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REVIEW ARTICLE

Revised European guidelines for the accreditation of sleep medicine centres

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Summary

The accreditation of sleep centres aims to ensure high-quality diagnosis and management of sleep centres. European accreditation standards were introduced in 2006, and were aimed at centres offering inpatient polysomnography and vigilance tests (Mean Sleep Latency Test and Maintenance of Wakefulness Test). Since then, the practice of sleep medicine has evolved, with greater use of ambulatory polysomnography and polygraphy. As a result, in many sleep centres, actual clinical practice, although of a high standard, is no longer in accordance with the published guidelines. The current criteria have been revised with the introduction of level-based criteria. Level 1 and 2 centres offer full diagnostic testing in a laboratory-based setting. Level 1 practices will usually be university affiliated, and have a full teaching and active research role. Level 3 and 4 practices may offer both inpatient and ambulatory testing. Level 3 practices perform polysomnography, while level 4 practices (usually monodisciplinary and focussed on sleep apnea) perform polygraphy only. The role of the medical and paramedical team, training, appropriate equipment, patient care pathways and patient management according to national/European recommendations is underlined for accreditation at each level. It is anticipated that the guidelines will be reviewed and if necessary revised after 4 years.

KEYWORDS
accreditation, Europe, guidelines, sleep medicine

1 | INTRODUCTION

Accrediting sleep medicine practices encourages high quality in the diagnosis and management of sleep disorders. Prior to 2006, accreditation of sleep medicine practices was developed independently by individual European countries with the proposition of a consensus-based harmonisation of procedures in 2004, which led to the publication of European accreditation guidelines in 2006 (Pevernagie, 2006). The initial European guidelines applied only to sleep medicine centres (SMCs), defined as centres capable of the diagnosis and treatment of a wide variety of sleep disorders, including hypersomnias. The authors proposed regular updating of the criteria to include the anticipated advances in sleep medicine.

Sleep medicine practice has indeed evolved, and the development of ambulatory polygraphy (PG) and polysomnography (PSG) means that the practice of sleep medicine has become more heterogenous. Technical advances in signal processing and analysis with the use of extended PG have the potential to offer more detailed studies in the ambulatory setting (Arnardottir et al., 2021).

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Increasing demand for clinical sleep services has led to the expansion of telemedicine, which offers medical care via synchronous or asynchronous telecommunication with a patient. This is a rapidly expanding field: while initially telemedicine connected the patient with a physician in a sleep centre, experience during the COVID epidemic showed the physician could be situated away from a sleep centre and manage many aspects of patient care remotely (Fauroux & Verbraecken, 2023; Shamim-Uzzaman et al., 2021a; Verbraecken, 2021). We anticipate that telemedicine for sleep medicine will evolve rapidly: international guidelines have been published with recommendations for the practice of telemedicine (Bae & Ehsan, 2021b). Telemedicine is not within the remit of this article, which deals with the accreditation of physical sleep centres.

While SMCs are important hubs for the diagnosis and management of central hypersomnias and complex cases, other pathologies such as obstructive sleep apnea (OSA) or insomnia can be managed entirely in the ambulatory setting practices. This has been reflected by the American Academy of Sleep Medicine (AASM) accreditation standards (AASM, 2022a; AASM, 2022b). They differentiate between the following.

1. Sleep medicine facilities that provide comprehensive management and laboratory testing of all sleep pathologies.
2. Independent sleep practices that manage patients with all sleep disorders and perform ambulatory sleep studies (home sleep apnea testing).
3. Specialty (non-sleep) practices that perform sleep apnea screening and diagnosis, and facilitate the management of sleep apnea via an AASM-accredited sleep facility.

In addition, under the old definition of SMCs it was not possible to differentiate between small SMCs and larger SMCs, usually located in a university teaching hospital setting that combines clinical work with research and teaching. Therefore, a revision of the previously published guidelines (Pevernagie, 2006) is needed.

The revision aims to establish new and more inclusive criteria for the accreditation of sleep practices, with the aim of assuring high-quality diagnosis and management of sleep pathologies for all practitioners. These revised criteria are aimed at National Sleep Societies (NSS) who are responsible for local accreditation activities with the intention of harmonising accreditation practices across Europe. Adopting a common set of criteria will facilitate cross-border comparison for both patients and doctors, and enable recruitment for European research projects.

