

Standards for Accreditation

Updated November 2016

The American Academy of Sleep Medicine (AASM) developed *Standards for Accreditation* with the primary purpose of ensuring that the highest quality of care is delivered to patients with sleep disorders. The constant evolution of sleep medicine necessitates an update to the *AASM Standards for Accreditation* to reflect the models of clinical practice that have emerged in recent years.

New research, policy and technology are shifting the field toward comprehensive patient management. Accreditation of entities that offer diagnostic testing and comprehensive management for sleep disorders is increasingly important as care focuses on improving population health and engaging patients while containing costs. As such, comprehensive sleep facilities must have the capability to provide patient management and testing related to all sleep disorders.

"Sleep facility" is used specifically to refer to sleep centers that comprise both a clinic, where patient evaluation and management occurs, and a laboratory, where diagnostic testing is administered through in-center sleep studies and home sleep apnea testing (HSAT). The clinic and laboratory may be housed in separate locations. By meeting these *Standards for Accreditation*, sleep facilities accredited by the AASM are accredited for all types of sleep testing, including in-center polysomnography (PSG), Multiple Sleep Latency Testing (MSLT), Maintenance of Wakefulness Testing (MWT) and HSAT.

High Quality Patient Care and Management

All qualified sleep medicine physicians and providers must be committed to providing quality patient care. Patients benefit greatly from direct personal interaction with the diagnosing/treating physician and other center staff providers. It is therefore the general position of the AASM that, in ideal circumstances, all patients evaluated and treated in an accredited sleep facility should be seen by a board-certified sleep physician or medical staff member prior to testing and the initiation of treatment. In appropriate instances, sleep facilities also may use telemedicine tools in the provision of sleep medicine services to expand interactions between sleep physicians and sleep patients.

However, the AASM recognizes that patient consultations may be restricted by some health plans or prevented by a variety of other reasonable and unavoidable circumstances. Every effort should be made to manage these conditions in the best interests of the patient and in a way that promotes high-quality care. It is the recommendation of the AASM that a sleep facility should include in its policies a description of any circumstances that prevent patient consultations.

Clinical Recommendations

The AASM uses a rigorous, evidence-based process to establish practice guidelines on a variety of topics that are relevant to the practice of sleep medicine. Accredited sleep facilities must adopt and follow all STRONG and STANDARD level recommendation statements in all active AASM Clinical Practice Guideline, Practice Parameter and Clinical Guideline papers. In addition, it is *recommended* that accredited entities adopt and follow all other recommendation statements (i.e., "Weak", Guideline, Option, and Consensus level recommendations) in all active AASM Clinical Practice Guideline, Practice Parameter and Clinical Practice Guideline, Practice Parameter and Clinical Practice Guideline, Practice Parameter and Clinical Statements (i.e., "Weak", Guideline, Option, and Consensus level recommendations) in all active AASM Clinical Practice Guideline, Practice Parameter and Clinical Guideline papers. It is also recommended that accredited sleep facilities follow applicable AASM Consensus and Position Statements.

Clinical Judgment

The AASM recognizes that the practice of sleep medicine, like all other medical disciplines, is dynamic and complex, requiring clinical judgment. AASM Clinical Practice Guidelines, Practice Parameters and Clinical Guidelines are not designed to limit physicians from using their medical judgment. Therefore, unique circumstances may require deviation from AASM clinical recommendations for the appropriate evaluation and management of select patients. However, in such instances, the AASM accredited facility is expected to keep documentation on file that provides justification for the deviation in standard clinical practice.

Compliance

Facilities accredited by the AASM must be in compliance with all accreditation standards at the time of application and throughout the accreditation period. If it is determined in the application review process that a facility is not in compliance with the required standards, the application will be returned, and the facility will need to resubmit its application once the required standards are met. The AASM reserves the right to revoke accreditation for facilities that are found to be non-compliant with the *Standards for Accreditation* during the period of accreditation.

Denial

Denial of accreditation will be recommended by the site visitor, reviewers, accreditation committee, or staff when one or more of the following conditions are identified:

- The facility fails to meet any of the accreditation standards that are indicated as "MANDATORY." Facilities will not be issued provisos for accreditation standards indicated as MANDATORY. (If granted accreditation with provisos, the facility receives a letter that describes certain stipulations that must be met by a specified deadline to retain accreditation.)
- 2. The facility is determined to be non-compliant with more than ten (10) non-mandatory accreditation standards.
- 3. The facility fails to resolve provisos within the period of time allotted to correct the provisos.
- The AASM has evidence that the facility submitted falsified documents or misrepresented information in seeking to achieve or retain accreditation.

Disclaimer

The AASM is one of multiple bodies that offer accreditation to entities that offer sleep medicine services. Accreditation by the AASM is a voluntary program offered to sleep facilities that meet the standards contained in this document. The AASM reserves the right to modify, add or remove accreditation standards at its own discretion and without notice. In addition, the AASM reserves the right to interpret the *Standards for Accreditation* as deemed appropriate.

