ACCREDITATION

ASSESSMENT

WORKSHEET

SLEEP DISORDERS SERVICES

This assessment worksheet has been designed to assist both the sleep service staff and the assessment team. Sleep service staff can use this checklist as part of their preparation for an assessment to the ASA Standard for Sleep Disorders Services (2016). **There is NO need to return the completed checklist to NATA.** The assessment team, i.e. the NATA lead assessor and the technical assessors can use this worksheet to assist in the collection of all relevant information during the assessment process.

References to the relevant clauses of the NATA Accreditation Criteria (NAC) have been provided. The Standard itself should be checked for further details as this worksheet provides only a brief summary of the clauses of the Standard.

Service Name:

Accreditation No:

Date reviewed:

Review conducted by:

Version of QM reviewed:

Service website address:

Date checked:

Reference to NATA accreditation appropriate:

Comments:

Some clauses in this worksheet have been highlighted where they are only relevant to particular sleep laboratories.
The following key has been used:

Blue highlight	Clause only applicable to laboratories providing paediatric services
Orange highlight	Clause applicable to laboratories that are ONLY providing sleep studies for diagnostic purposes
Purple highlight	Clause only applicable where unattended studies are provided

CLAUSE	REQUIREMENT	COMMENTS
4 MANAGEMENT REQUIREMENTS		
4.1 Organisation and management		
Legal entity 4.1.1	The service must be an entity or part of an entity that can be held legally responsible for its activities.	
Overall organisation and administration 4.1.2	The service must be organised and administered to meet its objectives and the needs of the population it serves. Resources must be sufficient to meets its workload without comprising minimum standards stated elsewhere in the standard and other relevant referenced documents. 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.	
Management system requirements 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.	
Relationship to host institution. 4.1.4	The relationship of the service to the host institution (if applicable) must be specified and clearly defined. There should be evidence of commitment by the host institution to its support. Where the service operates in a teaching hospital environment it must offer education programs for undergraduates and postgraduates and have a commitment to research.	
Managerial and technical personnel 4.1.5a	Managerial, technical and administrative personnel have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system.	
External influences 4.1.5b	Managerial, technical and administrative personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.	

CLAUSE	REQUIREMENT	COMMENTS
Code of Conduct 4.1.5c	Policies and procedures exist to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement and operational integrity.	
Conflicts of Interest 4.1.5d	Arrangements exist to ensure that where potential conflicts in competing interests may exist, they must be openly and appropriately declared.	
Confidentially 4.1.5e	Policies and procedures exist for protecting client's confidential information including procedures for protecting hard copy, electronic storage media and transmitted results from unauthorised access.	
Management Structure 4.1.5f	There must be a medical director, who is a sleep physician, responsible for the overall clinical standards and development of policies governing the services provided. The duties and responsibilities of the medical director must be documented. There must be clear, documented lines of accountability/responsibility between the medical director and all staff members.	
4.1.5f	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.	
Numbers of sleep staff 4.1.5g	There is sufficient sleep staff with direct presence and involvement to supervise the activities conducted by the service Rostering must allow for the following: • Staff must be in attendance throughout the study • Adequate time allocated for preparation of the patient, data collection and analysis Equipment verification and maintenance, preparation and processing of reports, and in-service education/professional development.	

CLAUSE	REQUIREMENT	COMMENTS
Service providing only sleep studies for diagnostic purposes Numbers of sleep staff 4.1.5h	There must be a sleep physician, responsible for overall clinical 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. There must be clear, documented lines of accountability/responsibility between the medical director and all staff members. 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. Rosters must also allow for equipment calibration and maintenance, preparation and processing of reports, and in service education/professional development.	
Organisational Chart 4.1.5i	An endorsed organisational chart shows the responsibility, authority and interrelationships of all personnel who perform work affecting the quality of the services provided.	
Service supervision 4.1.5j	The staff structure must 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.*	
Technical /scientific management 4.1.5k	The service must have senior technical/scientific personnel with overall responsibility for the management of the technical operations of the sleep disorders laboratory. *Qualifications required for senior technical/scientific staff are described in section 5.1.*	
Quality manager 4.1.5l	A quality manager with responsibility for the quality management system must be appointed.	
Managerial deputies 4.1.5m	The service must appoint deputies for key managerial personnel.	
Importance of roles 4.1.5n	The service must ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the quality management system.	