2 | METHODS

The development of revised accreditation criteria was commissioned by the European Sleep Research Society (ESRS). Members for the accreditation working party were appointed from within the Sleep Medicine Committee. Information was sought from all national European sleep societies concerning the practice of sleep medicine in their country and current accreditation practices. NSS representatives agreed that the practice of sleep medicine was changing, with an increase in home sleep studies (Type 2–4), and expressed enthusiasm for enlarging the criteria for accreditation to take into account clinical advances and encourage best practice. Agreed European standards were felt to offer increased visibility of sleep centres within Europe, and to facilitate both medical and paramedical mobility and research activities.

Consensus was achieved within the working party via a Delphi technique. The Delphi technique is a well-known process within the social sciences for achieving consensus. A team of experts uses an anonymised iterative voting process to achieve consensus on a series of points: if a point is unanimously agreed, there is no need to discuss it. Contentious areas are discussed with aggregation of the voting results allowing experts to adjust their answers in function of the groups response until consensus is achieved (Hasson et al., 2000). The working party had five participants drawn from representative European countries with accreditation experience who all took part in the Delphi process. The overall elements on which a centre should be accredited (medical and paramedical team, sleep facilities, centre activity, patient reports, documentation and archiving, teaching and research) achieved unanimity from the start of the process. The detailed criteria within each element required discussion, especially where there was divergence between different European countries, for example in initial and continuing sleep education for medical and paramedical staff or underlying structural differences in health care (e.g. reimbursement tied to accreditation). Where large national variations were known to exist, recommendations were formulated in order to allow the individual NSS to adapt to local requirements.

The initial proposed accreditation concept was presented to the Assembly of National Sleep Societies (ANSS) during the 2022 meeting. The further work on defining criteria was presented to the ANSS during the 2023 meeting and implementation was discussed. The proposed draft was discussed by the ESRS Sleep Medicine Committee and circulated to all 31 ANSS leaders for comments. Comments were discussed by the working party and integrated into the final document. The final draft of accreditation procedures was agreed by the ESRS board.

The new accreditation criteria take into account different sleep medicine practices and propose an accreditation by level (see Figure 1 and Table 1 to contrast the changes from the initial 2006 criteria). This permits the accreditation of all clinicians working in the sleep medicine field, from monodisciplinary structures using ambulatory PG to diagnose and manage sleep apnea, up to large centres capable of managing all sleep pathologies but also with a major research and teaching role.

Sleep medicine continues to evolve, and we anticipate that this document will be reviewed and if necessary revised after 4 years.

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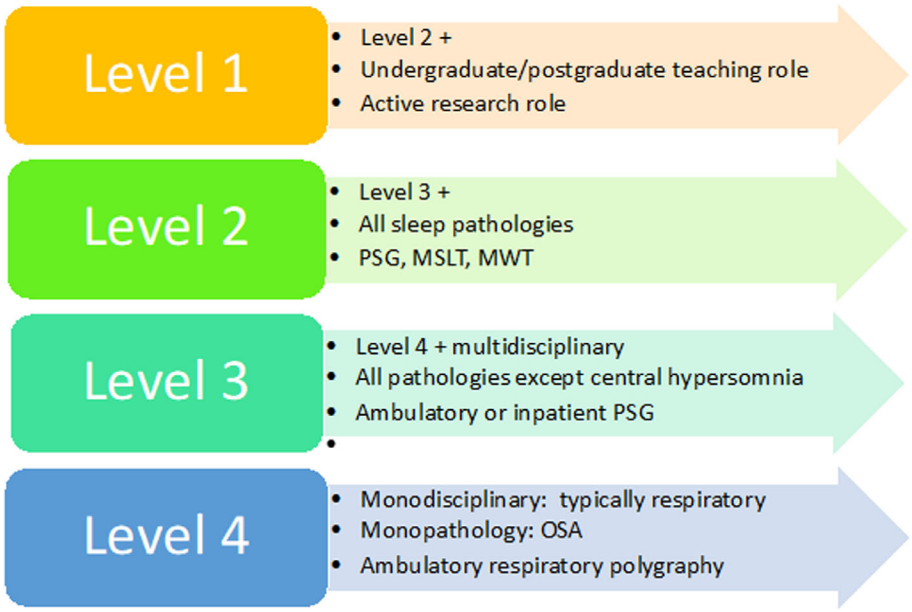

FIGURE 1 Levels of accreditation. MSLT, Mean Sleep Latency Test; MWT, Maintenance of Wakefulness Test; OSA, obstructive sleep apnea; PSG, polysomnography.