Facilities accredited by the AASM must comply with all applicable local, state and federal laws and regulations. If any law or government regulation conflicts with these *Standards for Accreditation*, the law or regulation supersedes the accreditation standard.

Glossary

AASM	American Academy of Sleep Medicine
AASM	The AASM Manual for the Scoring of Sleep and Associated Events:
SCORING Manual	Rules, Terminology and Technical Specifications
ABMS	American Board of Medical Specialties
ABSM	American Board of Sleep Medicine
ACGME	Accreditation Council for Graduate Medical Education
ADA	Americans with Disabilities Act
AED	Automated External Defibrillator
АНІ	Apnea-Hypopnea Index
ΑΟΑ	American Osteopathic Association
APRN	Advanced Practice Registered Nurse
A-STEP	Accredited Sleep Technologist Education Program
BRPT	Board of Registered Polysomnographic Technologists
СААНЕР	Commission on Accreditation of Allied Health Education Programs
CEC	Continuing Education Credit
СМЕ	Continuing Medical Education
COARC	Commission on Accreditation for Respiratory Care
CPR	Cardiopulmonary Resuscitation
CPSGT	Certified Polysomnographic Technician
CRT	Certified Respiratory Therapist
DME	Durable Medical Equipment
НІРАА	Health Insurance Portability and Accountability Act
HITECH	The Health Information Technology for
	Economic and Clinical Health Act
HSAT	Home Sleep Apnea Test
ICSD	International Classification of Sleep Disorders
ISR	Inter-Scorer Reliability
MSLT	Multiple Sleep Latency Test
мwт	Maintenance of Wakefulness Test
NBRC	National Board for Respiratory Care
OSA	Obstructive Sleep Apnea
OSHA	Occupational Safety and Health Administration
PA	Physician Assistant
PAP	Positive Airway Pressure
PHI	Protected Health Information
PSG	Polysomnography
QA	Quality Assurance
RDI	Respiratory Disturbance Index
REI	Respiratory Event Index

RLS	Restless Legs Syndrome
RN	Registered Nurse
RPSGT	Registered Polysomnographic Technologist
RRT	Registered Respiratory Therapist
RST	Registered Sleep Technologist

AASM Continuing Education Appendix

CME opportunities include:

- AASM Courses:
 aasmnet.org/upcomingcourses.aspx
- Journal of Clinical Sleep Medicine: aasmnet.org/JCSM
- AASM Online Learning Opportunities:
 aasmnet.org/learningcenter/learningmoduleprograms.aspx
- AASM MOC Modules: aasmnet.org/MOC

CEC opportunities include:

- AASM ISR Record Review: aasmnet.org/isr
- AASM A-STEP: aasmnet.org/astep
- AAST Learning Opportunities: go.aastweb.org/LearningCenter/Home.aspx

*AMA PRA Category 1 Credit or equivalent type of continuing education credit accepted/maintained by your profession will be accepted.

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A. General Standards

Facilities accredited by the AASM are considered qualified to perform all testing related to all sleep disorders listed in the current version of the International Classification of Sleep Disorders. This includes but is not limited to in-center polysomnography, MSLT, MWT and HSAT.

STANDARD

A-1 Facility Director (MANDATORY)

Facilities must appoint a facility director who is board-certified in sleep medicine (as defined in Standard B-2) by the ABSM, a member board of the ABMS or a member board of the AOA and who may be a MD, DO or PhD. See Standards B-1 through B-4 for additional requirements

STANDARD

A-2 Licensing (MANDATORY)

1. Facility License

Facilities must maintain a valid state license to provide health care services. If a valid state license is not required by applicable law, the facility may submit a certificate of occupancy and/ or permit to provide health care services. If no license, certificate or permit is required by applicable law, the facility director must submit a written attestation that the above is not required.

2. Individual Licensure

All professional staff (including MDs, DOs, PhDs, APRNs, PAs, and RNs) and technical staff (including RRTs, RSTs, RPSGTs and non-registered technologists) must maintain valid, unrestricted licenses commensurate with the services they perform in the state(s) where patients are seen, when required by state law. Each staff member must practice within the limits of his or her license. The AASM neither sanctions nor defends individuals practicing outside the scope of their license. Privileges and restrictions of licenses are contained in the practice act related to each license.

STANDARD

A-3 Medical Code of Conduct (MANDATORY)

Facilities and their physician staffs are required to follow the current opinions in the *Code of Medical Ethics* of the American Medical Association Council on Ethical and Judicial Affairs. The facility must have the ability to easily access the *Code of Medical Ethics*.

STANDARD

A-4 HIPAA Rules and Regulations (MANDATORY)

- 1. Facilities are required to abide by all current, applicable Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health ("HITECH") rules and regulations.
- 2. Facilities must operate under written policies that govern the practice of maintaining the confidentiality of Protected Health Information ("PHI"). It is the responsibility of the facility director that these

policies are in place. Written policies must address the importance of protecting PHI. Protecting PHI must be the responsibility of all personnel employed by the facility, and all employees must attest to their awareness that federal and state privacy laws, along with any additional privacy rules, protect PHI. Except as permitted by law, personnel shall not share any PHI with any party, including but not limited to other health care providers, health care institutions, DME companies, employers or payers.