CLAUSE	REQUIREMENT	COMMENTS
Appropriate communication 4.1.6, 4.2.1	Appropriate communication processes must be established and include the effectiveness of the management system. Records must be kept of these communications.	
4.2 Quality management system		
Scope of management system 4.2.1	The service's management system must define the type and extent of the services provided, such as branch services and unattended (home) studies.	
Policies and procedures 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 program. The documented policies and procedures reflect current knowledge and practice in the conduct of a sleep disorders service. Management must ensure the integrity of the management system when changes are made.	
Quality policy statement 4.2.3	The service must develop a quality statement that includes goals and objectives and reflects its commitment to good professional practice. The service must demonstrate evidence of commitment to development, implementation and continual improvement of the management system.	
Quality Objectives 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.	
Quality manual 4.2.5	The service must develop and maintain a quality manual that describes the management system and its structure. It must include a description of the structure and relationship of the documentation used in the quality system.	

CLAUSE	REQUIREMENT	COMMENTS
Roles and responsibilities 4.2.5 d	The roles and responsibilities of senior management (including medical director, senior technical/scientific staff and quality manager) must be defined in the quality manual.	
Access 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		
Procedures 4.3.1	The service must define, document and maintain procedures to control all documents that form its management system (internally generated or from external sources).	
Approval and issue 4.3.2.1	Documents are reviewed and approved by authorised personnel prior to issue, and are included on a master list or equivalent document which identifies the revision status and distribution	
Availability 4.3.2.2	All necessary quality documentation is available where required, authorised, reviewed and revised. Obsolete documents are promptly removed from all points of use, are suitably marked and are retained for legal or knowledge preservation purposes.	
Identification 4.3.2.3	Management system documents must be uniquely identified and include title, edition or current revision date or revision number, page numbering to total number of and the issuing authority(ies).	
Handwritten amendments 4.3.3.1	If hand written amendments are allowed, defined procedures are available, which include authorities, clear marking, initialling, dating, and formal re-issue.	
Electronic documents 4.3.3.2	Procedures must be established to describe how changes in documents maintained electronically are made and controlled.	

CLAUSE	REQUIREMENT	COMMENTS
4.4 Review of appropriateness of referral and patient preparation		
Appropriateness of referral 4.4.1	The sources and types of referrals must be relevant to the services provided. Each patient must have had an appropriate clinical evaluation prior to a study. A sleep service must conduct testing only on receipt of an appropriately authorised referral provided by a qualified sleep physician	
Appropriateness of referral 4.4.1c	Paediatrics: each patient should be evaluated by a paediatric sleep physician prior to a study.	
Deviations from referrals 4.4.2	Deviations from or additions to the referral must be documented in laboratory records and in the report to the referring medical practitioner.	
Service Referral/ Outsourcing 4.4.3	Where a sleep laboratory determines that further assessment is required for appropriate diagnosis or testing, the service must deem this to be subcontracted and assume responsibility for the quality of the subcontractor's work. An alternative appropriate arrangement is for the referring doctor to re-refer the patient to the other service provider.	
4.5 Subcontracting or onward referral of tests and services		
Notification of subcontracting 4.5.2, 4.5.3, 4.5.4	Subcontracting • The service must advise the referring doctor of the subcontracting or referral arrangements in writing and gain the approval of the referring doctor for ongoing management of the patient where appropriate. • The service must maintain a register and records of compliance with this Standard for all subcontractors that it uses for tests. • Where a test or service is subcontracted, the service is responsible for the subcontractor's work.	

CLAUSE	REQUIREMENT	COMMENTS
Engagement of third parties 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. The quality assurance system must include a documented program of proficiency testing and participation in an external proficiency testing program. Processes must be in place to evaluate, correct and communicate non-conforming work; with the third party. Regular peer reviewed physicians concordance process by the third party should be considered, with documentary evidence of such a process.	
4.6 External services and supplies		
4.6.1	The service must have a documented policy and procedure(s) for the selection, evaluation and purchasing of equipment, services and consumable supplies it uses 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.	
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.	

