Whatever the case, it is definitely essential to bring quality improvement into the mindset of the facilities as this will encourage a goal to strive for rather than simply meeting minimum requirements.

Accordingly, both safety issues and quality assurance issues should be integrated if not at the outset, then at the earliest stage of review. Quality improvement is the driver that underpins safety and quality. In fact facilities can more efficiently operate by integrating quality improvement into their overall quality management processes, thus minimising duplication of tasks and engendering a workforce culture that continually strives for improvement.

In terms of an implementation timeframe, this should take a priority as it will be the basis from which accreditation is drawn. It should be stressed that whilst facilities will be provided with assistance in these areas in order to achieve accreditation, there will be a timeframe which must be adhered to.

It should be anticipated that the health care facilities, and some accrediting bodies to a lesser extent, will seek incentives to adopt in particular the quality improvement processes as this will be a new or much expanded area that they will be developing. Considerations such as providing staff training will need to be thought through.

2. Separation between safety standards development and assessment of health services

The reasons provided by the commission in the alternative model are indeed appropriate to endorse such a separation. NATA itself operates as an accrediting body separate from the setting of standards as required by our own accreditation, ie. recognition through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA). We would encourage the development of national standards against which accrediting bodies assess, thus minimising the tendency of a proliferation of various standards. We would also suggest deferring such a process of developing standards to Standards Australia, a well-recognised standard setting body who has such mechanisms already in place. It should be noted too, that whilst NATA does not set standards, we do provide interpretive documentation for sector specific implementation of the standards and additional guidelines.

The question of having 2 separate bodies developing the standards for the proposed minimum safety standards and the quality improvement standards may be a moot point if the 2 elements were not separated but incorporated.

It would be appropriate that federal funding be provided particularly in the development and implementation stages of standards setting. Ongoing resource implications may be reviewed once the standards have been implemented and assessed for their effectiveness.

3. Accreditation of all settings of care where services are provided by registered health professionals

There is a perceived understanding by the public that the health care system is all encompassing and that they will be cared for in the most technically appropriate and safe way regardless of the setting in which that care is offered. Therefore, it is indeed appropriate that all settings are subject to the accreditation process and that those not so are clearly designated as such. This will have great resource implications on those facilities or services not currently accredited in any way but that does not mean that they should be exempt. In fact, it could be argued that these services should be prioritised in terms of achieving accreditation. The suggestion that this be achieved by a staged introduction of the quality improvement framework following initial compliance with the national minimum safety standards is quite appropriate. To not enforce the minimum safety standards as a whole would very much reduce the connotation of them being 'minimum' standards

At the outset of NATA accreditation of pathology laboratories the incentive was access to Medicare funds. It may be suitable to adopt the same or similar incentive to health care facilities with an appropriate lead-up time. By giving the facilities an opportunity to develop or implement their own strategies to meet the standards prior to a mandated time will aid in the transition particularly of those not currently accredited in any way.

4. Development of national minimum safety standards that apply across all (similar) settings of care

NATA supports the development of the national minimum safety standards and over-riding framework. However, the Commission should provide a clear definition on what it sees as 'Safety'. In terms of the specific input requested we have attempted to provide our viewpoint as follows:

1. A National Entity to develop standards using 'expert' working groups would be seen as necessary. This would afford both credentials and practical implementation to the standards from the outset.
2. NATA has found that standards which steer away from being prescriptive and only state a set of broad requirements(eg. the need to maintain infection control), rather than how to go about implementing those requirements, enables a variety of facilities to adopt those standards. The areas addressed by the standards could be modularized into functional areas or even into workforce areas. The functional areas might offer flexibility in terms of which standard/s are adopted by each healthcare sector depending on what their function is (eg. emergency care, diagnostics, allied health, corporate services/support services, outpatient services/community clinics, etc). However, it may be easier to implement standards that are arranged into workforce oriented areas (eg. medical practitioners, nursing, allied health, administrative/support staff, alternative therapies, patient transport, etc).
3. The priority order for the development of standards should definitely be risk-based. The aim should be to regulate and provide the public with a safe and technically competent healthcare service. Accordingly, the areas to first address are those that present the most uncertainty and risk to the public.
4. The question regarding whether the assessment outcome be 'pass' or 'fail' is not supported as it appears punitive and does not encourage a culture of improvement. Rather, a facility should be regarded as accredited in the areas that do meet the standards. A facility may be compliant in certain departments but not in others. Such a facility could than be accredited for those specific departments.
5. A failure to achieve accreditation must be linked to some form of identification such that the public can correctly interpret. One way of achieving this would be through access to funding such as on a tiered basis. For instance, any unaccredited facility has access only to a very limited source of government funding and those that achieve accreditation have full access to both government and private health insurance funding. It is essential that the concept of 'minimum' standards being met or not met is not lost on the public. Having said this, one cannot disadvantage those that have limited access to any healthcare facility because of geography or financial reasons.
6. The circumstances and consequences of a 'fail' rating would need to be considered in the context of the assessment. That is, whether an assessment is being made as an initial application for accreditation, or whether it is a scheduled reassessment of a previously accredited facility. An initial granting of accreditation should be given with all minimum standards being adequately met. Any subsequent assessments could then only 'fail' a facility once attempts have been made to rectify any shortfalls identified. There should be a reasonable and equitable timeframe that allows facilities to meet the accreditation requirements and be given access to any additional resources such as training in order to do so but also provides a degree of assurance to the public that their health care needs are being met.
7. In terms of sanctions and penalties, accreditation of any healthcare sector should have clearly described activities that the accreditation covers as referred to in point 4 above. That would mean they would have certain aspects of their service endorsed or accredited and others (that didn't meet the requirements) not so. The penalties would follow-on from this. If a system such as that outlined in point 5 above that links tiered

funding to accreditation was adopted, this would lend itself to those services that are accredited and those not.

8. As previously discussed, Pathology laboratories have enforced accreditation by way of linking their accreditation status to access to Medicare/HIC funding. Without accreditation, the laboratories are unable to access these funds. It would be difficult to mandate such a system across the healthcare sector but it may be possible to establish a tier-based system for funding access.
9. Desk top audits allow the review of documentation however they should be done in conjunction with on-site announced surveys and, only in special cases, unannounced surveys. It is stressed that review of documentation only confirms 'intent' and does not demonstrate actual practice as it occurs on-site. NATA has previously raised its significant concerns about the use of unannounced surveys as a regular option. These types of assessments should only be undertaken in instances that warrant the disruption to services and staff and their 'policing' nature. In the interests of the facility and the culture of improvement, unannounced surveys are best left as a final option when all other options have been explored or where there may be a significant risk to the public that needs to be investigated immediately. NATA does not support routine unannounced surveys.
10. Recognising accreditation bodies could be achieved by specifying that they themselves be evaluated (eg. through ILAC, IAF, ISQUA, etc). Many of these bodies will have their own requirements for such things as assessor training, competence and performance management. Alternatively a national entity, perhaps associated with that developed for the national minimum standards, could establish a criteria by which accrediting bodies are judged and thus deemed appropriately recognized. This alternative would create another layer and may not necessarily offer the added reassurance that ILAC, IAF or ISQUA could offer. This added layer could be negated by the first option of utilizing an external body.
11. The information that is supplied to the National Entity regarding assessment outcomes should be limited to a statement as to whether the facility has complied with the national minimum safety assurance standards or if there are any outstanding issues, including a list of such, that need to be addressed and the timeframe that the facility has been given to comply.
12. Timeframes for the development and implementation of national minimum safety standards need to be set by an expert working panel that is knowledgeable on the status of the healthcare sector in its current ability to achieve this. It would be prudent to consider public interest in such an enterprise and to include this in the timeframe estimations.
13. Resourcing for the changes will need to be considered in 3 phases. Firstly, the development phase in which standards and working parties are established and include a pilot of the proposed accreditation system. Secondly, the implementation phase in which healthcare facilities are introduced to the new framework and accreditation system. Thirdly, a maintenance phase in which facilities continue the accreditation and introduce the quality improvement changes. Both the development and implementation stages will require significant funding but also resources in terms of training, set-up and advisory services. Supporting facilities in the early phases will benefit the long-term outcomes of this project. This support does not go so far as to tell facilities how to implement the standards. NATA has found that facilities respond very well to assistance provided at the development and implementation stages of standards application. It engenders good working relationships including motivated improvement policies as the facilities become familiar with the standards and their applications.