- 3. Facility policies shall reflect that patients have a right to:
 - Review a privacy notice to inform them how PHI will be used and disclosed;
 - Request that uses and disclosures of PHI be restricted (facilities are not required to agree to the restrictions);
 - Inspect, copy and amend their medical records; and
 - Get an accounting of the disclosure of their PHI.
- 4. The facility director is responsible for ensuring that all appropriate personnel are trained regarding HIPAA regulations and that patients are informed of their rights under HIPAA, including the unauthorized solicitation of PHI by any person or company, through distribution of privacy practices notices. Proof of training shall be maintained by the facility.
- 5. The facility director must promptly notify all appropriate parties, including but not limited to a hospital compliance officer, attorney or other appropriate office within a hospital, of any HIPAA violations. Facilities must have or operate under written privacy breach notification policies and procedures which outline the processes to determine whether there has been the acquisition, access, use or disclosure of PHI in a manner not permitted under the HIPAA regulations which compromise the security or privacy of the PHI ("Breach"). If it is determined there is more than a low probability that PHI is compromised, notification shall be made in accordance with applicable law.

B. Personnel

STANDARD

B-1 Facility Director (MANDATORY)

Facilities must designate a single facility director who is board-certified (as defined in Standard B-2) in sleep medicine by the ABSM, a member board of the ABMS or a member board of the AOA. The facility director must be an unrestricted licensed physician or a PhD. See Standard A-1.

STANDARD

B-2 Facility Director Qualifications (MANDATORY)

The designated facility director must be a sleep specialist who meets one of the following requirements:

- 1. A physician or PhD who is board-certified in sleep medicine by the ABSM or a physician certified in sleep medicine by either a member board of the ABMS or a member board of the AOA.
- 2. A physician who has completed a 12-month ACGME-accredited or AOA-accredited fellowship in sleep medicine, is eligible to sit for the sleep medicine board examination, and is awaiting the first available opportunity to apply to an ABMS member board or AOA member board to sit for the sleep medicine examination. To retain accreditation, the ABMS or AOA examination in sleep medicine must be passed within two consecutive examination cycles.

B-3 Facility Director Responsibilities

The facility director:

- 1. Is responsible for serving as primary contact or designating a primary contact for the AASM and apprising the AASM of any changes to the facility.
- 2. Is responsible for ensuring there is a process for determining that only licensed health care professionals with prescriptive authority in the state where the patient would be tested can request a HSAT.
- 3. Is responsible for the qualifications of all medical and technical personnel.
- 4. Is responsible for the supervision and oversight of facility professional and technical staff.
- 5. Is responsible for assuring staff complies with the *Code of Medical Ethics* as well as any institutional ethics requirements.
- 6. Must provide direct and ongoing oversight of the testing protocols and the quality of testing including the proper operation and calibration of the equipment.
- 7. Must review, report, and manage the facility's quality assurance program on a quarterly basis as mandated in Section J.
- 8. It is recommended that the facility director spend a minimum of 8 hours per month fulfilling the above responsibilities. The facility director may fulfill this requirement by either physical presence in the center, and/or regular conference calls, virtual meetings and webinars with the professional and technical staff.

STANDARD

B-4 Facility Director Continuing Education (MANDATORY)

The facility director must earn at least 10 credits per year (averaged over three years) of AMA PRA Category 1 CME credit in sleep medicine. Compliance with CME requirements must be documented. See appendix for CME opportunities.

Physicians recently completing a sleep medicine fellowship will have the CME requirement waived for 36 months from the end date of the program.

STANDARD

B-5 Medical Staff Member (MANDATORY)

Sleep facilities whose facility director is not an appropriately licensed physician must have, at minimum, one physician (MD or DO) medical staff member with a valid, unrestricted license in the state where the center is located. Sleep facility medical staff members include physicians, licensed psychologists, APRN (all of whom may or may not be board-certified in sleep medicine) and physician assistants who hold a valid, unrestricted state license in states where patients are evaluated, diagnosed or treated. The AASM recommends medical staff members be board certified in sleep medicine.

STANDARD

B-6 Medical Staff Member Continuing Education

Medical staff members must earn at least 10 credits per year (averaged over three years) of AMA PRA Category 1 CME credit in sleep medicine. Compliance with CME requirements must be documented.

Medical staff members who have completed a formal training program within the previous 12 months will have their credit requirements waived. Upon completion of a training program, the applicable continuing education requirement in sleep medicine will be prorated based on the end date of the program. Education sessions conducted at the facility

are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the facility director. See appendix for additional CME opportunities.