CLAUSE	REQUIREMENT	COMMENTS
4.10 Corrective action		
4.10.1,	The service must take corrective action to eliminate the cause/s of nonconformities.	
Monitoring corrective action 4.10.2	The service must have a documented procedure for: • reviewing nonconformities; • determining the root causes of nonconformities; • evaluating the need for corrective action to ensure that nonconformities do not recur; • determining and implementing corrective action needed; • recording the results of corrective action taken; and • reviewing the effectiveness of the corrective action taken	
4.11 Preventive action		
4.11.1, 4.11.2	There must be a documented procure which includes: • reviewing service data and information to determine where potential nonconformities exist; • determining the root cause(s) of potential nonconformities; • evaluating the need for preventive action to prevent the occurrence of nonconformities; • recording the results of preventive action taken; and • reviewing the effectiveness of the preventive action taken.	
4.12 Continual improvement		
Improving management system effectiveness 4.12.1	The service must continually improve the effectiveness of its management system through reviewing a variety of information such as the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	

CLAUSE	REQUIREMENT	COMMENTS
4.12.2	Procedures must be in place to evaluate the quality of the service provided, correct identified problems, and advance the service's quality standards.	
4.13 Quality and technical records		
Procedures 4.13.1.1	The service must have a documented procedure for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality, technical and patient records. Record management procedures must apply to all forms of media.	
Record retention - equipment 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. For equipment records, the retention period will be the life of the equipment plus 7 years or other legislative requirement (whichever is the longer period).	
Identifying the staff member 4.13.1.3	All records must include the identity of the person making the record.	
Security and confidentiality 4.13.1.4	All records must be held secure and in confidence.	
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.	
Record system – content 4.13.2.2	The records system must include the information stated in the Standard to assess the appropriateness of the test and the quality of the procedure.	

CLAUSE	REQUIREMENT	COMMENTS
Record retention - testing 4.13.2.3	Final reports of the study must be retained with patient health records for the period required by appropriate authorities for health records.	
Polysomnography data 4.13.2.4	As a minimum, detailed polysomnography data must be retained until final reporting has occurred and appropriate treatment of the patient has been implemented.	
Video & audio recordings 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. Video or audio recordings critical to understanding or demonstrating the result of the study must be retained for the duration of the patient health record.	
Preventing record loss 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.	
Corrections to records 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 must be signed or initialled by the person making the correction and must 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		
Internal Audits 4.14.1,4.14.2	The service must plan and implement the evaluation and internal audit processes needed to 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; ensure conformity to the quality management system; and continually improve the effectiveness of the quality management system. The results of evaluation and improvement activities must be included in the input to the management review.	

CLAUSE	REQUIREMENT	COMMENTS
Referrals 4.14.3, 4.14.4	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.	
Feedback 4.14.4, 4.14.5	The service must seek information relating to whether the service has met the needs and requirements of referrers and patients. The service must encourage staff to make suggestions for improvement. Records must be kept of information collected and actions taken.	
Internal audits 4.14.6, 4.14.7	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: • conform to the requirements of this Standard and to requirements established by the service; and • are implemented, effective and maintained. The audit program must take into account technical and management areas to be audits, as well as the results of previous audits. The audit criteria, scope, frequency and methods must be defined and documented.	
Internal auditors 4.14.7	Audits must be conducted by staff trained to assess the performance of managerial and technical processes of the quality management system.	
Selection of Auditors 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.	
Responsibility 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.	
Corrective action 4.14.10	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.	

CLAUSE	REQUIREMENT	COMMENTS
Evaluation 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, 4.15.2, 4.15.3	Service management must review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care. Management reviews must include information from the results of evaluations and must address the elements stated in the Standard. The review must analyse the information for trends and patterns that indicate process problems.	
Review Output 4.15.4	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: improvement of the effectiveness of the quality management system and its processes; improvement of services to users; and resource needs.	
Actions and records 4.14.5, 14.4.6	Findings and actions arising from management reviews must be recorded, reported to service staff and completed within a defined timescale.	

