LABORATORY DOCUMENTATION

AN AUDIT QUESTIONNAIRE THAT EXAMINES SPECIFICALLY THE MANAGEMENT OF TECHNICAL ACTIVITIES CLAUSES IN ISO 15189

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ABSTRACT

The aim of this study was to design an audit questionnaire that focuses on the management of the technical activities in a Diagnostic Pathology Laboratory. The ISO 15189 Standard is written in such a way that it continually moves back and forth from topics where the auditor needs to question bench level staff, to topics where the auditor needs to question Technical Management Staff. This makes for a disjointed audit process – both Bench Staff and Technical Managers are repeatedly interrupted. The solution was to do a clause by clause analysis of the Standard and assign the major responsibility for the compliance to each clause to either Technical Managers or Bench Staff. The Clauses were then grouped under four topic headings regardless of whether they were a Section 4 or Section 5 Clause. Two questionnaires have emerged – the one described in this work and one directed primarily towards the activities of bench staff. There are 95 questions and it takes approximately two hours to complete.

KEY WORDS

ISO 15189, Audit, Technical Management, Questionnaire.

INTRODUCTION

Prior to devising this questionnaire we were only aware of one other such ISO 15189 (1) directed audit questionnaire viz that designed by the Singapore Accreditation Council (SAC) (2). Their questionnaire has the disadvantage that it goes through ISO 15189 in exact clause by clause order and re-expresses every statement within the clause as a question.

A similar approach has been taken by the Australian National Pathology Accreditation Advisory Council (NPAAC) in their document on Quality Management in Medical Laboratories (3). Two examples illustrate this point:

Text of Clause 4.3.2 as it appears in ISO 15189:- (c) only

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currently authorised versions of appropriate documents are available for active use at relevant locations, (d) documents are periodically reviewed, revised when necessary, and approved by authorised personnel, (e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use.

The questions raised by the SAC that correspond to these clauses are: Are procedures adopted to ensure that:- (c) current authorised versions of appropriate documents are available at all appropriate locations? (d) Documents periodically reviewed, revised where necessary and approved by authorised personnel? (e) Invalid or obsolete documents are promptly removed from all points of issue or use?

The NPAAC document (2) poses two questions to cover these three points:- (1) *Does the laboratory ensure that only currently authorised versions are available for active use at relevant locations?* (2) *Does the laboratory ensure that documents are periodically reviewed and revised when necessary and that these revisions are approved by authorised personnel?*

In our questionnaire we pose eleven “practical” questions on

document control:

1. How often do you review your documents?
2. How many documents are due for review?
3. Show me an example of an old version of a document and a new version of the same document?
4. Where are your Procedures Manuals?
5. Are they easily accessible for staff access?
6. Is it clear who wrote the documentation?
7. How do staff know that they are using the most current version of the document?
8. What do you do with your superseded documents?
9. Do you allow handwritten amendments to your documents?
10. How would you find out if a member of your staff has made a handwritten amendment?
11. Do all your documents show the page number total page numbers and a version date or number?

MATERIALS AND METHODS

The version of the ISO 15189 Standard used was that published by StandardsAustralia in 2004 (1). The method was to perform a complete clause by clause analysis of the ISO 15189 standard and assign the major responsibility for the compliance to that clause to either Technical Managers or Bench Staff.

The second step was to consolidate the topics of the ISO 15189 Clauses under the following activity group headings regardless of whether they were in Section 4 or Section 5 of the Standard.

- i. Management of Administrative Tasks.
- ii. Management of the Pre-analytical Processes.
- iii. Management of the Analytical Processes.
- iv. Management of the Post Analytical Processes.

In this way we ensured that what we regarded as a somewhat “artificial” split of quality systems from technical requirements that is imposed by the Standard, did not similarly impose an artificial split into our questionnaire structure.

Out of this work two questionnaires have emerged – the one described in this work and another one that is directed primarily towards Bench Staff responsible for performing laboratory procedures.