The AASM has adopted job descriptions that delineate the education, training, and responsibilities of sleep technologists, sleep technicians, and sleep technician trainees. All sleep technologists/technicians must be able to perform the duties listed in the AASM approved job descriptions. Standards B-7 through B-11 address requirements for sleep technologists, technicians and trainees. These standards do not differentiate between the various job descriptions or titles that facilities may use for the employment of sleep technicians and technologists. For example, a sleep technologist or technician whose primary responsibility is to score a sleep study is subject to the same accreditation standards as a sleep technologist or technician whose primary responsibility is sleep test monitoring. Specifically, CPR certification is required for <u>all</u> facility technical staff members, regardless of their duties.

STANDARD

B-7 Sleep Technicians and Technologists

- 1. Facilities must maintain appropriately trained, supervised, and, where required by state law, licensed sleep technologists. Technologist staffing at facilities must be adequate to address the workload of the facility and assure the safety of patients. The AASM recommends a patient to technologist ratio of 2:1 under usual circumstances for attended PSG at facilities.
- 2. Facilities must maintain appropriately trained, supervised, and, where required by law, licensed personnel. It is the responsibility of the facility director to ensure that training is provided and documented for technical personnel.
- 3. Technical staff must be trained on the proper use of HSAT devices including:
 - Device operations, application of sensors, use, maintenance, warnings and safety;
 - Instruction of patients in the use of HSAT devices;
 - · Troubleshooting of HSAT problems; and
 - Infection control.

STANDARD

B-8 Registered Sleep Technologist

Facilities must employ at least one sleep technologist that is registered in sleep technology or accepted to sit for the registry examination through one of the following organizations:

- 1. American Board of Sleep Medicine (ABSM)
- 2. National Board for Respiratory Care (NBRC)
- 3. Board of Registered Polysomnographic Technologists (BRPT)
- 4. Another organization that offers an equivalent examination accepted by the AASM

The registry exam must be passed within one year from acceptance to sit for the examination. The individual(s) fulfilling this standard must be present at the facility at least 30 hours per week. If the facility is open fewer than 40 hours per week, then the registered technologist(s) must be present at the facility for 75% of operating hours.

A facility that loses its sole registered technologist will have 120 days to fulfill this standard.

B-9 Sleep Technician and Technologist Continuing Education

All technical staff must participate in at least 10 hours per year (averaged over three years) of sleep-related continuing education credits. This must be documented for each technical staff member. Education sessions conducted at the facility are acceptable for fulfilling this standard provided the session has defined educational objective(s) and attendance is documented by a roster signed by the facility's facility director.

Each sleep technician and technologist must have valid CPR certification that includes skills training.

STANDARD

B-10 Non-registered Sleep Technologist

All technologists and technicians conducting sleep testing who are not registered by the ABSM, BRPT, or NBRC:

1. Must be enrolled in or have completed the A-STEP Online Self Study Modules. Non-registered technologists and technicians must complete A-STEP Online Self Study Modules within two years of enrollment.

OR

2. Must be enrolled in or have completed training in polysomnography in a program accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or a Commission on Accreditation for Respiratory Care (CoARC) program with the polysomnography option.

STANDARD

B-11 Scoring Personnel

Scoring personnel must be one of the following: RST, RPSGT, CPSGT, respiratory therapists with the sleep disorders specialist certification (either CRT-SDS or RRT-SDS), or medical staff members/PhDs board-certified in sleep medicine (as defined in Standard B-2). Non-registered sleep technologists (as defined in Standard B-10) may score only under the supervision of one of the above while adhering to Standard B-10.

STANDARD

B-12 Addressing Problems during HSAT

- 1. The facility must have and comply with a written protocol that provides oncall coverage to address problems encountered during HSAT.
- 2. All patient and technical problems encountered during testing hours must be documented in a secure log. Quarterly audits must be conducted of these logs to identify trends related to device, sensor or service issues.

STANDARD

B-13 Employee Background Checks

The facility shall comply with all background check requirements which may be required by federal, state or local law. In the absence of such requirements, the facility shall conduct criminal background checks of all new employees. The facility shall utilize information obtained in this process only to the extent such information is relevant to the job duties of a particular person.

C. Patient Policies

STANDARD

C-1 Patient Acceptance for In-center Testing

Facilities must maintain a Policy and Procedures Manual that addresses patient acceptance policies for in-center testing. Written policies for patient acceptance must include:

- Adherence to all applicable, current AASM guidelines (including Diagnostic Practice Parameters, which can be found at.aasmnet.org/practiceparameters.aspx?cid=120);
- Age limitations;
- A mechanism for acceptance;
- Evidence based criteria for exclusion; and
- Information required from a referring health care provider prior to all sleep testing.

Facilities must demonstrate their acceptance and testing of patients with the full spectrum of sleep diagnoses as delineated by the current edition of the *International Classification of Sleep Disorders*. The testing portion of this standard can be met by providing a list of diagnoses or tests performed over a period of at least six months.