CLAUSE	REQUIREMENT	COMMENTS
5. TECHNICAL REQUIREMENTS		
5.1 Personnel		
Competence 5.1.1	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.	
Cardiopulmonary resuscitation 5.1.1a	The service must ensure that all medical, technical, scientific and nursing staff are trained in cardiopulmonary resuscitation and that a basic level of competence is maintained and evaluated regularly.	
Cardiopulmonary resuscitation 5.1.1a	Where paediatric services are provided, specific training in paediatric basic life support is required.	
Appraisal system 5.1.1b	A staff appraisal system must be in operation that includes a written report,	
Orientation and training 5.1.1c	Programs must be in place to orientate new staff, and for continuing education of existing staff. Staff must have access to education and opportunities must be made available for senior staff to attend relevant professional meetings.	
Job descriptions 5.1.2	Roles and responsibilities of staff members must be specified in job descriptions.	
Senior Medical Staff 5.1.2a & b	Senior medical staff must have specific, detailed training in sleep disorders and meet the criteria set by RACP and ASA guidelines. The Medical Director must be on site 12 hours/month and lead and participate in regular unit staff meetings with technical and nursing staff.	

CLAUSE	REQUIREMENT	COMMENTS
Experience requirements for supervising scientist/ technologist 5.1.2c	A scientist/technologist, to be able to function in a supervisory capacity under medical direction, must have a minimum of two (2) years' experience in a sleep disorders service and a tertiary degree in biological or physical sciences, or equivalent qualification. The Scientist/Technologist in Charge must be on site for at least twenty (20) hours per week for a full-time service.	
Experience requirements for scientist/technologist 5.1.2d	Basic qualifications for sleep scientists/technologists will depend on the local regulatory requirements. 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.	
Experience requirements for Paediatric services 5.1.2e	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. All staff working in a paediatric sleep service requires specific training in working with children and young people.	
Training records 5.1.3	Training records must be maintained that are sufficiently detailed to demonstrate competence in relevant aspects of the service. Evidence of recognition of overseas qualifications must be available.	
5.2 Accommodation and environmental conditions		
Facility 5.2.1	Adequate sites and equipment must exist for the service to meet its objectives and comply with statutory requirements.	
5.2.1	Paediatric laboratories must have appropriate facilities to care for sick children or children with complex conditions.	

CLAUSE	REQUIREMENT	COMMENTS
Laboratory safety 5.2.1	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) [6] as a medical device and the public summary must indicate that the equipment is suitable for use.	
Identification 5.2.1	The service must be identified by signage, telephone and stationery so that it can be easily found and/or accessed.	
Reception, Waiting Rooms 5.2.1a (i)	The reception area and waiting room conform to generally accepted standards for medical suites in size, appearance, privacy, lighting and furniture.	
Facilities – Bedrooms 5.2.1a (ii-x & xiv,xv)	Appropriately furnished bedrooms conducive to sleep and of adequate size. The rooms conform to local regulations with respect to entrances, exits and fire precautions. Separate bedrooms with comfortable bedding, storage for personal effects and adequate lighting. There are conveniently located and adequate toilet and shower sites. The monitoring room is located in close proximity to the bedrooms and a patient call system is available from bedrooms to monitoring room. Staff must be able to monitor the live recording of all physiological signals for all studies simultaneously. For titration studies, staff must be able to adjust device settings from the monitoring room Office space exists with adequate space, furniture, lighting and privacy for analysis of sleep studies. Adequate storage exists for secure storage of records, consumables and equipment. The sites are regularly cleaned. Adequate access to bathrooms, to a supply of drinking water and storage of personal equipment for staff.	

CLAUSE	REQUIREMENT	COMMENTS
5.2.1a (iv)	In the case of paediatric laboratories, the bedroom must be child-safe and age-appropriate. Sites for a parent to sleep in the child's bedroom should be available.	
Facilities – Access to medical resources 5.2.1a (xi)	Provision must be made for advice and medical emergencies, and should include an on-call roster for medical staff, CPR training for all staff, availability of resuscitation equipment, oxygen and suction, and easy access to the laboratory and the patient.	
Facilities – Access to medical resources - Paediatric 5.2.1a (xii)	In the case of paediatric laboratories, a team trained in paediatric cardiopulmonary resuscitation must be available on-site for the duration of the study. All staff must be trained in paediatric cardiopulmonary resuscitation. A complete range of age-appropriate resuscitation equipment must be available in the laboratory for the duration of the studies and oxygen and suction must be available at the bedside.	
Facilities – Non-medical emergencies 5.2.1a (xiii)	Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies (Fire and Safety).	
Unattended based services		
Facilities – Reception, Waiting and Consultation Rooms 5.2.1b (i)	The reception area and waiting room conform to generally accepted standards for medical suites in size, appearance, privacy, lighting and furniture.	
Facilities – Bedrooms 5.2.1b (ii - v & viii,ix)	The service has appropriately furnished private rooms appropriate for the activity. The rooms conform to local regulations with respect to entrances, exits and fire precautions. Office space exists with adequate space, furniture, lighting and privacy for analysis of sleep studies. Adequate storage exists for secure storage of records, consumables and equipment. The sites are regularly cleaned. Adequate access to bathrooms, to a supply of drinking water and storage of personal equipment for staff	