5. Assessment of non-clinical and technical compliance

NATA would like to suggest the use of the term technical 'competence' rather than 'compliance'. Our core activity is the assessment of technical 'competence' against national and international standards and guidelines. Technical 'competence' is the key feature that differentiates accreditation from certification as per ISO definitions. As an accrediting body (not a certifying body) that is recognised internationally we must adhere to the correct use of these definitions and terms and so would appreciate this key element reflect that. We would suggest changing this to:

Assessment of non-clinical compliance and technical competence.

The commission has stated that for specific areas, NATA will continue as the primary accrediting body. This highlights NATA's role as the sole accrediting body eg. for pathology, which is reflected in the Memorandum of Understanding NATA has with the Australian Government and underpinned by legislation.

As stated, assessment of technical competence is the delineating factor between accreditation and certification bodies according to ISO definitions. NATA complies with ISO 17011 (*Conformity Assessment – general requirements for accreditation bodies accrediting conformity assessment bodies*) and assesses pathology laboratories against quality management and technical competence standards as defined in ISO 15189, or radiology practices against ISO/IEC 17025. The inclusion of technical competence exceeds any assessment based purely against quality management systems which is afforded by certification bodies (who are themselves accredited, for example, by JAS-ANZ). This in itself recommends NATA to be recognised throughout the health care community as the prime accreditation body where services are technically based and results generated eg. a test, an examination.

It is appropriate that technical competence and non-clinical compliance remain separate and be recognized formally by a national body. Bodies such as NATA have specific requirements placed on them, such as ISO 17011 requirements, which must not be reduced or compromised by integration into a healthcare-wide scheme.

6. Development of a national framework for quality improvement

NATA welcomes the proposal for a national quality improvement framework as described in the alternative model.

In terms of structure and content of a quality improvement framework, what is the definition of quality in this context? If quality was linked to customer satisfaction, the customer being the patient in a healthcare setting, then there already exists a quality industry based around the ISO 9001:2000 standard as an example. This standard embraces the aspect of quality and quality improvement. It is 'customer' focused and could easily be equated to a 'patient' focus to meet the patient centered outcomes aimed at in this initiative. It would provide for a customer definition of quality which could be adopted by the quality improvement framework. This standard starts from the premise that quality must be seen through the eyes of the customer, and the service provider is bound to seek out what expectations its customers have. In the context of the proposed alternate model the national minimum safety standards may also set minimum customer expectations. The onus would be on the healthcare providers themselves to demonstrate that they have sought out their customer's expectations and established their quality parameters on this basis. In addition to the generic standard ISO 9001 on quality management systems, there is also information with particular reference to healthcare in the previous Standards Australia handbook, CB 097-2002: Healthcare services – A Guide to ISO 9001:2000.

It should be noted, however, that the quality system as per ISO 9001 does not lend itself to quality when it is defined in terms of specific metrics around patient care outcomes, such as mortality rates or readmittance. The quality framework would then need to blend both quality system and specific clinical/technical requirements together. This then moves away from ISO 9001 certification and towards technical competence accreditation like that which exists with NATA/RCPA assessments.

The quality improvement framework should be developed in-line with the minimum safety standards (as previously mentioned). It would be simpler to adopt existing standards where these are available rather than go about creating a new standard.

There are elements of the existing accreditation process that NATA applies where a focus on quality improvement is already in place. In the pathology laboratory the interaction between clinician and laboratory is assessed but not so much the interaction between the healthcare facility per se (eg. hospitals) and the pathology laboratory. There are departments within the laboratory that have quite an interface with the facility (usually co-located) that is not well addressed by either the current hospital accreditation nor NATA's. Examples of this include blood banking and infection control interactions. This may be an avenue that could be addressed through a national framework.

7. Establishment of a national body to lead and coordinate changes

A national body to lead and coordinate the proposed changes would provide an over-arching reference point from which initiatives can be managed and directed allowing the development and implementation to be facilitated. It may be preferable to create a new body that would operate with statutory powers to give it the legislative weight required particularly in view of the intention to have facilities comply with the standards on a national basis. Furthermore, due to the wide ranging activities covered by all healthcare sectors it may be appropriate to establish subcommittees who would then report to the national body. If input is sought from accrediting bodies we would like to be considered as active participants on any working party/committee or even representation on the national body itself.

