Standard for Sleep Disorders Services

March 2019

Contents

Introduction

The Standard for Sleep Disorders Services has been developed from ISO 15189:2007 and the ASA document Accreditation of Sleep Disorders Services 2009. The Standard has been produced on behalf of the Australasian Sleep Association (ASA) by a Steering Committee with the support of NATA.

This second edition cancels and replaces the first edition (ASA Standard for Sleep Disorders Services 2012), and has been updated to align with ISO 15189:2012. The Standard was revised by the Sleep Disorders Services Accreditation Advisory Committee (AAC) with the support of NATA.

This third edition (March 2019) cancels and replaces the second edition (ASA Standard for Sleep Disorders Services 2016), and has been updated to align with the current paediatric guidelines. The Standard was revised by the ASA Paediatric Working Group and the Sleep Disorders Services Accreditation Advisory Committee (AAC) with the support of NATA.

1. Scope

This Standard contains a set of minimum standards to support the delivery of high quality sleep disorders services in both the public and private sectors. In addition, these standards provide a suitable framework for continuous quality improvement.

The requirements for the competence of services offering sleep disorders services are described in this document hereafter referred to as the Standard for Sleep Disorders Services.

This Standard describes all the requirements that sleep disorders services must comply with, and incorporates the quality management principles from the standard ISO 15189:2012 Medical laboratories – Particular requirements for quality and competence, Australasian Sleep Association (ASA) standards and relevant statutory requirements. This document also provides interpretive detail of the ASA standards.

This Standard is applicable to all sleep disorders services irrespective of size, range of studies or number of staff. It should, however, be noted that it is not possible to set rigid requirements for all aspects of a sleep disorders service's operation. Some flexibility is necessary so that each service's unique situation can be considered.

This Standard is for use by sleep disorders services in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognising the competence of sleep disorders services.

2. Terminology and presentation

It is recognised that not all clinical activities are performed in a 'laboratory'. Accordingly, the expression 'service' is used throughout this document. The term 'service' refers to both sleep disorders services centres and/or laboratories.

The word 'must' is used throughout this document and describes mandatory requirements. The word 'should' is used where guidance is provided but does not preclude other acceptable practices. Where a smaller size font has been used i.e. a 'Note', this indicates a matter of an advisory or informative nature.

3. Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1. accreditation

procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks

3.2. accreditation body

authoritative body that performs accreditation

3.3. adult laboratory

a sleep service which conducts studies on persons who are older than 15 years of age

Note: ***Local transitions from paediatric to adult care can vary.***

3.4. calibration

is an operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (1). Calibrations are normally carried out by an external calibration authority and an endorsed test report is obtained for this work.

3.5. competence

demonstrated ability to apply knowledge and skills

3.6. documented procedure

specified way to carry out an activity or a process that is documented, implemented and maintained

Note: ***The requirement of a documented procedure may be addressed in a single document or by more than one document.***

3.7. paediatric laboratory

a sleep service which conducts studies on persons who are less than 18 years of age.

3.8. quality management system

management system to direct and control an organisation with regard to quality

3.9. quality policy

overall intentions and direction of a service related to quality as formally expressed by management

Note: ***Generally the quality policy is consistent with the overall policy of an organisation and provides a framework for setting quality objectives.***

3.10. referral

a "referral" is a request to a specialist or a consultant physician for investigation, opinion, treatment and/or management of a condition or problem of a patient, or for the performance of a specific examination(s) or test(s) (2)

3.11. technical staff

suitably qualified health professionals including nurses, physiologists, scientists and technologists

3.12. validation

confirmation, through provision of objective evidence, that specified requirements have been fulfilled

Note: ***Confirmation can comprise activities such as:***
- ***comparing a method with a recognised "gold standard" method***
- ***undertaking further tests, demonstrations or calculations***
- ***reviewing documents prior to issue***

3.13. verification

confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

Note: ***Confirmation can comprise activities such as:***
- ***perform alternative calculations***
- ***comparing new design specifications with a similar proven design,***
- ***undertaking tests and demonstrations, and***
- ***reviewing documents prior to use.***

It is also an examination of the condition of an artefact i.e. the reference of known value, to determine that it has not been adversely affected by constant use. By performing a verification on an instrument, a facility is able to determine if the instrument has changed since its last calibration.

4. Management requirements

4.1. Organisation and management responsibility

4.1.1. The service must be an entity or part of an entity that can be held legally responsible for its activities.

4.1.2. The service must be organised and administered to meet its objectives and the needs of the population it serves.

- **(a)** The service's resources (staffing, equipment, sites and finances) must be sufficient to meet its workload without compromising the minimum standards set in this document and in the ASA Guidelines for Sleep Studies in Adults (3) and Adult and Paediatric Sleep Curricula (4). Sufficient medical, technical, nursing and administrative staff must be employed to adequately meet service needs. This will depend on the workload, organisation, patient complexity and type of equipment and circumstances of the individual service.
- **(b)** Regular scheduled meetings must occur at appropriate intervals for the purposes of service provision planning, quality assurance, clinical review, in-service education and, where applicable, research. There must be records of these meetings. Action statements are encouraged where applicable.

4.1.3. The service must meet the relevant requirements of this Standard when carrying out work in its permanent facilities, and/or at sites outside the permanent facilities for which it is responsible.

4.1.4. The relationship(s) of the service to its host institution (if applicable) and to related services must be appropriate to the discharge of its responsibilities. These relationships must be specified and clearly defined. There should be evidence of commitment by the host institution to its support.

- **(a)** Where the service operates in a teaching hospital environment, it must offer education programmes for undergraduates and postgraduates and have a commitment to research.
- **(b)** A commitment to research can be demonstrated by reference to current projects, recent presentations (abstracts) and publications.

4.1.5. A sleep disorders service must:

- **(a)** have managerial, technical and administrative staff who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system.
- **(b)** have arrangements to ensure that its managerial, technical and administrative staff are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.
- **(c)** have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement and operational integrity.
- **(d)** have arrangements in place to ensure that where potential conflicts in competing interests may exist, they must be openly and appropriately declared.
- **(e)** have policies and procedures for protecting client's confidential information including procedures for protecting hard copy, electronic storage media and transmitted results from unauthorised access.

(f) have a defined organisation and management structure:

i) There must be a medical director who is a sleep physician responsible for overall clinical standards and development of policies governing the services provided. The responsibilities of the medical director must include professional, scientific, consultative, advisory, organisational, administrative, research and educational matters relevant to the services offered. These should be ratified through the governance structure of the host institution as necessary. The sleep physician will adhere to the Code of Professional Behaviour as defined by the Royal Australasian College of Physicians (5). In the case where services are provided to children (less than or equal to 15 years), there must be an identified Paediatric sleep physician with responsibilities to oversee services provided to children.

ii) The duties and responsibilities of the medical director must be documented.

iii) There must be clear, documented lines of accountability/responsibility between the medical director and all staff members. These must represent the actual manner in which the service is organised, be regularly reviewed and readily available to all staff.

iv) A senior scientist/technologist must be appointed to take responsibility for the technical aspects of the service including quality assurance, calibration and/or verification, equipment safety and maintenance and rostering of scientific/technical staff.

(g) The organisation and management structure of the service may vary according to the type of activity(ies) offered but for a service incorporating a sleep laboratory:

i) There must be sufficient sleep staff with direct presence and involvement to supervise the activities conducted by the service (see Note 1 below).

ii) For sleep studies, rostering must allow for the following conditions:

- A technologist must be in attendance throughout the study (see Note 1 and 2 below)
- Adequate time for preparation of the patient and data collection and analysis must be allocated (see Note 3 below). Case mix must be taken into account when studies of extra complexity are undertaken, for example: non-invasive or invasive ventilation trials, or titration of CPAP in patients with respiratory failure. Rosters must allow for equipment verification and maintenance, preparation and processing of reports, and in-service education/professional development.

Note 1: ***In a freestanding service, (i.e. a laboratory located away from a hospital that has emergency back-up) two (2) staff trained in emergency procedures should be in attendance for the duration of the study to ensure safety and security of patients and staff.***

Note 2: ***"Technical staff must be in attendance throughout the study". Short absences from the site (e.g. toilet breaks taken away from the laboratory) during a routine diagnostic or CPAP titration study may be covered by staff who have limited technical expertise in sleep studies but nevertheless are able to attend to the needs of the patient and are trained in emergency procedures. More prolonged absences from the site (e.g. meal breaks), or short absences during complex studies (e.g. NIV trials), should be covered by other technical staff.***

Note 3: ***Adequate staff time must be allowed for preparation of the patient, data collection and analysis:***
In an adult service, at least 45 minutes for the preparation of each patient prior to study, an hour for completion of duties following termination of the study; in general, a ratio of no less than one (1) technologist to three (3) patients overnight; and an average of at least two (2) hours analysis must be allowed for each study.