CLAUSE	REQUIREMENT	COMMENTS
Facilities – Access to medical resources 5.2.1b (vi)	Provision must be made for advice and medical emergencies. These should include an on-call roster for medical staff, CPR training for all staff and a protocol for dealing with a patient who requires medical treatment.	
Facilities – Non-medical emergencies 5.2.1b (vii)	Provisions complying with relevant site and statutory requirements must be made for non-medical emergencies (Fire and Safety).	
5.3 Equipment		
General Equipment 5.3.1	The service must have a documented procedure for the selection, purchasing and management of equipment. • The service must operate with all equipment must be capable of performing polysomnography consistent with established standards. • Polysomnography software must allow for the recording and full disclosure of the raw signals. • Equipment must be replaced as needed to ensure the quality of procedure results. • Each item of equipment must be uniquely labelled.	
General Equipment 5.3.1	In paediatric laboratories, appropriately sized sensors and equipment should be available.	
Equipment Acceptance 5.3.2	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.	

CLAUSE	REQUIREMENT	COMMENTS
Operating manuals and procedures 5.3.3	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.	
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. The procedure must address the elements stated in the Standard.	
Biological calibrations 5.3.4.2	Prior to each study a signal check 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.	
Maintenance and repair 5.3.5	The service must have a documented program of preventive maintenance Equipment must be maintained in a safe working condition and in working order Defective equipment must be taken out of service and clearly labelled. 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. Equipment performance must be verified before being returned to use.	
Adverse incidents 5.3.6	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.	
Equipment Records. 5.3.7	Records must be maintained for each item of equipment that contributes to the performance of studies. The records must include the elements stated in the Standard. 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).	

CLAUSE	REQUIREMENT	COMMENTS
Consumables 5.3.8	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		
Managing 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 that are consistent with good professional practice. It is expected that patients will be clinically evaluated prior to the sleep study. On presentation to the sleep laboratory, administrative procedures must be implemented to capture clinical or demographic information in the event that inadequate information is received prior to presentation.	
Managing demand 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 cases perceived to be urgent.	
Suitability on presentation 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.	
Patient identification 5.4.4, 5.4.5	Patients must be positively identified upon presentation to the service using a minimum of three identifiers. Patients and their associated records (worksheets etc.) must be uniquely identified during all stages of testing.	
5.5 Sleep Disorders Services Processes		
Escalation of patient care 5.5.1.1	The service must have documented policies and procedures which describe the escalation of patient care and call for emergency assistance.	

CLAUSE	REQUIREMENT	COMMENTS
Methods and procedures 5.5.2	The methods for the conduct of sleep studies must be consistent with recognised standards, including the relevant ASA guidelines and, where applicable, paediatric guidelines. Types of sleep studies performed and the parameters measured must be specified.	
5.5.3 Attended studies methods		
Full disclosure of raw data 5.5.3.1	Sleep studies must allow full disclosure of the raw signals, which must be adequately labelled and verified.	
Analysis and scoring 5.5.3.2	Methods for the analysis of sleep studies must be consistent with recognized standards, including the relevant ASA guidelines . Scoring and interpretation of the data should conform to the AASM Manual for the Scoring of Sleep and Associated Events in conjunction with ASA Guidelines for Sleep Studies	
Analysis and scoring 5.5.3.2	In the case of paediatric laboratories, scoring and interpretation should be age appropriate and conform to the AASM Manual for the Scoring of Sleep and Associated Events) and the ASA/ ASTA addendum document.	
Tests of daytime sleepiness 5.5.3.3	The methods for multiple sleep latency testing (MSLT), maintenance of wakefulness (MWT) and related studies must be consistent with established standards, including the relevant ASA guidelines.	
PAP studies 5.5.3.4	The laboratory must have established methods for the study of patients using positive airway pressure devices. The laboratory must have appropriate methods for titration and efficacy studies. A laboratory may implement alternate methods to establish patients on PAP therapy but must have access to full laboratory diagnostic or efficacy studies for more difficult cases. Services conducting more complex services such as bi-level must be able to demonstrate on-going competencies.	