8. Review of surveyor training

A review of the current arrangements for surveyor training and competency is indeed worthwhile. It could be tackled by a working group of interested parties or perhaps representatives from bodies that currently conduct training such as accreditation bodies or healthcare professional groups. This was a particular area of concern from the submissions which rightfully want to ensure competency and consistency amongst assessment outcomes and recommendations.

NATA has developed a staged process in which it's peer assessors participate. It provides sufficient formal training in combination with on-the-job experience that does not place too onerous a load on this precious workforce. It also makes use of NATA staff who lead each assessment team, coordinate the assessment schedule, provide information on precedence and interpretation of the standards and provide guidance and feedback on the performance to its assessors to maintain consistency across facilities and between assessments.

A full review of existing arrangements for surveyor training and assessment of that training would provide information on how to best train and maintain competency of surveyors as well as managing the aspect of the time expected of the surveyors. A significant limiting factor is the participation in any training program particularly when volunteer surveyors are being utilised. The option of paying assessors is not the best approach in NATA's view. Not only will this cost ultimately be passed on to the public but professional assessors can lose currency in

their respective professions and there is some loss of the peer review nature/value adding that NATA enjoys with its assessor pool.

The resource implications may be offset somewhat by the accrediting bodies providing the training. However, some incentives will need to be considered as it becomes more and more difficult to maintain sufficient 'volunteer' surveyors. Considerations may include formal recognition of status as a surveyor which reflect the individuals seniority, etc.

9. Associated reforms

Unannounced surveys represent somewhat of a philosophical challenge to the way that NATA approaches it's assessments. We feel that they detract significantly from the culture of improvement and support that we offer our clients even though we do indeed have a mandate to apply unannounced assessments if the need arose. We view the assessment day as the final stage in the overall recent history of that facility, requiring documented evidence of its work over the previous 3 years as is the case for pathology laboratories. This then does not support the argument that unannounced surveys reflect a facilities day-to-day operations more accurately than a planned visit.

The piloting of tracer methodology will be an interesting exercise. Such a vertical audit of a patients journey through their healthcare episode may not lend itself to this methodology (obviously not real-time) but this needs to be further evaluated in terms of effectiveness and benefits, before being implemented as a suitable tool.

Developing a best practice guide to standards development and review is good in theory but probably not a priority. As referred to earlier in this submission, Standards Australia should be deferred to with regards to this.

Mapping standards could occur in line with the development of national minimum standards and the quality improvement framework as this may assist the development of those standards.

The issue of public reporting of accreditation outcomes needs to be fully assessed from a legal viewpoint. The Commission should define more clearly what is intended by 'public reporting of accreditation outcomes'. That is, what information is to be made available and for what purpose. It would be prudent to limit public reporting to a facility's accreditation status and the scope of that accreditation.

Developing a process of mutual recognition of accreditation processes and outcomes will help to maintain the consistency of the process itself across the various bodies and various facilities and services that are involved. This will need to be done with consideration of the requirements placed on the various bodies such as those imposed by ISO 17011 in NATA's case.

General Comments

Much has been made of the perceived drift from an assessment approach based on peer assessment to a more compliance/inspectorate approach. This issue is not limited to the recent history of quality assessment in the healthcare industry, it is a general issue within the quality auditing fraternity. NATA's position on this remains very much in the field of peer assessment to engender quality improvement, foster relations with healthcare facilities and minimise the 'policing' aspects. The misuse of unannounced surveys would follow-on from this.

Assessor training and performance in terms of consistency has been raised quite rightly throughout this consultation process. The competence of assessors (surveyors) and their ability not only to tick the box, but to add value during the assessments is critical to the assessment process. This issue should feature in the alternate model so credible assessor training is essential. We regard on-site witnessing of assessors during their training by seasoned professional assessors of the right type is the best way to ensure suitable assessor performance of communication is learnt – this cannot be taught solely out of a book nor in a class room. Witnessing must be a cornerstone on this regard.

In terms of implementation issues, the speed at which the alternative model is established and the degree of disruption that will be felt in existing arrangements for some tangible gain can be facilitated by grafting the national quality framework assessment on to existing quality assessment regimes. Further review of the model as it is applied can be examined at periodic intervals and recommendations made in due course.

The concept of a national approach to safety and quality of healthcare and the alternative model proposed by the Commission is an important and progressive step in the evolution of Australia's healthcare system. Such expansive and comprehensive consultation and consideration of such is to be applauded. NATA looks forward to the next phase and the recommendations that result from it.