RESULTS

These are presented in two parts. The first part presents which

Table 1: Allocation of the selected ISO 15189 clauses to defined management activities

Management of	Corresponding ISO 15189 Clauses	
Administrative Tasks	4.3	5.1
	4.9	5.1.2
	4.10	5.1.11
	4.12	5.2
	4.14	5.2.1.
		5.2.2.
Pre-Analytical Processes		5.2.8
		5.3
		5.3.3
		5.5.1
	4.6	5.4
		5.4.3
		5.4.5
		5.4.8
		5.6.2
Analytical Processes		5.4.7
		5.6
		5.6.1
		5.6.4
Post Analytical Processes	4.5	5.5.5
	4.5.1	5.5.7
	4.5.4	5.8
		5.8.3 e,g,k
		5.8.9
		5.8.12
		5.8.14

of the ISO 15189 clauses were assigned to the four activity group headings defined under Methods (Table 1). The second part is the full questionnaire.

Assignments of Clauses to Activity Group Headings:

- i. Management of Administrative Tasks
  - (a) Document Control (4.3) and Review of Procedure Manuals (5.5.3).
  - (b) Incident Reports and their Corrective Actions (4.9 and 4.10).
  - (c) Performance Indicators – Records and Reviews (4.12).
  - (d) Audit Reports and their Corrective Actions (4.14).
  - (e) Laboratory Environments (5.2, 5.2.1, 5.2.2).
  - (f) Laboratory Equipment, Inventory, Maintenance Records and Calibration (5.3).
  - (g) Training Records (5.1.2, 5.1.11).
  - (h) Minutes of Staff Meetings (5.2.8).

- (i) Staff Resources: Relevant Textbooks and Journal Articles (5.5.1).
- (j) Arrangements for the Support for Out of Hours Staff (5.1).
- ii. Management of the Pre-analytical Process
  - (k) Reagent Purchase, Inventory and Control (4.6).
  - (l) Specimen Rejection (5.4.8).
  - (m) Provision of Client Information – i.e. Specimen Requirements, Patient Preparation, Specimen Handling, Storage and Disposal (5.4, 5.4.3, 5.4.5).
  - (n) Uncertainty of Measurements (5.6.2).
- iii. Management of the Analytical Processes
  - (o) Worklists (5.4.7).
  - (p) Internal Quality Assurance Periodic Review (5.6, 5.6.1).
  - (q) External Quality Assurance Programme Performance and Review (5.6.4).
- iv. Management of the Post Analytical Processes
  - (r) Reporting of Results (5.8, 5.5.5, 5.5.7, 5.8.3e, 5.8.3g, 5.8.3k, 5.8.9, 5.8.14).
  - (s) Work Performed by Referral Laboratories (4.5, 4.5.1, 4.5.4) and its Reporting (5.8.12).

The Audit of Technical Management Questionnaire

(a) DOCUMENT CONTROL (4.3) AND REVIEW OF PROCEDURE MANUALS (5.5, 5.5.2, 5.5.3)

Clause 4.3 related questions:

1. How often do you review your documents?
2. How many documents are due for review?
3. Show me an example of an old version of a document and a new version of the same document?
4. Where are your Procedure manuals?
5. Are they easily accessible for staff access?
6. Is it clear who wrote the documentation?
7. How does staff know that they are using the most current version of the document?
8. What do you do with your superseded documents?
9. Do you allow handwritten amendments to your documents?
10. How would you find out if a member of your staff has made a hand written amendments?
11. Do all your documents show the page number,

total page numbers and a version date or number?