In a paediatric service, 1-2 hours for the preparation of each patient prior to the study, an hour for completion of duties following termination of the study; in general a ratio of no less than one (1) technologist to two (2) patients overnight (a higher staffing ratio may be required for more complex patients/studies); and an average of four (4) hours analysis

must be allowed for each study. Rosters should allow study commencement at, or close, to the child's normal bed time.

(h) For services providing sleep studies only for diagnostic purposes:

i) A sleep physician must be appointed to take overall responsibility for the clinical aspects of the service including quality assurance of medical reporting, incoming referrals and ensuring that appropriate onward referral is made.

ii) There must be clear, documented lines of accountability/responsibility between the medical director and all staff members. These must represent the actual manner in which the service is organised, be regularly reviewed and readily available to all staff.

iii) A senior scientist/technologist must be appointed to take responsibility for the technical aspects of the service including quality assurance, signal verification, equipment safety and maintenance and rostering of scientific/technical staff. Rosters must also allow for equipment verification and maintenance, preparation and processing of reports, and in service education/professional development.

(i) specify through the use of an endorsed organisational chart the responsibility, authority and interrelationships of all staff who perform work affecting the quality of the services provided.

(j) provide adequate supervision of all staff involved in the provision of tests or services. Specific requirements for supervision of medical, scientific and technical staff are described in Section 5.1.

(k) have senior technical/scientific staff with overall responsibility for the management of the technical operations of the service. Qualifications required for senior technical/scientific staff are described in section 5.1.

(l) appoint a member of staff as quality manager with responsibility for the quality management system. The quality manager must have direct access to the highest level of management at which decisions are made on service policy or resources.

(m) appoint deputies for key managerial staff/positions.

Note: ***Individuals may have more than one function and it may be impractical to appoint deputies for every function.***

(n) ensure that its staff are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

4.1.6. Service management must ensure that appropriate communication processes are established within the service and that communication takes place regarding the effectiveness of the management system. Records must be kept of these communications.

4.2. Quality management system

4.2.1. The service must establish, implement and maintain a documented quality management system which:

(a) covers all activities performed at the service's permanent site and at sites located away from its permanent facilities (for example, home based services);

(b) defines the type and extent of the services provided, such as satellite services and home studies, and be appropriate to the size and scope of the service; and

(c) must be communicated to, understood and implemented by all staff.

4.2.2. The service must maintain a manual which specifies its organisation and administration, staffing and direction, policies and procedures, staff development and education, sites and equipment, and quality assurance programme. The documented policies and procedures must reflect current knowledge and practice in the conduct of a sleep disorders service.

The integrity of the management system must be maintained at all times, including when changes to the service occur, ensuring the quality of all work performed.

4.2.3. The service's goals and objectives must be specified in a quality policy statement. The quality policy is issued under the authority of senior management, and includes:

(a) management's commitment to good professional practice and compliance with these Standards; and
(b) continual improvement of the effectiveness of the quality management system and to the quality of all services provided.

4.2.4. Senior management must establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organisation. The quality objectives must be measureable and consistent with the quality policy.

4.2.5. A quality manual (however named) must describe the quality management system and the structure of the documentation used in the quality management system. The quality manual must include or make reference to the supporting procedures and include the quality policy statement. It must outline the structure of the documentation in the quality management system and reflect roles and responsibilities for technical and quality management.

The service must establish and maintain a quality manual that includes:

(a) the quality policy or makes reference to it;
(b) a description of the scope of the quality management system;
(c) a presentation of the organisation and management structure of the service and its place in any parent organisation;
(d) a description of the roles and responsibilities of senior management (including medical director, senior technical/scientific staff and quality manager) for ensuring compliance with this Standard;
(e) a description of the structure and relationship of the documentation used in the quality management system;
(f) the documented policies established for the quality management system and reference to the managerial and technical activities that support them.

4.2.6. All staff must have access to and be instructed on the use and application of the quality manual and the supporting documents.

4.3. Document control

4.3.1. General

The service must define, document and maintain procedures to control all documents and information (internally generated or from external sources) that form its management system documentation.

Note: ***In the context of a sleep disorders service "document" could be policy statements, procedures, equipment manuals, computer software and templates, calibration records, forms, informational documents and educational guides. These may be on various media, whether hard copy or electronic, and they may be digital, analogue, photographic or written.***

4.3.2. Document approval and issue

4.3.2.1. All documents issued to service staff as part of the management system are reviewed and approved by authorised staff prior to issue. A master list, or equivalent document, identifying the current revision status and distribution of documents must be maintained.

4.3.2.2. Procedures must be adopted to ensure that:

(a) only current authorised versions of appropriate documents are available for use at relevant locations;
(b) documents are periodically reviewed, revised when necessary, and approved by authorised staff;
(c) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use; and
(d) obsolete documents retained for legal or knowledge preservation purposes are suitably marked.

4.3.2.3. All documents relevant to the management system must be uniquely identified, to include:

(a) title;
(b) edition or current revision date, or revision number, or all of these;
(c) page number to total number of pages (e.g. "Page 1 of 5", "page 2 of 5"); and
(d) authority for issue.

4.3.3. Document changes

4.3.3.1. If the service's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments must be defined. Amendments must be clearly marked, initialled and dated. A revised document must be formally re-issued as soon as practicable.

4.3.3.2. Procedures must be established to describe how changes to documents maintained in computerised systems are to be made and controlled.

4.4. Review of appropriateness of referral and patient preparation

4.4.1. The sources and types of referrals to the service must be relevant to the services provided. Each patient must have had an appropriate clinical evaluation prior to a study. While the service can perform tests referred by other clinicians without direct consultation with the patient, one of the reporting consultant medical staff of the service must obtain and review sufficient information prior to the test to ensure that it is appropriate to the patient's condition.

(a) A sleep service must conduct testing only after the necessity for such has been determined and appropriately documented by a qualified sleep physician, consultant respiratory physician or a medical practitioner working under his/her supervision.
(b) Polysomnography and other testing must only be performed for those disorders of sleep for which it is of established clinical value.
(c) In the case of children, each patient must be evaluated by a paediatric sleep physician prior to a study. The evaluation includes considering whether the proposed sleep study environment is safe and appropriate for that child.

4.4.2. Deviations from or additions to the referral for services may be necessary from time to time but must be documented in service records and in the report to the referring medical practitioner.

4.4.3. Where a sleep service determines that further assessment is required for appropriate diagnosis or testing, e.g. referral from a home sleep study facility to a facility conducting full attended polysomnography, the service must deem this to be subcontracted and assume responsibility for the quality of the work of the subcontractor. An alternative appropriate arrangement is for the referring doctor to re-refer the patient to the other service provider.

Where a sleep service delegates some of its activities to an external provider, the service must deem this to be subcontracted and assume responsibility for the quality of the work of the subcontractor. (See section 4.5)

4.5. Subcontracting or onward referral of tests and services

This clause applies in those cases where a service is required to subcontract part of its normal service (e.g. due to temporary incapacity, excess workload or specialised services) or where a service subcontracts due to the need for further expertise and the results of the subcontracted service(s) are incorporated into the service's test reports [see Note].

4.5.1. Services are encouraged to develop a broad range of skills in the management of sleep disorders. Where this is limited (e.g. to sleep breathing disorders) the service must have established processes for onward referral of patients to physicians with other specialities with a common interest in sleep disorders to ensure that clinical problems are directed to clinicians with relevant expertise and to facilitate advancement in clinical standards. (e.g. management of a patient referred with excessive somnolence to a "respiratory" sleep disorders service in whom sleep disordered breathing is subsequently excluded as a cause). Onward referral is not considered sub-contracting.

4.5.2. Where a service enters a subcontracting arrangement, the service must advise the referring doctor of the subcontracting or referral arrangements in writing and, where appropriate, gain the approval of the referring doctor for ongoing management of the patient.

4.5.3. Where a sleep study or service is subcontracted, the service is responsible for the subcontractor's work.

4.5.4. The sleep service must maintain a register of all subcontractors that it uses for tests and record the evidence of compliance with this Standard for the work in question.

4.5.5. Services that engage third parties for the purpose of analysis or reporting of studies must demonstrate a quality assurance system pertaining to the activities of the third party. This quality assurance system must include:

- **(a)** a documented program of proficiency testing which measures the capability of its technologists and the reliability of its results;
- **(b)** participation in a proficiency testing program that is provided by external test providers, where available;
- **(c)** processes to evaluate and correct non-conforming work; and
- **(d)** a well-defined system to communicate and resolve issues of non-conformance with the third party.