CLAUSE	REQUIREMENT	COMMENTS
5.5.4 Unattended Sleep Study methods		
Patient referral 5.5.4.1	Systems must be in place to refer the patient for a full laboratory study where appropriate. Where a home sleep study is performed which fails to confirm the clinical diagnosis, systems must be in place to refer the patient for a full laboratory study.	
Type of device used 5.5.4.2	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.	
Full disclosure of raw data 5.5.4.3	Unattended (home) studies must allow full disclosure of the raw signals.	
5.5.5 Method Selection		
Method review 5.5.5.1	Method selection and documentation must be regularly reviewed to ensure currency and in accordance with document control procedures.	
Laboratory Procedure Manuals 5.5.5.2, 5.5.5.3, 5.5.5.4	Standard tests and procedures performed by the laboratory must be described in detail in a service manual. Each test should be separately described with detail as stated in the standard. 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.	
New methodology 5.5.6.1	There must be a procedure for the introduction of new methodology.	

CLAUSE	REQUIREMENT	COMMENTS
Validation of methods 5.5.6.2	The service must validate non-standard methods, service designed or developed methods, standard methods used outside their intended scope and validated methods subsequently modified.	
Polysomnography software 5.5.6.3, 5.5.6.4	Laboratories should establish a collection of polysomnograms covering a range of clinical conditions that can be reanalysed when new software is installed. Computations for derived parameters should be validated against a manual method of calculation whenever a method or report is changed.	
Uncertainty of measurement 5.5.7	Reporting physicians must be aware of intra- and inter-laboratory scoring concordance as an indicator of uncertainty of measurement.	
Computers and Control of data 5.5.8.1, 5.5.8.2, 5.5.8.3	The service must establish processes to manage the security and confidentiality of all data relating to a patient's episode of care. Access to the electronic media must be controlled by password and media must be physically located within a secure area of laboratory or clinic. The service must maintain secure copies of reports and clinical information that has been distributed to referring clinicians. Copies may be electronic or hard copy. The service must implement appropriate processes to ensure that all data is copied to backup media whilst still under consideration in the patient's management.	
5.6 Assuring the quality of the service		
Quality Control 5.6.2	Quality control procedures must be documented. The documentation must include the elements stated in the standard.	

CLAUSE	REQUIREMENT	COMMENTS
Quality Indicators 5.6.3, 5.6.4, 5.6.5	The service must establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-study, study (methods) and post-study processes. Quality indicators must be: • Planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. • Periodically reviewed, to ensure their continued appropriateness, and action taken where appropriate.	
Quality control - 5.6.6.1, 5.6.6.2 , 5.6.7	Performance indicators must be established to: • review all aspects of the study including referrals, performance of the study, staging/scoring and reporting. (diagnostic services) • Examine provision of treatment to patients attending the sleep service (treatment service)	
Proficiency testing 5.6.8	The service must participate in a proficiency testing programme(s) appropriate to the sleep studies performed. 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. The performance in proficiency testing must be reviewed and discussed with relevant staff. When predetermined performance criteria are not fulfilled staff must participate in the implementation and recording of corrective action. Physicians should participate in regular peer reviewed concordance processes.	
5.7 Post-study procedures, including ongoing patient care		
5.7.1 Services providing ongoing management of patients		
Treatment protocols 5.7.1.1	Anticipated that clinical interactions between physicians and patients will be carefully performed and follow evidence based guidelines – clinical history, examination of patient, need for diagnostic test and type of test to be performed is apparent.	