STANDARD

C-2 Patient Acceptance for HSAT

Facilities must maintain a Policy and Procedures Manual that addresses evidence based patient acceptance policies for HSAT. Written policies for patient acceptance must include:

- Adherence to all applicable, current AASM guidelines (including J Clin Sleep Med. 2007 Dec 15;3(7):737-47);
- Age limitations;
- A mechanism for acceptance;
- Evidence based criteria for exclusion; and
- Information required from a referring health care provider prior to all sleep testing.

HSAT should adhere to the criteria of high pretest probability according to the AASM guidelines. If the AASM guidelines are not used, as in the case of insurance mandate or medical exception, then a written protocol explaining acceptance criteria, rationale, and follow-up procedure on negative tests and positive tests must be in place.

STANDARD

C-3 Record Review of Direct Referrals

For patients directly referred, the facility director or appropriately licensed medical staff member must review the information provided for each patient and determine if the requested test is indicated according to Standard C-1/C-2. Evidence of communication with the referring clinician should be recorded in the patient record for every PSG or HSAT. This should include a history and physical received from the referring clinician and a sleep study report sent back to the referring clinician.

D. Facility and Equipment

STANDARD

D-1 Permanent Address

Facilities must have a permanent, physical address.

STANDARD

D-2 Phone Line

Facilities, including both the clinical and laboratory settings if they are separate, must have a designated phone line(s) to directly receive incoming calls. Facilities must have immediate communications access to emergency services (medical, fire and security).

STANDARD

D-3 Signage

Facilities must have signage on the outside of the facility or in a directory identifying the facility.

STANDARD

D-4 Stationery

Facilities must have professional stationery that includes the name, address, and phone number of the facility. For hospital-based facilities, this standard will be met provided the facility is located on the site carrying the primary address listed on the hospital's stationery.

STANDARD

D-5 Use of Space

Accreditation is granted to a single facility, generally defined by a physical space used primarily for conducting sleep testing. All of the elements required to conduct sleep tests must be available within the defined testing space. The administrative office(s) and/or staff clinician office(s) of the facility may be separate from the laboratory testing site.

STANDARD

D-6 Testing Bedrooms – Physical Characteristics

All testing bedrooms must be single occupancy, private and comfortable, have hard floor-to-ceiling walls, and a privacy door that opens directly to a corridor or common use area such that the patient can access the testing bedroom without having to pass through another testing bedroom.

STANDARD

D-7 Testing Bedrooms & Emergency Care

Patient testing bedrooms must not have any impediments to the delivery of emergency care. The patient testing rooms:

- 1. Must be of sufficient size to accommodate emergency personnel access with a minimum of 24 inches of available clear space on three sides of the bed;
- 2. Must include a testing bed with a mattress not smaller than a standard hospital bed.

STANDARD

D-8 Bathrooms

The facility must have clean bathrooms with a minimum ratio of one bathroom for every three testing rooms; these bathrooms

must each contain a toilet and a sink. Each bathroom must have a working privacy door. Sole access to a shared bathroom shall not be through a testing bedroom.

STANDARD

D-9 Handicap Testing Bedroom and Bathroom

At least one testing bedroom and bathroom at each facility must be handicap accessible as defined by local building regulations and the Americans with Disabilities Act (ADA).

STANDARD

D-10 Control Room

The dimensions of the control room must not be less than 40 square feet total or 20 square feet per testing bedroom, whichever is larger.

STANDARD

D-11 Communication

The facility must maintain a two-way communication system between the patient bedroom and the control room and/or facility personnel.

STANDARD

D-12 Video Recording

The facility must have continuous visual monitoring and video recording of patients during testing. Time-delayed photographs will not be considered compliant with this standard.

STANDARD

D-13 Polysomnographic Equipment

The facility must use polysomnographic equipment that meets all of the "RECOMMENDED" minimal technical and digital specifications in the current version of *The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications* (AASM Scoring Manual).

STANDARD

D-14 Portable Recording Equipment

All HSAT equipment must be FDA-approved and meet the minimum requirements of the current AASM guidelines. Equipment must provide a measure of respiratory events per unit time (AHI, RDI or REI). Equipment must allow for the display of raw data for manual scoring and editing.

All reusable equipment must have a unique identifier so that it may be assigned to a patient and tracked. The identifier must be recorded and used to assist in failure investigation and a plan for preventing future failures must be documented. HSAT equipment must have the capability that all PHI and physiologic data can be erased following each use of the device.

Equipment used must have the capability to meet all HSAT accreditation standards outlined in Section F.

STANDARD

D-15 PAP Therapy

The facility must maintain equipment for the delivery of positive airway pressure therapy for sleep apnea, including remote control of the device (e.g., pressure output, device mode).

E. Policies and Procedures

STANDARD

E-1 Policy and Procedures Manual

Facilities must maintain a Policy and Procedures Manual. The manual must contain all policies, procedures, and protocols specific to the facility, and must be consistent with all current AASM Practice Parameters, AASM Clinical Guidelines, AASM Clinical Practice Guidelines and AASM Best Practice Guidelines (available at http://www.aasmnet.org/practiceguidelines.aspx). The manual must contain all policies and procedures required within these *Standards for Accreditation*.