In addition, participation in a regular peer reviewed physicians concordance process by the third party should be considered, with documentary evidence of such a process.

Note: ***Subcontracting refers to the situation in which a service has an agreement with another entity to provide services on its behalf. Examples are:***

- ***Where a service providing home diagnostic services has an exclusive agreement with another service providing attended services to provide an in laboratory service for an appropriate patient.***
- ***Where a service, which undertakes the clinical management of patients, has established a contractual arrangement with a provider of CPAP equipment to supply and manage the technical aspects of the CPAP therapy.***
- ***Referral to another service to take over one or more aspects of the patient's care is considered to be onwards referral rather than subcontracting.***
- ***Where a sleep physician refers a patient for further medical evaluation or treatment this constitutes a new service with the sleep physician as customer and should not be treated as subcontracting.***

4.6. External services and supplies

4.6.1. The service management must define and document its policies and procedures for the selection, evaluation and use of purchased external services, equipment and consumable supplies that affect the quality of its services.

4.7. Feedback

4.7.1. The service must establish a relationship with referrers that encourages two-way communications and encourages feedback both positive and negative.

> ***Note:*** ***Services are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way (e.g. surveys).***

4.8. Resolution of complaints

4.8.1. The service must have a documented procedure for the management of complaints or other feedback received from clinicians, patients, service staff or other parties. Records must be maintained of all complaints and of investigations and corrective actions taken by the service.

4.9. Identification and control of nonconformities

4.9.1. Service management must have a documented procedure to be implemented when it detects that any aspect of the service's activities do not conform to the agreed requirements of its management system or those of the referring clinician. These must ensure that:

- **(a)** staff responsible for problem resolution are designated;
- **(b)** the actions to be taken are defined;
- **(c)** the medical significance of the nonconforming activities is considered and, where appropriate, the referring clinician/ requestor informed;
- **(d)** studies are halted and reports withheld as necessary;
- **(e)** corrective action is taken immediately;
- **(f)** the reports of nonconforming studies already released are recalled or appropriately identified, if necessary;
- **(g)** the responsibility for authorisation of the resumption of activities is defined; and
- **(h)** each episode of nonconformity is documented and recorded, with these records being reviewed at regular intervals by service management to detect trends and initiate preventive action.

> ***Note:*** ***Nonconforming studies or activities occur in many different areas and can be identified in many different ways, including clinician complaints, quality control indications, equipment verifications, checking of consumable materials, staff comments, studies, reporting, service management reviews, internal and external audits, and external assessments.***

4.10. Corrective action

4.10.1. The service must take corrective action to eliminate the cause(s) of nonconformities. Corrective actions must be appropriate to the effects of the nonconformities encountered.

4.10.2. The service must have a documented procedure for:

- **(a)** reviewing nonconformities;
- **(b)** determining the root causes of nonconformities;
- **(c)** evaluating the need for corrective action to ensure that nonconformities do not recur;
- **(d)** determining and implementing corrective action needed;
- **(e)** recording the results of corrective action taken; and
- **(f)** reviewing the effectiveness of the corrective action taken.

Note: ***Action taken at the time of the nonconformity to mitigate its immediate effects is considered "immediate" action. Only action taken to remove the root cause of the problem that is causing the nonconformities is considered "corrective" action.***

4.11. Preventive action

4.11.1. The service must determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems.

4.11.2. The service must have a documented procedure for:

- **(a)** reviewing service data and information to determine where potential nonconformities exist;
- **(b)** determining the root cause(s) of potential nonconformities;
- **(c)** evaluating the need for preventive action to prevent the occurrence of nonconformities;
- **(d)** determining and implementing preventive action needed;
- **(e)** recording the results of preventive action taken; and
- **(f)** reviewing the effectiveness of the preventive action taken.

Note: ***Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints.***

4.12. Continual improvement

4.12.1. The service must continually improve the effectiveness of its quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.12.2. Procedures must be in place to evaluate the quality of the service provided, correct identified problems, and advance the service's standards.

4.13. Quality and technical records

4.13.1. General Records

4.13.1.1. The service must have a documented procedure for the identification, collection, indexing, access, filing, storage, maintenance and safe disposal of quality, technical and patient records. Record management procedures must apply to all forms of media such as electronic or paper copy.

4.13.1.2. Retention times must be established and documented for all record types in accordance with legislation or contractual obligations, including raw data, video and audio-visual recordings and final reports. In the case of equipment records, the retention period will be the life of the equipment plus seven (7) years or other legislative requirement (whichever is the longer period).

4.13.1.3. All records must include the identity of the person making the record. It is recognised that a number of staff may be involved in sleep study processes or other procedures. It is the service's responsibility to identify the critical step(s) in the procedure and ensure that the identities of the staff concerned are recorded.

Note: ***Some examples of records required by these standards include sleep study records, internal audit records, management review records, complaints, staff training records, quality assurance records (including quality control, proficiency testing, and corrective action), equipment maintenance and calibration records.***

4.13.1.4. All records must be held secure and in confidence.

4.13.2. Technical and patient records

4.13.2.1. The records system must include a copy of each referral and report relating to the performance of the study including details such as the endorsement (if applicable) and identification of the person who authorised the report.

4.13.2.2. The records system must include the following:

- **(a)** The referral which includes relevant clinical details;
- **(b)** a minimum of three patient identifiers;
- **(c)** an identifier to uniquely identify a study or service;
- **(d)** the date of study or examination;
- **(e)** the type of study or service;
- **(f)** original study observations and calculations;
- **(g)** the identity of the person performing various components of the study or service; and
- **(h)** any other information relevant to the study or service.

4.13.2.3. Record retention times will vary by the nature of the record. Final reports of the study must be retained with patient health records, either in hard copy or electronic form, for the period required by appropriate authorities for health records.

4.13.2.4. It is preferable that detailed polysomnography data be retained for the same duration as health records but at a minimum it must be retained until final reporting has occurred and appropriate treatment of the patient has been implemented.

4.13.2.5. Video and audio recordings taken during the overnight sleep study must be retained until final reporting of the sleep study is complete. Where a detailed overnight recording, video or audio is critical to understanding or demonstrating the result of the study, for example video of a movement disorder, the relevant record must be retained for the duration of the patient health record (see Note).

> ***Note:*** ***For audio and video signal processing procedures, within the limits of known data storage media, organisational procedures should be developed to ensure that the media bearing the images or their data does not degrade and that the medium can be replayed in the future when newer equipment and technology has developed***

4.13.2.6. As far as practicable, all records must be indelible and data and observations recorded in such a manner that prevents amendment or loss of the original.

4.13.2.7. When mistakes occur in records, each mistake must be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records must be signed or initialled by the person making the correction and must also include the date the change was made. In the case of records stored electronically, equivalent measures must be taken to avoid loss or change of original data.

4.14. Evaluation and Audits

4.14.1. The service must plan and implement the evaluation and internal audit processes needed to:

- **(a)** demonstrate that the pre-study, study, post-study and supporting processes are being conducted in a manner that meets the needs and requirements of referrers and patients;
- **(b)** ensure conformity to the quality management system; and
- **(c)** continually improve the effectiveness of the quality management system.

4.14.2. The results of evaluation and improvement activities must be included in the input to the management review.

4.14.3. Authorised staff must periodically review the types of sleep studies provided by the service to ensure that they are clinically appropriate for the referrals received.

4.14.4. The service must seek information relating to whether the service has met the needs and requirements of referrers and patients. Records must be kept of information collected and actions taken.

4.14.5. Service management must encourage staff to make suggestions for the improvement of any aspect of the service. Suggestions must be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management must be maintained.

4.14.6. The service must conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-study, study, and post-study processes:

(a) conform to the requirements of this Standard and to requirements established by the service; and
(b) are implemented, effective and maintained.

*Note: **The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The service may decide to focus on a particular activity without completely neglecting the others.***

4.14.7. Audits must be conducted by staff trained to assess the performance of managerial and technical processes of the quality management system. The audit programme must take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods must be defined and documented.

4.14.8. Selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Auditors must, wherever resources permit, be independent of the activity to be audited.

4.14.9. The service must have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records.

4.14.10. Staff responsible for the area being audited must ensure that appropriate action is promptly undertaken when nonconformities are identified. Corrective action must be taken without undue delay to eliminate the causes of the detected nonconformities.