Clause 5.5, 5.5.2 and 5.5.3 related questions:

1. How many of your procedures are in house procedures?
2. Have you validated your in house procedures and if so where are the records of those validations?
3. Where you have performed method validations have you complied with the National Association of Testing Authorities (NATA) requirements on page 13 of their Field Application Document (FAD) (4) 5.5.2 (i), (ii) and (iii)?
4. For non in house procedures have you evaluated/ checked their performance for medical testing using normal and patient samples?
5. Do your staff use 'abbreviated procedures' eg method cards, pocket books, flip files etc – if so how have you ensured that they are adequate? Have you included them into your document control system?
6. Do your staff use package inserts from Medical Testing Kits and if so how do you document control them?
7. Do you use the package inserts enclosed with your Quality Control Material and if so how do you document control them?
8. Do you have any procedure or interpretative documentation displayed on walls, in flip files and if so how do you document control them?
9. How do you document control the Procedure Manuals supplied with Medical Testing Instrumentation?
10. Do the NATA criteria 5.5.1 (ii), (iii), or (iv) on page 13 of their FAD apply to your area and if so do you comply?

(b) INCIDENT REPORTS AND THEIR CORRECTIVE ACTIONS (4.9 and 4.10)

1. How many incident reports have been issued in the last twelve months that have involved your area?
2. How many of these incident reports are still 'open' ie the corrective action has not been completed and why?
3. How many corrective action requests have been issued in the last twelve months that have involved your area?
4. How many of these corrective action requests

are 'open' i.e. the corrective action has not been completed and why?

5. If there have been no corrective action requests issued in the past twelve months does this reflect that there have been no problems in your area?

(c) PERFORMANCE INDICATORS – RECORDS AND REVIEW (4.12)

1. What quality indicators do you use in your area that can pick up potential sources of non-conformance and/or opportunities for improvement?
2. What opportunities for further education and training are available for staff in your area?

(d) AUDIT REPORTS AND THEIR CORRECTIVE ACTIONS (4.14)

1. When your area was last audited?
2. Do you have a copy of that Audit Report available for us to discuss?
3. Are there any incomplete corrective actions relating to that last audit?
4. Are there any aspects of your activities that you would like to have audited in the near future?

(e) LABORATORY ENVIRONMENT (5.2, 5.2.1, 5.2.2)

1. Do you have adequate space to perform all aspects of your work in?
2. Does the physical layout of your area comply with the principles of a LEAN (5) design that ensures an efficient and logical flow of specimens and analytical work through your area?
3. Are there any risks of cross contamination happening?
4. Where do you store your samples that
  - Are awaiting analysis
  - Have been analysed
  - Have to go into long term storage and are all these locations maintained at the correct temperature for this purpose?
5. Do you have temperature records for these various storage locations?
6. What are the NPAAC Guidelines (6) for long term sample and record storage as they relate to your area and do you comply with them?
7. Where is your Safety Manual?
8. Are there additional safety requirements that

apply to your area and how do you ensure that staff have been trained in these extra safety procedures/precautions?

(f) LABORATORY EQUIPMENT, INVENTORY, MAINTENANCE RECORDS AND CALIBRATION (5.3 + FAD page 12, 5.6.3)

1. Do you have up to date records of Make, Model, Serial Number and purchase date of all your instruments?
2. Where are your maintenance records for all your instruments used in medical testing?
3. Does your staff have easy access to the maintenance records and do they know who to contact if a particular instrument needs maintenance or repair during your absence eg. While you are on leave?
4. Have you documented the frequency (ie a calendar) of preventative maintenance for all your instruments and is this being adhered to?
5. What mechanisms are in place that ensures that you are informed if an instrument is considered to be malfunctioning?

{For Transfusion Medicine the NATA FAD has specific requirements detailed on page 12 under 5.3, are these being adhered to and is this documented in a relevant procedure(s) and record(s) ?}

{For Microbiology the NATA FAD has specific requirements detailed on page 19 under 5.6.3b, are these being adhered to and is this documented in a relevant procedure(s) and record(s) ?}

(g) TRAINING RECORDS (5.1.2, 5.1.11, 5.1.12)

1. Where are your training records and are they up to date?
2. Do your training records show the identities of the trainer?
3. Do your training records show that both the trainer and trainee sign off at defined stages of the process?
4. Have you documented retraining triggers for your area?
5. Are you adhering to all the NATA requirements as specified on page 11 of the FAD under 5.1, 5.1.2 and 5.1.11 for training and continuing education?