STANDARD

E-2 Required Protocols: PSG, HSAT, MSLT, MWT, and PAP Titration

Facilities must maintain written protocols in paper or electronic form for all of the following tests: comprehensive PSG, MSLT, MWT, titration of PAP therapy and HSAT. Facilities are encouraged to use "Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea" (J Clin Sleep Med. 2008;4(2):157–171) in constructing PAP titration protocols.

STANDARD

E-3 Other Protocols

If facilities conduct esophageal pressure monitoring, actigraphy, end-tidal CO_2 monitoring or transcutaneous CO_2 monitoring, then they must maintain protocols for these procedures. If facilities conduct other tests not specifically mentioned in Standard E-2 or E-3, they must also maintain protocols for these procedures consistent with applicable standards of care.

STANDARD

E-4 Pediatric Protocols

Facilities that test sleep patients under the age of 13 years must maintain age specific protocols in the Policy and Procedures Manual for comprehensive PSG, titration of PAP therapy and capnography.

STANDARD

E-5 Equipment Maintenance

The facility must have a written plan for monitoring of all patient-related equipment for electrical and mechanical safety. The written plan must include specific instructions regarding documentation of compliance in an equipment maintenance log. The plan must address monthly visual inspection of equipment by staff for apparent defects; adhering to manufacturer's recommendations for monitoring and maintenance of recording equipment; and annual electrical safety testing by a certified electrician or biomedical engineer.

- 1. The facility must have a written procedure for infection control including cleaning and inspecting equipment; this includes sterilization, high-level disinfection, or the application of germicidal agents after each use that is consistent with the manufacturers' recommendations, federal and state health policy regulations and institutional standards.
- 2. All devices and sensors associated with a failed test (e.g. no data, inadequate data, or corrupt data) must be removed from service and tested for proper function prior to next use.
- 3. Reported or detected failures of devices, sensors or processes must be categorized and analyzed for cause and a plan for preventing future failures must be documented.
- 4. The facility must physically separate clean and dirty devices in compliance with its infection control plan.

E-6 HSAT Equipment Procedures

- 1. Specific instructions must exist for HSAT device and sensor packing, shipping and storage.
- 2. Facilities must have a policy in place that documents the procedure(s) used to delete all PHI and physiologic data from HSAT equipment following each use of the device.

F. Data Acquisition, Scoring and Reporting

STANDARD

F-1 Signal Acquisition

The signals collected must meet the requirements of the current version of AASM Scoring Manual. The facility must use either the "RECOMMENDED" or "ACCEPTABLE" montages in the scoring manual.

STANDARD

F-2 PSG Reports

Reports of polysomnography must include all the "RECOMMENDED" and/or "ACCEPTABLE" parameters from chapter II. Parameters to be Reported for Polysomnography of the current version of the AASM Scoring Manual. When the AASM Scoring Manual allows for options in scoring, the report must indicate which option is used.

STANDARD

F-3 HSAT Reports and Recommendations

Reports of HSAT must include all the "RECOMMENDED" and/or "ACCEPTED" parameters from chapter IX. Home Sleep Apnea Testing (HSAT) Rules for Adults in the current version of the AASM Scoring Manual. Any recommendations for next management steps (based upon test results and clinical information), if provided, must be consistent with applicable AASM Standards of Practice, AASM Practice Guidelines, AASM Clinical Practice Guidelines and AASM Best Practice papers.

STANDARD

F-4 Conducting MSLT and MWT

The MSLT and MWT must be conducted using the protocol described in the most current version of the AASM Practice Parameters.

STANDARD

F-5 PSG Scoring

Each epoch of each PSG must be scored for sleep staging, arousals, respiratory events and limb movement in accordance with the most current version of AASM Scoring Manual.

STANDARD

F-6 Computer-assisted Scoring

If used, computer-assisted scoring of PSG must be reviewed epoch-by-epoch and edited by staff as defined in Standard B-11 for accuracy.

STANDARD

F-7 Inter-scorer Reliability

Inter-scorer reliability (ISR) must be determined between each scorer and the facility director or a medical staff member board-certified (as defined in Standard B-2) in sleep medicine or a corporate-appointed physician or PhD board-certified in sleep medicine; such individual must be an employee of the corporation and serves as the

reference sleep specialist. ISR assessment must be conducted for each individual facility. In cases where a corporateappointed individual serves as the reference standard for ISR, the facility director or medical staff member must attest in writing that he/she has reviewed the results of the ISR assessment and will take corrective action when results fall below the facility's level of acceptable agreement as defined in its quality assurance program.