4.14.11. The service must evaluate the impact of procedures and potential failures on study results as they affect patient outcomes, and must modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

4.15. Management review

4.15.1. General

Service management must review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care.

4.15.2. Review input

The input to management review must include information from the results of evaluations of at least the following:

(a) the periodic review of referrals, and suitability of procedures;
(b) assessment of referrer and patient feedback;
(c) staff suggestions;
(d) internal audits;
(e) risk management;

(f) use of quality indicators;
(g) reviews by external bodies or assessors;
(h) results of participation in external proficiency testing;
(i) monitoring and resolution of complaints;
(j) performance of suppliers;
(k) identification and control of nonconformities;
(l) results of continual improvement including current status of corrective actions and preventive actions;
(m) follow-up actions from previous management reviews;
(n) changes in the volume and scope of work, staff, and premises that could affect the quality management system; and
(o) recommendations for improvement, including technical requirements.

4.15.3. Review activities

The review must analyse the input information for causes of nonconformities, trends and patterns that indicate process problems.

This review must include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The quality and appropriateness of the service's contribution to patient care must, to the extent possible, also be objectively evaluated.

4.15.4. Review output

The output from the management review must be incorporated into a record that documents any decisions made and actions taken during management review related to:

(a) improvement of the effectiveness of the quality management system and its processes;
(b) improvement of services to users; and
(c) resource needs.

Note: ***The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a quality management system is being established.***

4.15.5. Findings and actions arising from management reviews must be recorded and reported to service staff.

4.15.6. Service management must ensure that actions arising from management review are completed within a defined timeframe.

5. Technical Requirements

5.1. Staff

5.1.1. The service management must ensure that all staff members are appropriately qualified for their tasks by education, training, and/or experience. When staff are undergoing training, appropriate supervision must be provided.

(a) The service must ensure that all clinical and technical staff are appropriately trained in basic life support, and that a basic level of competence is maintained and evaluated annually. In the case of paediatric laboratories, specific training in paediatric basic life support relevant to the age range and case mix of the patients studied is required.

(b) A staff appraisal system must be in operation that includes a written report, the staff member involved is made aware of the contents of the report, and a plan to address deficiencies is defined.

(c) Programs must be in place to orientate new staff, and for continuing education of existing staff taking into account results of performance appraisal, service objectives and quality assurance activities. Staff must have access to education programmes that maintain and develop their knowledge and skills, and opportunities must be made available for senior staff to attend relevant professional meetings (state, national, international).

5.1.2. Roles and responsibilities of staff members must be specified in job descriptions.

(a) The senior medical staff must have specific, detailed training in sleep disorders and meet the criteria set by RACP and ASA guidelines (3) (4).

(b) The Medical Director must be present on site for at least twelve (12) hours/month and lead and participate in regular unit staff meetings with technical staff

(c) Technical staff, to be able to function in a supervisory capacity under medical direction, must have a minimum of two (2) years' experience in a relevant age-equivalent sleep disorders service and a tertiary degree in biological or physical sciences, or equivalent qualification. In larger or more complex services, the Scientist/Technologist in Charge should have completed the Registered Polysomnographic Technologist™ (RPSGT) qualification (see Note) or equivalent. The Scientist/Technologist in Charge must be on site for at least twenty (20) hours per week for a full-time service.

Note: ***The Registered Polysomnographic Technologist™ (RPSGT) is an internationally recognised credential representing the highest certification in the field for the health care professionals who clinically assess patients with sleep disorders. These qualifications are administered by the Board of Registered Polysomnographic Technologists™ in the USA.***

(d) For employment as technical staff, basic qualifications will depend on the local regulatory requirements for classification as either scientific or technical staff (e.g. a tertiary degree). Staff will acquire skills either through accredited tertiary training and/or "on the job" training and mentoring from a suitably qualified senior sleep scientist/technologist. In smaller services where this "on the job" training is not available, linkages with another service should be established to provide this training and mentoring role.

(e) For any given paediatric case mix, it may be appropriate and advantageous to utilise staff with backgrounds in nursing in paediatric services for some technical staff roles. Where this occurs the nursing staff must have undergone appropriate training for their technical role i.e. equivalent to other technical staff performing that role.

5.1.3. Training and competence

(a) Training records must be maintained that are sufficiently detailed to demonstrate training in relevant aspects of the service. Proof of qualifications, membership of

professional societies and hours of attendance at the service may be requested as part of the assessment process. Evidence of recognition of overseas qualifications must be available. All staff working in a paediatric sleep service require specific training in working with infants, children and young people, commensurate with the duties they perform.

(b) Following appropriate training the service must assess the competence of each person to perform assigned tasks according to established criteria.

(c) Ongoing competence must be assessed periodically.

Note: ***The records are not required to be stored in the service, but can be maintained in other specified locations, providing they remain accessible as needed.***

5.2. Accommodation and environmental conditions

5.2.1. Adequate sites and equipment must exist for the service to meet its objectives and comply with statutory requirements.

Paediatric laboratories must have appropriate facilities to care for sick children or children with complex conditions (6)

The site must meet the standards of safety consistent with State occupational health and safety regulations, including infection control, handling of gas cylinders, fire and electrical safety and general safety procedures. Electrical supply to the monitoring room and the bedrooms of the service must be, at a minimum, at body protected standard (class B (AS specification)). Monitoring equipment must be listed on the Australian Register of Therapeutic Goods (ARTG) (7) as a medical device and the public summary must indicate that the equipment is suitable for use.

The service must be identified by signage, telephone and stationery so that it can be easily found and/or accessed.

(a) Attended services

i) The service must have a reception area and waiting room that conform to generally accepted standards for medical suites in size, appearance, privacy, lighting and furniture.

ii) The sleep service must have comfortably furnished bedrooms conducive to sleep and of sufficient size (minimum approximately 2.5 x 3.5 metres) to allow access in an emergency, with adequate lighting, sound-proofing, exclusion of light during the study, air conditioning, emergency oxygen and suction, resuscitation equipment and security.

iii) The rooms must conform to local regulations with respect to entrances, exits and fire precautions.

iv) There must be a separate bedroom for each patient with comfortable bedding, storage for patient personal effects and adequate lighting (including for reading).

v) In the case of paediatric laboratories the bedroom must be child-safe and age-appropriate, with age-appropriate bedding for each patient. Sites for a parent to sleep in the child's bedroom must be available. (6)

vi) There must be conveniently located and adequate toilet and shower sites.

vii) The monitoring room must be located in close proximity to the bedrooms and a patient call system must be available from bedrooms to the monitoring room.

viii) Attending staff must be able to visualise/monitor the live recording of all physiological signals for all studies simultaneously.

ix) For positive airway pressure (titration) studies, staff must be able to adjust device settings from the monitoring room.

x) The facility must have office space with adequate space, furniture, lighting and privacy for analysis of sleep studies.

xi) There must be adequate storage space for the safe and secure storage of records, consumables and equipment.

xii) Provisions must be made for advice and medical emergencies. These should include an on-call roster for medical staff, Basic life support BLS training for all clinical and technical staff, availability of resuscitation equipment, oxygen and suction and easy access to the service and the patient.

xiii) In the case of paediatric laboratories, staff trained in paediatric BLS appropriate to the age of the patient must be available on-site for the duration of the study, and there must be clearly documented protocols for managing paediatric medical emergencies. A complete range of age-appropriate resuscitation equipment (including automated external defibrillation (AED)) must be available in the service for the duration of the studies, including oxygen and suction at the bedside.

xiv) Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies (Fire and Safety).

xv) The sites must be regularly cleaned.

xvi) The facility must provide adequate access to bathrooms, to a supply of drinking water and storage of personal equipment for staff.

(b) Home based services

i) The service must have a reception area and waiting room that conform to generally accepted standards for medical suites in size, appearance, privacy, lighting and furniture.

ii) The service must have appropriately furnished private room(s) in which to set-up patients for their home study. The room(s) should be an adequate size for the function with adequate lighting, air conditioning and security and appropriately furnished for the activity.

iii) The rooms must conform to local regulations with respect to entrances, exits and fire precautions.

iv) The facility must have office space with adequate space, furniture, lighting and privacy for analysis of sleep studies.

v) There must be adequate storage space for the safe and secure storage of records, consumables and equipment.

vi) Provisions must be made for medical advice and medical emergencies. These should include an on-call roster for medical staff, BLS training for all staff and a protocol for dealing with a patient who requires medical treatment.

vii) Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies (Fire and Safety).

viii) The sites must be regularly cleaned.

ix) The facility must provide adequate access to bathrooms, to a supply of drinking water and storage of personal equipment for staff.