6. Does any of your staff make interpretative comments on results and if so how is this monitored for consistency?

(h) MINUTES OF STAFF MEETINGS (5.2.8)

1. Please show me the agendas and minutes of your last six staff meetings for this area?
2. Are these minutes placed in a location where all staff can access them?
3. Do you record attendances at these meetings?
4. How do staff who are unable to attend these meetings get to know about the business discussed at them and the decisions that were made?

(i) STAFF RESOURCES : RELEVANT TEXTBOOKS AND JOURNAL ARTICLES (5.5.1)

1. Where do you keep text books and journals that staff needs to have access to as part of their work?
2. Do you comply with NATA FAD minimum requirements on textbooks – see FAD clause 5.1.2 ii on page 12?

(j) ARRANGEMENTS FOR THE SUPPORT FOR OUT OF HOURS STAFF (5.1)

1. Do you comply with the NATA FAD clause 5.1 requirements on page 11?
2. Are there documented procedures and records to support the effectiveness of these arrangements?

(k) REAGENT PURCHASE, INVENTORY AND CONTROL (4.6)

1. Do you purchase third party reagents or consumables for any of your instruments and if so have you independently confirmed that they are equivalent in practice to the instrument manufacturer's recommended product?
2. Do you have an inventory control system for key reagents and consumables used in your area?
3. Who is responsible for initiating the purchase of items required to restock your inventory?
4. Who is responsible for checking the condition, quantities and timeliness of deliveries to your area?

5. How do you document events where the supply of reagents and consumables have fallen short of your specifications for timeliness of delivery, quantities delivered, physical condition of the deliveries, frequent breaks/changes in Lot Numbers, deliveries with inadequately short Use By Dates, refusal to take back into store and/or replace free of charge rejected deliveries and other criteria that you have defined as being essential for these materials?
6. Do you comply with the NATA FAD clause 4.6.3 requirement on page 10?

(l) SPECIMEN REJECTION (5.4.8)

1. Where have you documented the criteria for rejecting primary samples and secondary aliquots of primary samples?
2. Where do you record the fact that a primary sample or secondary aliquot has been rejected?
3. How do you inform clients that one of their primary samples or secondary aliquots has been rejected?
4. Are there documented circumstances under which you will proceed to process and report results on a primary samples or secondary aliquots which under your criteria you would normally have rejected?
5. Do you involve a Pathologist when any of these adverse events occur?

(m) PROVISION OF CLIENT INFORMATION – ie. SPECIMEN REQUIREMENTS, PATIENT PREPARATION, SPECIMEN HANDLING, STORAGE AND DISPOSAL (5.4, 5.4.3, 5.4.5)

1. Does your Primary Sample Collection Manual – adequately refer to the patient preparation, sampling and specimen containers required for the tests performed in your area?
2. Are all your tests on the Specimen Requirements Database and are they up to date?
3. Who can update this information and who covers for that person in this activity when they are on leave, absent etc?
4. Do any of your specimens require to be transported under controlled conditions eg at 4 degrees, immersed in formalin, must be delivered within 15 minutes etc and if so what mechanisms do you have in place to check that this has been