CLAUSE	REQUIREMENT	COMMENTS
Treatment protocols 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. The sleep 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 ASA and AASM. Where a service does not offer a particular treatment service in-house, procedures must be in place and documented for the referral to a suitably qualified clinical service which will provide the service on behalf of the sleep service.	
PAP treatment 5.7.1.3	Sleep services must have established processes for the prescription, supply and monitoring of CPAP treatment. Therapy and treatment follow-up must be consistent with good professional practice. This requires a diagnostic study prior to prescription of CPAP. Early follow-up after implementation of treatment is required to determine whether problems affecting treatment adherence exist. Where the service does not provide CPAP services in house, there must be an established relationship with a small number of suitably qualified CPAP providers who are able to perform these tasks on behalf of the service.	
CPAP therapy 5.7.1.4, 5.7.1.5	Once CPAP therapy continues there is evidence of further review to assess the patients' progress – including adherence with CPAP, clinical response, and further review if necessary. Service should have relationship with appropriately trained dental practitioner for the construction of oral appliances and for referral to ENT surgeon where surgical interventions are considered appropriate.	
Paediatric service 5.7.1.6	Procedures must be in place for referral to ENT services performing more complex airway surgery.	
Non-sleep medical issues: management and referral 5.7.1.7, 5.7.1.8	Procedures must be in place for referral of patients with complex respiratory and non-respiratory issues to other specialist services which might include cardiology, ENT, endocrinology, psychiatry, clinical psychology and other specialist service including dental and ENT services as above. Procedures must be in place for referral of complex insomnia patients where services cannot be provided in-house.	

CLAUSE	REQUIREMENT	COMMENTS
Services providing diagnostic services only Treatment protocols 5.7.2.1	A physician involved in the diagnosis or assessment of a patient has a duty to ensure that appropriate follow-up is implemented. A sleep service performing only diagnosis must have in place systems to: • Assess and provide advice to referring doctors on the suitability of the diagnostic method. • Provide a comprehensive summarised report to the referring doctor on results of the study. • Ensure that the referring doctor is provided with adequate information to form an opinion about the necessity for treatment. • Where requested offer advice to the referring doctor about ongoing management of the patient. • Implement urgent clinical review if severe SDB is detected on PSG or other acute problems needing immediate intervention are identified.	
5.8 Reporting of results		
Maintaining a patient record 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 Correspondence, including patient letters and PSG reports should be completed promptly (within ten (10) working days) following each patient contact.	
Information to reporting physician 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. The sleep physician must review the sleep study raw data epoch by epoch. 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. The service must publish and have available to reporting physicians normal reference values for commonly derived indices that include estimates of uncertainty where available.	

CLAUSE	REQUIREMENT	COMMENTS
Opinions and interpretations 5.8.3	While analysis of the sleep study may be performed by a well-trained technologist, interpretation is the responsibility of the interpreting sleep physician. Computerized analysis systems are considered aids to the process: final analysis must be performed manually and involve reference to the raw data, as must interpretation by the responsible sleep physician.	
Reporting 5.8.4	The service must have a documented policy and procedure which describes the processes for reporting, including: • Report authorisation and delegation for issuing of preliminary and final reports. • Preliminary reports must be checked and authorised and the status of the report evident prior to issue. • Where a service issues a preliminary report prior to the final report, the final report must contain a reference to the preliminary report.	
Report Format 5.8.5, 5.8.6, 5.8.7, 5.8.8	A sleep study report must: • clearly identify the service; • clearly identify the site where the study was performed; • clearly identify the patient; • include the date of the study and the date of the report; • contain clinical or technical observations about the conduct of the study, which could influence the interpretation of the study results; • contain the study results along with an interpretive summary statement signed by the interpreting sleep physician • be consistent with current ASA and AASM documents. Each page of a multi-page document must bear a statement of the page number and the total number of pages. 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. The report format must be designed to accommodate each type of sleep study carried out and to minimize the possibility of misunderstanding and misuse.	

CLAUSE	REQUIREMENT	COMMENTS
Revised Report 5.8.9	When an original report is revised there must be written instructions regarding the amendment so that: • the revised report is clearly identified as an amendment report and includes reference to the date of the original report; • the revised report shows the date of the change and the name of the person responsible for the change; A copy of the original report must be maintained. When the reporting system cannot capture amendments, changes or alterations, a record of such must be kept.	
Appropriate security 5.8.10	Appropriate security must be in place for any results transmitted by electronic or any other means. • The service must have a documented protocol for the verbal release of results. • The service must have a documented protocol for the electronic transmission of results. • 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. • 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. • 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.	