5.3. Equipment

Note: ***For the purposes of this Standard, service equipment includes hardware and software of instruments, sensors, and measuring systems.***

5.3.1. General Equipment

The service must have a documented procedure for the selection, purchasing and management of equipment.

(a) The service must operate with all equipment capable of performing polysomnography consistent with established standards (8) (9) (10) (11) (12), including the relevant ASA guidelines (3).

Polysomnography software must allow for the recording and full disclosure of the raw signals

(b) Audio-visual monitoring of patients (by infrared or low light video) must be recorded for paediatric patients and is desirable for adult patients.

(c) The service must replace equipment as needed to ensure the quality of procedure results.

(d) Each item of equipment must be uniquely labelled, marked or otherwise identified.

(e) In paediatric laboratories, the sensors and other equipment interfaced with the patient must be appropriately sized and a range of sizes must be available for each study.

5.3.2. Equipment acceptance testing

The service must verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any procedures concerned.

Note: ***This requirement applies to equipment owned by the service and equipment on loan.***

5.3.3. Equipment instructions for use

Equipment must be operated at all times by trained and authorized staff.

Current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, must be readily available.

The service must have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration.

5.3.4. Equipment verification

5.3.4.1. The service must have a documented procedure for the verification or checking of polysomnography equipment and sensors as well as other equipment that directly or indirectly affects results. This procedure must include:

(a) taking into account conditions of use and the manufacturer's instructions;

(b) verifying the required measurement accuracy and the functioning of the measuring system (Note1) at defined intervals (Note 2);

(c) safeguards to prevent adjustments or tampering that might invalidate results;

(d) the date the verification was performed and the results of each verification must be recorded; and

(e) results of each verification must be monitored for trends that may indicate equipment drift or malfunction. Action must be taken and recorded where required.

5.3.4.2. Prior to each study a biological signal verification must be done and recorded on the patient file. This requires a patient to perform a series of physiological manoeuvres to verify that equipment is functioning. (Note 3)

5.3.4.3. The service must have a documented process in place to verify signal quality when biological signal verification cannot be performed (e.g. paediatric).

Note 1: ***The fidelity of EEG, EOG and EMG signals is dependent on polysomnogram gains, filters and response times that should be verified against an externally applied square wave voltage of appropriate frequency and voltage.***
Quantitative signals where polysomnogram gains should be adjusted against a standard include pulse oximetry, sound level meters, positive airway pressure, transcutaneous carbon dioxide monitors and position sensors.
Qualitative signals, which should be verified for satisfactory performance, include nasal pressure sensors, oronasal thermal sensors, respiratory inductive plethysmographic sensors, microphones and video monitors.
Standard physical verifications should be used wherever possible.

Note 2: ***Equipment verification intervals***
Services are responsible for ensuring that all equipment used produces consistent and reliable data, and where appropriate, traceable results.
When establishing an equipment verification program, consideration must be given to the following:

- ***history of stability;***
- ***frequency of use;***
- ***accuracy required;***
- ***requirement for traceability of measurement;***
- ***ability of staff to perform in-house verifications;***
- ***satisfactory participation in proficiency testing programs.***

Note 3: ***For the biological signal verification, all signals should be checked but in particular EEG, EOG, EMG, leg EMG, respiration and sound must be included.***

5.3.5. Equipment maintenance and repair

(a) The service must have a documented program of preventive maintenance which, at a minimum, follows the manufacturer's instructions.

(b) Equipment must be maintained in a safe working condition and in working order. This must include examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical and biological materials by authorised persons.

(c) Whenever equipment is found to be defective, it must be taken out of service and clearly labelled. The service must ensure that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria. The service must examine the effect of any defects on previous studies and institute immediate action or corrective action (see 4.10).

(d) The service must take reasonable measures to decontaminate equipment before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

(e) When equipment is removed from the direct control of the service, the service must ensure that its performance is verified before being returned to use.

5.3.6. Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment must be investigated and reported to the manufacturer and appropriate authorities, as required.

5.3.7. Equipment records

Records must be maintained for each item of equipment that contributes to the performance of studies.

(a) These equipment records must include, but not be limited to, the following:

i) identity of the equipment;
ii) manufacturer's name, model and serial number or other unique identification;
iii) contact information for the supplier or the manufacturer;
iv) date of entering into service;
v) location;
vi) condition when received (e.g. new, used or reconditioned);
vii) manufacturer's instructions;
viii) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the service;
ix) maintenance carried out and the schedule for preventive maintenance;
x) equipment performance records that confirm the equipment's ongoing acceptability for use; and
xi) damage to, or malfunction, modification, or repair of the equipment.

(b) These records must be maintained and must be readily available for the life of the equipment plus seven (7) years or other legislative requirement (whichever is the longer period).

5.3.8. Consumables

The service should have a documented procedure for the storage and inventory management of consumables.

5.4. Pre-study procedures, including handling of patient referrals

5.4.1. Procedures must exist for the prompt, efficient handling of patient referrals, clinical assessment, documentation, communication with the referring doctor, and protection of patient confidentiality, all of which are consistent with good professional practice. Prior to the sleep study, patients must be clinically evaluated, or the need for the test must be clearly established. On presentation to the sleep service, administrative procedures must be implemented to capture clinical or demographic information in the event that inadequate information is received prior to presentation.

5.4.2. The service must have processes in place to cope with the demand for its services. Where demand for services exceeds capacity, the service must have a system for prioritizing referrals, which includes timeframes for categorising and performing urgent studies and implementation of treatment. This should include a process for escalation of urgent referrals.

For example, in adults, urgent cases may include:

- Patients with suspected significant OSA working in occupations where safety is critical should be investigated within 4 weeks of referral to the service. Examples of such an occupation may be a bus driver or a crane operator or other occupations where the OSA condition potentially places a risk to themselves or others in the community; or
- Patients with significant comorbidities such as unstable ischemic heart disease or heart failure, hypercapnia respiratory failure, pulmonary hypertension or neuromuscular disease where sleep hypoventilation is suspected.

5.4.3. The service must have processes in place to assess the suitability for and appropriateness of the study requested for the patient on presentation for their sleep study. Where clinical circumstances are such that the study requested may need to be varied, there must be systems in place for the scientific/technical staff to obtain appropriate clinical input from a medically trained person.

5.4.4. Patients must be positively identified upon presentation to the service using a minimum of three identifiers.

5.4.5. Patients and their associated records (worksheets etc.) must be uniquely identified during all stages of the study.

This must be achieved by the either

- use of a unique service number; or
- patients and associated records are uniquely identified by the use of three patient identifiers (e.g. patient's name, date of birth and medical record number/ service number, or address).

5.5. Sleep Disorders Services Processes

5.5.1. General

The quality of sleep studies and/or activities may be influenced by many factors including staff, accommodation and environmental conditions, methods and equipment. The quality of the service may be influenced by additional factors such as the referral, review and treatment processes in place and the linkages and communication with other health professionals.

The exact manner in which the technical requirements are applied will depend upon the nature of the service provided. These are explained further in sections 5.3 and 5.4. However, irrespective of the nature of the service, the general intent of technical requirements of Section 5 must be met by any service seeking accreditation.

In general, sleep studies should be of at least eight (8) hours duration. With the exception of multiple sleep latency testing (MSLT) and maintenance of wakefulness (MWT's), nap studies are not indicated for the diagnosis of sleep disorders.

NOTE: ***Nap studies may be deemed appropriate in patients under 12 months of age, as determined by the Paediatric Sleep Physician.***

5.5.1.1. The service must have documented policies and procedures which describe the escalation of patient care and call for emergency assistance.

5.5.2. Methods and method validation

The methods for the conduct of sleep studies must be consistent with recognized standards, including the relevant ASA guidelines (3) and, where applicable, paediatric guidelines (14). Types of sleep studies performed and the parameters measured must be specified.

5.5.3. Attended studies methods

5.5.3.1. Sleep studies must allow full disclosure of the raw signals, which must be adequately labelled and verified. The equipment must conform to specifications (linearity, sensitivity, frequency response, signal to noise ratio, stability) that ensure collection of meaningful, interpretable results.

5.5.3.2. Methods for the analysis of sleep studies must be consistent with recognized standards, including the relevant ASA guidelines (3). Scoring and interpretation of the data should conform to the AASM Manual for the Scoring of Sleep and Associated Events (15) in conjunction with ASA Guidelines for Sleep Studies (3). In the case of paediatric laboratories, scoring and interpretation should be age appropriate (14) (16) and conform to the AASM Manual for the Scoring of Sleep and Associated Events (15) and the ASA/ ASTA addendum document (17).