- done correctly for your samples?
  5. Are your clients aware of the tests that you examine in batches less frequently than daily or refer elsewhere and how have you communicated this to them?
  6. Where do you store your specimens to be analyzed, those specimens that have been analyzed and those specimens that need to be retained and/or referred on to another internal or referral laboratory?
  7. Do you have long term storage of samples ie longer than one week and if so do you have an inventory of those samples to assist with their retrieval?
  8. When, where and how do you dispose of old samples?
  9. Please show me records of samples that you have rejected for analysis because they did not have the "three points of positive patient ID" on the tubes and/or the request form?
  10. Are all your staff aware of the procedures to follow when they receive inadequately labeled samples and forms? Is this part of their documented training?
  11. Do you comply with the NATA FAD clause 5.4.3 and 5.4.5 requirements on page 12?
- (n) UNCERTAINTY OF MEASUREMENTS (5.6.2 and FAD page 19)
1. How many of your tests have had their Uncertainty of Measurement quantitated?
  2. On the basis of the Calculated Uncertainty of Measurement calculations do you have any tests which fall short of the performance required for clinical use?
  3. Are you familiar with the NPAAC document on Uncertainty of Measurement (7) and have you followed their guidelines where they have given worked examples for tests that you perform?
  4. Do you comply with the NATA FAD requirements mentioned under Clause 5.6.2 on page 19?
- (o) WORKLISTS (5.4.7)
1. Do you use numbering systems (i.e secondary numbers on specimens) in addition to the unique laboratory accession number and if so how do you ensure that there are no opportunities for mismatches?
2. Have you documentation that describes how your staff is to perform the secondary numbering (if applicable)?
  3. Do you comply with the NATA FAD requirements mentioned under Clause 5.4.7 on page 13?
- (p) INTERNAL QUALITY ASSURANCE PERIODIC REVIEW (5.6, 5.6.1)
1. Do you run internal quality controls with all your assays and if so they are all materials that are 'third party' controls, i.e. controls manufactured and calibrated by suppliers independent of the instrument manufacturer?
  2. How do you train staff in your area in the performance and evaluation of quality control?
  3. Please show me some records/evidence that you periodically discuss internal QC performance with your staff.
  4. Do you comply with all the relevant QC requirements mentioned in the NATA FAD under Clause 5.6.1 on page 14?
- (q) EXTERNAL QUALITY ASSURANCE PROGRAMME PERFORMANCE AND REVIEW (5.6.4 and FAD page 20)
1. Are there any tests in your area for which there is no external QAP?
  2. Do you comply with all the relevant requirements mentioned in the NATA FAD under Clause 5.6.4 on page 20?
- (r) REPORTING OF RESULTS (5.8, 5.5.5, 5.5.7, 5.8.3e, 5.8.3g, 5.8.3k, 5.8.9, 5.8.14)
1. Do you comply with all the relevant requirements mentioned in the NATA FAD under Clause 5.8 and all sub-clauses that they have highlighted, see page 20-22?
- (s) WORK PERFORMED BY REFERRAL LABORATORIES (4.5, 4.5.1, 4.5.4 AND ITS REPORTING (5.8.12)
1. Do you have an up to date list of the laboratories that you refer work to?
  2. When did you last check that they were accredited to ISO 15189 standard to perform this work?

3. What mechanisms are in place to check that there are no transcription errors between the hard copy reports received from the external lab and the version/synopsis that appears in your laboratory computer system?
4. Do you comply with the relevant requirements mentioned in the NATA FAD under Clause 4.5, 4.5.1, 4.5.4 (on page 10) and 5.8.12 (on page 22)?

DISCUSSION

This approach has proved to be a success for all parties concerned with the internal audit process. An unexpected finding has been that because the questionnaire was issued to Technical Managers before the audit many of them took the opportunity to gather the documentation and records in anticipation of the audit. This also speeded up the process of auditing. Technical Auditors have welcomed the innovation as it makes better use of their time and the audit remains relevant to their roles and responsibilities in the laboratory. We envisage applying this audit to every diagnostic pathology discipline in our organization on an annual basis.

ACKNOWLEDGEMENTS

The author would like to acknowledge the support and interest of Dr. Katherine Marsden, Director of Pathology Services and Dr. Peter Vervaart, Principal Scientist in this work.

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