For comprehensive PSG, the following parameters must be compared: sleep staging epoch-by-epoch agreement, respiratory events, leg movements and arousals. Sleep technologists must be blinded to the scoring of the facility director/medical staff member and to all other scoring technicians. Comparisons between each scorer and the facility director/medical staff member must be made on 200 consecutive 30-second epochs in each of three polysomnograms per quarter, for a total of 12 polysomnograms per year. Comprehensive PSG studies must report agreement between scorer and the facility director/ medical staff member as percent concordance defined as the quotient of the total number of epochs of agreement for a given parameter and the total number of epochs in the analysis sample multiplied by 100. Sleep-related breathing event comparisons for laboratory PSG must include analysis by total number of events and by the following event types: obstructive apnea, central apnea and hypopnea. If the facility reports respiratory effort related arousals, this event must be included in the comparison. Use of the AASM Inter-Scorer Reliability program fulfills the requirements of this standard.

STANDARD

F-8 Diagnosis of Sleep Disorders

Only a licensed physician, and APRN in certain states, can diagnose a medical condition such as obstructive sleep apnea or snoring. An individual board certified in sleep medicine (as defined in Standard B-2) must review the diagnoses based upon the interpretation of a sleep study made by individuals who are not certified in sleep medicine (as defined in Standard B-2).

STANDARD

F-9 Subcontracting HSAT

Accredited facilities may subcontract home sleep apnea testing. The subcontract may not include diagnosis of a medical condition; this must remain the responsibility of the facility's appropriately licensed physician or APRN, as appropriate. The facility must have a written agreement with the subcontractor to this effect that clearly identifies the specific expectations of the subcontractor and requiring the subcontractor to meet all applicable AASM HSAT Standards. The facility is responsible for assessing the performance of the subcontractor in meeting contractual obligations on an annual basis.

STANDARD

F-10 Subcontracting Scoring

When a subcontractor scores sleep studies, the facility must have a written agreement with the subcontractor that enumerates the performance expectations of the subcontractor. The scorers of the subcontractor must meet all applicable AASM Accreditation standards for scoring personnel. The facility is responsible for assessing the performance of the subcontractor in meeting contractual obligations including meeting applicable standards on an annual basis.

G. Patient Evaluation and Care

STANDARD

G-1 Patient Management (MANDATORY)

Facilities must document in the medical record ongoing evaluation, management and follow-up of each patient with sleep disorders. Facilities must be able to show medical records to demonstrate management of an adequate range of sleep disorders. All sleep disorders are defined by the current edition of the *International Classification of Sleep Disorders*.

H. Patient Records

STANDARD

H-1 Medical Records

All facilities must maintain appropriate medical records for every patient evaluated and/or tested in the facility. Medical records of patients seen by the medical staff members must document all interactions with the patient, referring provider or provider's representative, and insurance company. Medical records must include the referral letter/prescription for testing, with or without consultation by medical staff members of testing facility.

Prior to testing, all patient medical records must include: patient questionnaires or other screening assessment, history and physical, as well as medications record. Potential serious medical conditions that might lead to medical emergencies while at the testing facility should be noted and carefully reviewed. The record must be reviewed and approved for study by the facility director or appropriately licensed medical staff member.

STANDARD

H-2 PAP Assessment

Patients prescribed PAP treatment by the facility's medical staff members must be offered a follow-up positive airway pressure assessment within 12 weeks of treatment initiation. PAP assessment must minimally include a measurement of treatment use and clinical response to the therapy as determined by both of the following requirements:

- 1. Documentation of review of device download confirming response to therapy and adequate adherence as defined by the AASM; and
- 2. Documentation of subjective response to therapy such as a questionnaire or patient report during face-to-face encounter.

The patient medical record must contain documentation of the assessment as described above or written evidence of followup attempts to obtain the PAP treatment assessment. If inadequate response to therapy is present on the device download or the patient's subjective report, there must be follow up visits scheduled or offered to the patient. These visits should include assessment of causes of intolerance or non-acceptance of the device and review of device download and device-patient interface.

STANDARD

H-3 Database/Storage

The facility maintains a cumulative database or spreadsheet of all patients' sleep diagnoses, using current code numbers from the current edition of the *International Classification of Sleep Disorders*. The facility must store the raw data (excluding video) from all sleep tests (including but not limited to PSG, MSLT, and HSAT) for a minimum of five years or as required by law if longer. Electronic copies may be provided to other treating sleep physicians who are not affiliated with the facility in accordance with patients' request for release of medical information.

I. Emergency Procedures

STANDARD

I-1 Emergency Plan

Facilities must have a written emergency plan accessible in paper or electronic format delineating the following:

1. Mechanisms and specific details for contacting emergency personnel;

- 2. The facility personnel to be contacted in an emergency; and
- 3. Specific responsibilities of the medical and technical staff.

Emergency policies must include policies and procedures for the following:

- 1. Cardio-pulmonary emergencies with equipment required in Standard I-4
- 2. Neurologic emergencies, particularly seizures
- 3. Psychiatric emergencies, particularly suicidal ideation
- 4. Environmental emergencies including fire, weather, belligerent patients, and bomb threats

STANDARD

I-2 HSAT Emergency Procedure

The facility must instruct the patient to call emergency services (911) in the event of an emergency during a HSAT.