5.5.3.3. The methods for MSLT, MWT and related studies must be consistent with established standards (8) (9) (10) (11) (12), including the relevant ASA guidelines (3). It is expected that sleep services must able to perform MSLT's and MWT's or have an affiliation with a service with that capacity, to enable the further investigation and diagnostic refinement of the sleepy patient e.g. to confirm or exclude the presence of pathological daytime sleepiness in difficult cases, or to assist in the diagnosis of narcolepsy (Note 1).

5.5.3.4. The service must have established evidence-based methods for the study of patients using positive airway pressure (PAP) devices. The service must have appropriate methods for titration and efficacy studies. A titration study is used to determine required therapy settings. Efficacy studies may be required to confirm adequate treatment of respiratory events during sleep. A service may implement alternate methods to establish patients on PAP therapy but must have access to full attended titration or efficacy studies for more

difficult cases (see Notes 2, 3, 4). Services conducting more complex services such as bi-level must be able to demonstrate on-going competencies.

Note 1: ***A full overnight sleep study in a sleep service must be performed prior to performing an MSLT. A home sleep study is not acceptable as an alternative.***

Note 2: ***Titration studies require the technologist to adjust treatment based on observed physiological events and must only be undertaken by a technologist who has undertaken appropriate in-service training. A schedule for this training must be established and a training diary kept. Successful management of bi-level PAP titration studies requires a higher degree of training than CPAP studies and should be conducted in a service where nursing staff or highly trained technical staff are present. A higher staff/patient ratio is required when studies of extra complexity are undertaken, for example non-invasive or invasive ventilation trials, or titration of CPAP in patients with respiratory failure.***

Note 3: ***Where split night studies are used by the service, there must be a clear protocol for the selection of appropriate patients, including the severity of sleep disordered breathing in the diagnostic component, minimum duration of diagnostic data and latest time where PAP will be initiated.***

Note 4: ***A service may utilise alternate methods of establishing a patient on CPAP therapy. Commonly this involves auto-titrating CPAP devices. Where alternate methods are used, the service must demonstrate the quality and appropriateness of the method by measurement of performance indicators such as adherence to treatment. (refer ASA Guidelines (3))***

5.5.4. Unattended Sleep Study methods

5.5.4.1. Current ASA guidelines (3) indicate that studies using a Type 2 device can be used in suitable patients as part of a diagnostic pathway to both rule in and rule out suspected obstructive sleep apnoea. In addition, unattended sleep studies using Type 3 and 4 devices may be appropriate to rule in obstructive sleep apnoea in a high-risk population without significant co-morbidity (3). There is a lack of data to show that they are effective at ruling out obstructive sleep apnoea. The exclusive use of home sleep studies in an unselected population presenting with a sleep disorder is inappropriate (18). The sleep physician responsible for reviewing and/or providing the referral must triage the patient to a home service or an attended study depending on the nature of the presenting signs, symptoms, pre-test probability and comorbidities. Systems must be in place to refer the patient for a full attended study where appropriate e.g. where a home sleep study is performed which fails to confirm the clinical diagnosis [See Note 1].

5.5.4.2. The type of device used for measurement in the home may be similar to that described in the ASA guidelines (3) as Type 2, 3 and 4 devices (See Note 2). Type 3 and 4 devices can be used to confirm diagnosis of OSA in patients with moderate to high pre-test probability when integrated into a package of care that includes an appropriate level of physician expertise and access to Type 1 and Type 2 studies. The limitation of Type 3 and 4 devices must be appreciated before they are used to make diagnostic and therapeutic decisions (3) .

5.5.4.3. As for attended studies, unattended studies must allow full disclosure of the raw signals.

Note 1: ***Where a service provides only unattended sleep studies it is necessary to have a process in place to refer on or subcontract to a service that offers full attended studies. [See Items 4.4, 4.5].***

Note 2: ***Each Type 2 study should allow at least 1.5 hours for analysis. This means that for each five (5) studies performed each night, the equivalent staffing of at least 1 FTE member must be employed for this purpose.***

5.5.5. Method Selection

5.5.5.1. Method selection and documentation must be regularly reviewed to ensure currency and in accordance with document control procedures.

5.5.5.2. Standard tests and procedures performed by the service must be described in detail in a service manual.

5.5.5.3. Each test must be separately described with the following detail included or cross-referenced from other sources, preferably under appropriate subheadings:

- **(a)** The purpose of the test;
- **(b)** A description of the equipment used, with special reference to its specifications and their applicability to the measurement;
- **(c)** The equipment verification procedure;
- **(d)** The procedure for performance of the test;
- **(e)** Troubleshooting: problems that may be encountered in the performance of each test and their appropriate remedies;
- **(f)** Specific quality assurance, including details of quality control steps required for the method;
- **(g)** Cleaning and maintenance;
- **(h)** Infection control and other safety requirements;
- **(i)** Records and Reports (with samples, including interpretation of the results); and
- **(j)** Normal values and prediction equations used to interpret the results.

5.5.5.4. Appropriate cross-referencing (e.g. to manufacturer's manual) under each subheading could minimise redundancy while ensuring that all issues relevant to each test have been addressed. The method must be authorised for use.

5.5.6. Validation of standard and non-standard methods

5.5.6.1. There must be a documented procedure for the introduction of new methodology, which includes whether validation or verification is required. Appropriate records of validation/verification studies must be kept for the lifetime of the method plus seven (7) years. The documentation of the validation/verification process must include a description of the studies carried out, the results obtained, comments concerning the suitability of the method for use in the service and any relevant limitations of the method. Staff with the authority must review the validation results and record the review. The method must be authorised prior to patient testing.

5.5.6.2. The service must validate the following:

- **(a)** non-standard methods;
- **(b)** service designed or developed methods;
- **(c)** standard methods used outside their intended scope; and
- **(d)** validated methods subsequently modified.

The validation must be as extensive as is necessary and confirm, through provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the procedure have been fulfilled.

5.5.6.3. Changes in computer software may introduce errors into calculations and reports. Laboratories should establish a collection of polysomnograms covering a range of clinical conditions that can be reanalysed when new software is installed.

5.5.6.4. Polysomnography software often provides great flexibility in reporting of derived parameters. These derivations rely on computation that should be validated against a manual method of calculation whenever a method or report is changed.

5.5.7. Estimation of uncertainty of measurement

The nature of polysomnography precludes rigorous, methodological and statistically valid calculation of the uncertainty of measurement. Many factors influence the variation in measures of polysomnography including patient factors, night-to-night variability, signal

loss and sleep scoring discordance. Reporting physicians must be aware of intra- and inter-service scoring concordance as an indicator of uncertainty of measurement.

5.5.8. Control of data

5.5.8.1. The service must establish processes, to manage the security and confidentiality of all data relating to a patient's episode of care, including subcontracting work. This includes not only polysomnography data but also treatment information and clinical information. Polysomnography data must be retained on industry standard electronic media. CD, DVD and external hard disk are appropriate. Access to the electronic media must be controlled by password and media must be physically located within a secure area of the service (See Note 1).

5.5.8.2. The service must maintain secure copies of reports and clinical information that have been distributed to referring clinicians. Copies may be electronic or hard copy.

5.5.8.3. The service must implement appropriate processes to ensure that all data are copied to backup media whilst still under consideration in the patient's management (See Note 2).

Note 1: Electronic copies of distributed reports should be converted from an editable format to a secure format or otherwise protected from edit and erasure at the time of distribution to the referring clinician.

Note 2: Data must be copied to backup media immediately following acquisition. Access to the backup media must be limited to authorised staff. Backup should be maintained until the data have been reported and that episode of care is complete. At that time, the backup may be deleted although the primary data source must be maintained.

5.6. Assuring the quality of the service

5.6.1. A service must have quality control procedures for monitoring the validity of tests and services undertaken. This requires procedures to be established for internal quality control and external proficiency testing.

5.6.2. Quality control procedures must be documented:

(a) A record must be retained to show that appropriate quality control measures have been taken, that the quality control results are acceptable, if not, that remedial action has been taken. Where patient records form part of the quality control process, confidentiality must be respected.

(b) Where appropriate, quality control data must be recorded in such a way that trends in analysis can be readily evaluated.

(c) Administrative reviews must be conducted on study records to ensure completeness and correctness of the reports issued.

5.6.3. The service must establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-study, study (methods) and post-study processes.

5.6.4. The process of monitoring quality indicators must be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

5.6.5. The indicators must be periodically reviewed, to ensure their continued appropriateness, and action taken where appropriate.

5.6.6. Diagnostic services - Quality Control

5.6.6.1. The service must have established methods for assessing the quality of measurements and analysis including periodic assessment of inter-observer variability in analysis of sleep studies.

5.6.6.2. The performance of studies/activities must be monitored by using quality control procedures appropriate to the type and frequency of the studies/activities undertaken. Performance indicators must be established. Quality control includes review of all aspects of the study including referrals, performance of the study, staging/scoring and reporting.

5.6.7. Treatment services - Quality Control

The provision of treatment to patients attending the service must be subject to appropriate quality control processes. Suitable performance indicators must be established. Examples could include performance indicators such as:

(a) Compliance with guidelines;
(b) Timeliness of CPAP provision service (time from diagnostic study to initiation of treatment);
(c) Overall CPAP adherence of referred patients;
(d) Timeliness of implementation of other treatment modalities;
(e) Complaints and customer feedback;
(f) Patient outcomes on treatment (i.e. change in ESS pre-post CPAP therapy); or
(g) Feedback must be obtained from an outsourced CPAP provider, contain the required information (as defined by the contract) and be provided in a timely manner.

5.6.8. Proficiency Testing

5.6.8.1. The service must participate in a proficiency testing programme(s) appropriate to the sleep studies performed. The service must monitor the results of the proficiency testing programme(s) and implement corrective actions when predetermined performance criteria are not fulfilled.

Note: ***All staff who conduct analysis of clinical sleep studies must participate in this programme(s). Participation frequency of at least twice per year per eligible staff member is considered the minimum standard.***

5.6.8.2. The service must establish a documented procedure for proficiency testing participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the proficiency testing programme.

Physicians should participate in a documented peer reviewed physician concordance process at regular intervals.

5.6.8.3. Alternative approaches

If a proficiency testing programme(s) is not available, the service must develop other approaches and provide objective evidence for determining the acceptability of study/activity results.

Whenever possible, this mechanism must utilise appropriate sleep study data.

Note: ***Examples of such approaches may include:***
- ***sleep studies or study fragments previously analysed; or***
- ***exchange of sleep studies or study fragments with other sleep disorders services.***

5.6.8.4. Evaluation of service performance

The performance in proficiency testing must be reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff must participate in the implementation and recording of corrective action. The effectiveness of corrective action must be monitored. Proficiency testing results must be evaluated for trends that indicate potential nonconformities and preventive action must be taken.

5.7. Post-study procedures, including ongoing patient care

5.7.1. Services providing ongoing management of patients

5.7.1.1. It is anticipated that clinical interactions between physicians and patients will be carefully performed and follow evidence based guidelines. At this review the risk factors for OSA should be established. The potential consequences of OSA should be considered. Other relevant co-morbid illness and the implications for the patient's sleep disorder will be reviewed. Other sleep comorbid illness will be looked for (e.g. insomnia). The need for a diagnostic test and the type of diagnostic test to be performed (e.g. home versus attended PSG) will be apparent. The reasons for further testing will be carefully explained to the patient (19).

5.7.1.2. All patients/families must have the results and implications of a sleep study appropriately explained to them by a sleep specialist with the opportunity for them to ask questions. How this is best achieved (phone, face to face clinic, telehealth, etc.) will depend on the reason for referral, patient circumstances and the sleep study findings. Whilst other means may suffice, a face to face consultation should be offered, and must be available. Clinical decisions will include an appropriate recommendation of a therapy for a patient. The service must have documented protocols and procedures for the implementation and follow-up of treatment for patients with a sleep disorder. Protocols should be based on current best available evidence as defined from time to time by the ASA and AASM (20) (21) (22) (23). Treatment may comprise positive airway pressure (of various types), oral appliances, upper airway surgery, positional therapy (bed head elevation and/or keeping people in the lateral posture during sleep) and bariatric surgery or other therapies geared towards loss of weight and must always include general lifestyle advice including instruction on sleep hygiene. Where a service does not offer a particular treatment option in-house, procedures must be in place and documented for the referral to a suitably qualified clinical service, which will provide the activity on behalf of the sleep disorders service

5.7.1.3. Services must have established processes for the prescription, supply and monitoring of PAP treatment. Therapy and treatment follow-up must be consistent with good professional practice (20). This requires a diagnostic study prior to prescription of PAP. Early follow-up after implementation of treatment is required to determine whether problems affecting treatment adherence exist. Where the service does not provide PAP services in-house, there must be an established relationship with suitably qualified PAP providers (20) who are able to perform these tasks on behalf of the service (Note 2). Irrespective of whether PAP provision and follow-up is in-house or outsourced, there must be mechanisms in place for timely reporting of PAP problems and adherence to treatment. Services must implement a quality control program to monitor the performance of their PAP provision service. Processes to monitor the quality of the service are discussed in section 5.6.

5.7.1.4. Where provisional prescriptions are provided to patients at the conclusion of a CPAP titration study before physician consultation/review, the service must have a documented policy and procedure which describes the processes for provisional prescriptions and for updating the provisional prescription with the final reported CPAP pressure and study result when available.

5.7.1.5. Paediatric services must have clear protocols in place for management of all forms of non-invasive ventilation and invasive ventilation provided by the service.

5.7.1.6. Once the patient commences PAP therapy there must be evidence of further clinical review to assess the patient's progress. This may include: ensuring the patient's adherence with PAP is optimised, review to assess the clinical response of PAP therapy after an appropriate trial and consideration of other therapies if the patient is not adhering to PAP therapy or wishes to consider an alternative therapy. Clinical review will also ensure there is further

investigation of those who have residual excessive daytime sleepiness despite effective PAP therapy.

5.7.1.7. It is recognised that PAP will not be a suitable therapy for all patients. The service should have a relationship with an appropriately trained dental practitioner for the construction of oral appliances and be able to refer patients to an ENT surgeon where surgical interventions are considered appropriate (20) (21) (22) (23).

5.7.1.8. A paediatric service must have procedures for referral to ENT and facio-maxillary services performing more complex airway surgery.

5.7.1.9. Procedures must be in place for referral of patients with both complex respiratory and non-respiratory sleep issues to other specialist services, which might include cardiology, ENT, endocrinology, psychiatry, clinical psychology, intensive care and other specialist service including dental as above. It is envisaged that a service will have strong and easily identifiable links with most, if not all, of these components of a Sleep Medicine Service.

5.7.1.10. Services should provide a specialist insomnia assessment and management service, incorporating a multidisciplinary approach to insomnia diagnosis and management, which should include clinical psychology. Procedures must be in place for referral of complex insomnia patients where services cannot be provided in-house. Paediatric services should provide specialist behavioural sleep management services, including for Disorders of the Initiation and Maintenance of Sleep and Circadian Rhythm Disturbances. Procedures must be in place for referral of management of behavioural sleep problems to appropriate personnel where services cannot be provided in-house.

Note 1: ***Documentation of treatment procedures should include a decision tree or flow chart that is appropriately referenced to best practice guidelines.***

Note 2: ***It is inappropriate for a sleep service to profit from both the diagnosis and the devices used for treatment of sleep disorders. This is a conflict of interest (20). For example, where a service provides CPAP equipment in-house this should be a not-for-profit enterprise with due recognition that there are costs involved in providing this service. It is preferred that purchase of CPAP equipment by patients for long term use at home should be outsourced to a suitably qualified independent CPAP supplier once the need for treatment has been established.***

5.7.2. Services providing studies for diagnostic sleep tests only

5.7.2.1. Once a physician is involved in the diagnosis or assessment of a patient, they have a duty to ensure that appropriate follow-up is implemented, even if they do not provide that follow-up themselves. A service providing diagnostic tests only must have systems in place to:

- **(a)** Assess and provide advice to referring doctors on the suitability of the diagnostic method;
- **(b)** Provide a comprehensive summarised report to the referring doctor on the results of the study (see Note);
- **(c)** Ensure that the referring doctor is provided with adequate information to form an opinion about the necessity for treatment;
- **(d)** Where requested offer advice to the referring doctor about ongoing management of the patient; and
- **(e)** Implement urgent clinical review, either in-house or through a subcontracting arrangement. This is most relevant if severe sleep disordered breathing (SDB) is detected on PSG or other acute problems needing immediate intervention are identified (e.g. ventricular tachycardia).

Note: ***On request or by agreement, the service must make available the raw data from the study to enable the referring doctor to form his or her own opinion of the study. In many situations, access to raw data is instructive in understanding the complexity and severity of the condition being managed.***

5.8. Analysis and reporting of results

5.8.1. A patient record must be maintained, which is well ordered and contains all study reports, records of consultations, copies of correspondence, working and/or final diagnoses and, where appropriate, clearly defined treatment/follow-up recommendations. Recommended treatments must be consistent with current knowledge and practice. Correspondence, including patient letters and PSG reports, should be completed promptly (within ten (10) business days) following each patient contact.