STANDARD

I-3 Emergency Drills

Facilities must conduct and document drills of their emergency procedures on an annual basis. At a minimum, the facility conducts and documents annual drills of their response to cardio-pulmonary emergencies.

STANDARD

I-4 Emergency Equipment

Facilities must have appropriate equipment to address possible emergencies. At a minimum, all facilities must have either an automated external defibrillator (AED) or access to an on-site medical emergency response team. The facility maintains and documents the maintenance of all emergency equipment according to manufacturers' recommendations. The facility maintains and documents training of personnel on emergency equipment.

J. Quality Assurance

STANDARD

J-1 Facility Quality Assurance Program

Facilities must have a QA program that addresses the following indicators:

- 1. A process measure for OSA;
- 2. An outcome measure for OSA;
- 3. An outcome measure for another sleep disorder (e.g. RLS, Insomnia or Narcolepsy); and
- 4. Inter-scorer reliability as outlined in Standard F-7.

These measures may be chosen from the AASM Quality Measures (available at http://www.aasmnet.org/QualityMeasures.aspx).

STANDARD

J-2 HSAT Quality Assurance Program

The facility must have a QA program for HSAT that addresses two process measures and one outcome measure. These measures may be chosen from the AASM Quality Measures (available at http://www.aasmnet.org/QualityMeasures.aspx).

J-3 Quality Improvement

The facility must establish minimal thresholds for the quality assurance metrics. Quarterly, the facility director must attest to the effectiveness of quality improvement efforts and address plans for remediation of metrics that do not meet the minimal threshold. Quarterly reports must be signed and dated by the facility director and maintained for at least five years.

K. Safety

STANDARD

K-1 Facility Safety

The physical facility(s) used by the facility complies with all required standards, regulations and codes for construction, fire safety and building codes applicable in the jurisdiction where the facility is located and appropriate to the facility type.

STANDARD

K-2 Occupational Safety

The facility must demonstrate compliance with all applicable OSHA requirements as well as appropriate state authorities. This includes but is not limited to:

- 1. Access to safety data sheets for hazardous materials;
- 2. Availability of personal protective equipment; and
- 3. Eyewash stations when required.

STANDARD

K-3 Hazardous Materials

The facility disposes of all hazardous materials in compliance with the manufacturer's recommendations and applicable laws and regulations.

STANDARD

K-4 Patient Safety Risk Analysis

The facility must complete and document an analysis of safety risks to patients related the procedures performed by the facility. This analysis must be updated periodically and no less frequently than every five years. The risk analysis must be reviewed, and the review documented, on an annual basis. Examples of risks may include: patient falls after receiving hypnotics, slippery shower surfaces, and uneven ground to/ from the facility. The facility must implement policies and procedures to mitigate risks identified.

STANDARD

K-5 Patient Safety Related Significant Adverse Events

Within the facility, the facility director must document the occurrence of significant adverse events for its patient population. At a minimum, the following events must be considered significant adverse events:

- Patient or staff death
- Permanent loss of function or of a body part by a patient or staff
- An event that leads to the hospitalization of a patient or staff
- An event that requires activation of an emergency medical response

- Sexual or physical assault of a patient or staff or allegations thereof
- Release of a minor or a patient lacking capacity or competency to an unauthorized individual
- Elopement of a patient
- Complications arising from the effects of hypnotics used for the purpose of sleep testing
- Any event required by the applicable jurisdiction to be reported to a government agency

K-6 Analysis of Significant Adverse Events

The facility must create a policy and procedure for performing a root cause analysis of any significant adverse events. Consistent with the policy, the facility must conduct an investigation of all significant adverse events that occur.

STANDARD

K-7 Safety Risks Unique to In-center Sleep Testing

Recognizing the unique vulnerability of patients and staff in a sleep testing environment, facilities must have explicit policies and procedures to minimize the risk for assault or allegations of inappropriate behavior during the testing timeframe. This may include the use of continuous video monitoring throughout the patient encounter in the lab and/or specific training for the use of chaperones during interactions between patients and staff.

L. Patients' Rights

STANDARD

L-1 Patients' Rights

Facility must have a patients' bill of rights and ensure patients are informed of these rights. If the facility is part of a larger organization, it may use its organization's bill of rights. Otherwise, the facility must have a patients' bill of rights that addresses at least the following:

- 1. The right to accurate and easily-understood information proposed about the patient's health care and the providers of such care. If the patient speaks another language, has a physical or mental disability or just doesn't understand something, help should be given so that the patient can make informed health care decisions.
- 2. The right to know treatment options and take part in decisions about care. Parents, guardians, family members, or others can speak for the patient, if the patient cannot make his/her own decision.
- 3. The right to considerate, respectful care from your doctors and other health care providers that does not discriminate against the patient.
- 4. The right to talk privately with health care providers and to have health care information protected.
- 5. The right to read and copy your own medical record, the right to ask that your doctor change the record if it is not correct, relevant or completed.
- 6. The right to examine and receive a detailed explanation of any medical bill and the right to information regarding financial assistance the facility may offer