5.8.2. Relevant information regarding the study and associated raw data must be provided to allow the reporting physician to assess the quality and accuracy of the study.

- **(a)** The sleep physician must review the sleep study raw data epoch by epoch.
- **(b)** The observations of overnight technologist(s) and the scoring technologist(s) must be available for review by the reporting physician. There must be the opportunity to provide feedback to the scoring technologist involved where issues or training opportunities are identified.
- **(c)** The service must publish and have available to reporting physicians normal reference values for commonly derived indices that include estimates of uncertainty where available.

5.8.3. While analysis of the sleep study may be performed by technical staff, interpretation is the responsibility of the interpreting sleep physician. Whilst computerised analysis systems are considered aids to the process the final analysis must be performed manually and involve reference to the raw data, as must interpretation by the responsible sleep physician.

Note: Computerised analysis is not recommended for paediatric studies

5.8.4. Opinions and interpretations, including treatment recommendations must be made by a suitably qualified sleep physician.

5.8.5. For paediatric studies, technical staff analysing the study must be trained and deemed competent in paediatric analysis and the interpretation must be completed by a paediatric sleep physician.

5.8.6. The service must have a documented policy and procedure which describes the processes for reporting, including:

- **(a)** Report authorisation and delegation for issuing of preliminary and final reports.
- **(b)** Preliminary reports must be checked and authorised and the status of the report evident prior to issue.
- **(c)** Where a service issues a preliminary report prior to the final report, the final report must contain a reference to the preliminary report.

5.8.7. A sleep study report must:

- **(a)** clearly identify the service;
- **(b)** clearly identify the site where the study was performed;
- **(c)** clearly identify the patient;
- **(d)** include the date of the study and the date of the final report;
- **(e)** contain clinical or technical observations about the conduct of the study, which could influence the interpretation of the study results;
- **(f)** contain the study results along with an interpretive summary statement signed by the interpreting sleep physician; and
- **(g)** be consistent with current ASA and AASM documents.

5.8.8. Each page of a multi-page document must bear a statement of the page number and the total number of pages.

5.8.9. A study report may include results of studies performed by another service if the source of those study results is clearly identified on the study report.

5.8.10. The report format must be designed to accommodate each type of sleep study carried out and to minimize the possibility of misunderstanding and misuse.

5.8.11. Revised Reports

5.8.11.1. When an original report is revised there must be written instructions regarding the amendment so that:

- **(a)** the revised report is clearly identified as an amendment report and includes reference to the date of the original report;
- **(b)** the revised report shows the date of the change and the name of the person responsible for the change; and
- **(c)** the service must retain a copy of the original report.

5.8.11.2. When the reporting system cannot capture amendments, changes or alterations, a record of such must be kept.

5.8.12. Appropriate security must be in place for any results transmitted by electronic or any other means.

- **(a)** The service must have a documented protocol for the verbal release of results.
- **(b)** The service must have a documented protocol for the electronic transmission of results.
- **(c)** Study reports may be electronically issued (including from a site other than the accredited site) if the reports have been appropriately authorised for release. The adequacy of such arrangements will be reviewed at assessment.
- **(d)** Copies (hard copy or computer records) of study reports must be retained by, or accessible to, the accredited service. Care must be taken to ensure that copies of handwritten comments are also retained by the issuing site.
- **(e)** The service must be able to demonstrate appropriate controls over the electronic generation, access, storage and backup of results and reports and program controls such as password protection. If the report is to be accessed from a website by the client there must be an appropriate control in place to ensure the report can only be downloaded in a protected format.

6. References

Standards

AS 2243 *Safety in laboratories* Parts 1 to 10 (as appropriate)
AS ISO 15189 *Medical Laboratories –Requirements for Quality and Competence*

Works Cited

1. **ISO/IEC.** Guide 99 International vocabulary of metrology - Basic and general concepts and associated terms (VIM). 2007.
2. **Australian Government Department of Health.** Medicare Benefits Schedule Book. [Online] http://www.health.gov.au/mbsonline.
3. Guidelines for Sleep Studies in adults - a position statement of the Australasian Sleep Association. **Douglas JA, Chai-Coetzer CL, McEvoy D, Naughton MT, Neill AM, Rochford P, Wheatley JR, Worsnop C.** *Sleep Medicine*, 2017, Vol 36, S2-S22.
4. **RACP.** Sleep Medicine Advanced Training Curriculum. Adult and Paediatric. 2013. https://www.racp.edu.au/docs/default-source/default-document-library/sleep-medicine-adult-medicine-advanced-training-curriculum
5. **RACP.** RACP Code of Professional Behaviour. [Online] 2008. http://www.racp.edu.au/page/racp-governance.
6. Australasian Sleep Association Clinical Practice Guidelines for Performing Sleep Studies in Children. **Pamula Y, Nixon GM, Edwards E, Teng A, Verginis N, Davey MJ, Waters K, Suresh S, Twiss J, Tai A.** Sleep Medicine, 2017, Vol 36, S23-S42.
7. **Therapeutic Goods Administration.** Australian Register of Therapeutic Goods. [Online] Department of Health. https://www.tga.gov.au/australian-register-therapeutic-goods.
8. *Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test.* **Littner et al.** s.l. : Sleep, 2005, Vols. 28(1): 113-121.
9. *The Clinical use of the MSLT and MWT. Review by the MSLT and MWT taskforce of the Standards and Practice Committee of the American Academy of Sleep Medicine.* **Arand D, Bonnet M, Hurwutz T, Mitler M, Rosa R and Sangal RB.** s.l. : Sleep, 2005, Vols. 28(1): 113-121.
10. *The Maintenance of Wakefulness Test in Normal Healthy Subjects.* **Banks S, Barnes M, Tarquinio N, Pierce RJ, Lack LC and McEvoy RD.** s.l. : Sleep, 2004, Vols. 27(4): 799-802.
11. **Mitler MM, Carskadon MA and Hirshkowitz M.** Evaluating sleepiness. [book auth.] Roth T, Demet WC (editors) Kryger MH. *Principles and Practice of Sleep Medicine, 3rd edition, Philadelphia.* s.l. : WB Saunders, 2000.
12. *A Normative Study of the Maintenance of Wakefulness Test (MWT).* **Doghramji K, Mitler MM and Sangal RB, etal.** s.l. : Electroencephalography and Clinical Neurophysiology, 1997, Vols. 103:554-562.
13. *Guideline update: Diagnosis and treatment of sleep disordered breathing.* **Fleetham J, Ayas N, Bradley D et at.** s.l. : Can Respir J, 2011, Vols. 18(1):25-47.
14. American Thoracic Society: Standards and indications for cardiopulmonary sleep studies in children. **Louglin GM, Broullette RT, co-chairs.** s.l. : Am J Respir Crit Care Med, 1996, Vols. 153:866-878.
15. **Berry RB, Albertario CL, Harding SM, Lloyd RM, Plante DT, Quan SF, Troester MM and Vaughn BV for the American Academy of Sleep Medicine.** The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications. Version 2.5, 2018.
16. **Anders T, Emde R, Parmelee A, editors.** A manual of standardized terminology, techniques and criteria for scoring of states of sleep and wakefulness in newborn infants. s.l. : Los Angeles CA: UCLA Brain Information Service/Brain Research Institute, 1971.
17. **Suresh S, etal.** ASTA/ASA Addendum to AASM Guidelines for recording and scoring of paediatric sleep. s.l. : ASA, 2011.
18. *Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients.* **Portable Monitoring Taskforce of the American Academy of Sleep Medicine.** s.l. : J Clin Sleep Med, 2007, Vols. 3(7): 737-747.
19. *Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults.* **Epstein LJ, et al.** s.l. : J Clin Sleep Med, 2009, Vols. 5(3): 263-276.

20. **Thornton, A.** Position Paper: Best Practice Guidelines for Provision of CPAP Therapy v2.2. [Online] 2009. www.sleepaus.on.net/cpapsupply22a.pdf .
21. **ASA.** Dental Appliance Therapy for the Treatment of Sleep-disordered Breathing. 2010.
22. *Practice Parameters for the Use of Autotitrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patiens with Obstructive Sleep Apnea Syndrome: An update for 2007. An American Academy of Sleep Report.* **Morgenthaler TI, etal.** s.l. : Sleep, 2008, Vols. 31(1): 141-147.
23. *Practice Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults.* **Aurora RN, et al.** s.l. : Sleep, 2010, Vols. 33(10): 1408-1413.