TABLE 1 Proposed changes 2006–date.

Clinical practice	Accreditation under 2006 criteria	Accreditation under updated criteria
Ambulatory respiratory monitoring	No	Yes
Ambulatory PSG	No	Yes
Hospital-based PSG without MSLT/MWT	No	Yes
Hospital-based PSG + MSLT/MWT	Yes	Yes
Hospital-based PSG + MSLT/MWT with research and teaching	Not distinguished	Yes

Abbreviations: MSLT, Mean Sleep Latency Test; MWT, Maintenance of Wakefulness Test; PSG, polysomnography.

2.1 | Accreditation by level

The new accreditation criteria take into account different sleep medicine practices and propose an accreditation by level (Figure 1).

A centre can check which level is appropriate for them using the checklist provided by the ESRS.

3 | CRITERIA FOR ACCREDITATION

3.1 | Management and medical staff

3.1.1 | Management of the centre

All centres (Levels 1–4) must have a responsible physician, who is a member of the relevant NSS, with initial sleep training according to national requirements or with the European somnologist diploma (Grote et al., 2022; Pevernagie et al., 2009) and having experience in sleep medicine. The director of the centre is responsible for employing an appropriate number of medical and paramedical personnel to manage the patient load and provide high quality of care in every case.

3.2 | Composition of the medical team

Level 4: monodisciplinary (typically respiratory physicians).

Level 3: multidisciplinary team with experience of managing all sleep pathologies with the exception of central hypersomnia.

Levels 2 and 1: multidisciplinary team with experience of managing all sleep pathologies including central hypersomnia.

3.2.1 | Training of the medical team

All medical staff must have initial sleep training as recognised by their NSS or the European somnologist diploma (Grote et al., 2022; Pevernagie et al., 2009). All medical staff must be able to show evidence of relevant continuing medical education *as approved by their NSS*.

3.2.2 | Medical cover for inpatient PSG/PG

Levels 1 and 2 (and level 3 centres if they have inpatient beds) must guarantee medical care at all times. In case of emergency, appropriately trained medical staff must be available at all times. This may be provided by an attending physician who does not necessarily have to be part of the core sleep team.

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3.3 | Technical staff

Paramedical (e.g. nurses, technologists, physiotherapists) staff must have sufficient knowledge of diagnostic and therapeutic procedures to assure high-quality recordings.

Paramedical staff must be trained according to NSS standards. Professional certification, if available, is recommended. Paramedical staff must show evidence of continual education to keep skills up to date.

In all centres with inpatient nocturnal PSG (levels 1 and 2, and possibly level 3), dedicated trained paramedical staff must be available throughout the night to monitor recordings and deal with emergencies. Staffing levels should follow NSS guidelines.

In all level 1 and 2 centres, trained sleep technicians must be available during the entire period of testing to supervise vigilance testing carried out according to AASM criteria (AASM, 2022a; AASM, 2022b).

3.4 | Administrative staff

All centres should have permanent secretarial staff to answer patient queries, organise appointments and keep patient records.

3.5 | Facilities and equipment

All centres and their activity should be easily identifiable with appropriate signage and letter/electronic communication headings containing contact information.

All centres must have detailed written protocols in paper or electronic form covering all the procedures performed by the centres (e.g. ambulatory and inpatient PG/extended PG, ambulatory and inpatient PSG, Mean Sleep Latency Test (MSLT), Maintenance of Wakefulness Test (MWT), actigraphy, titration of ventilation, capnography, oesophageal manometry) consistent with national guidelines (or European/AASM guidelines if national guidelines are not available; AASM, 2023; Krahn et al., 2021; Maski et al., 2023; Penzel, 2022).

3.6 | Sleep studies

Polygraphy (type 3 see Table 2) must be performed using modern equipment capable of providing ≥ 4 good-quality respiratory signals (Kapur et al., 2017). Extended PG adds additional signals, but systems are heterogenous and there is variability in use across Europe.

If used, extended PG should be validated against gold-standard PSG in published studies, accepted by the NSS and performed and interpreted by medical and paramedical staff with specific training in the technique.

Polysomnography (type 1 or type 2 see Table 2) must be performed and interpreted following current AASM guidelines (AASM, 2023). Equipment must be technically adequate and capable of providing good-quality signals, which are free from artefact.

TABLE 2 Types of sleep studies.

	Equipment	Setting
Type 1	PSG (EEG + 4 + respiratory parameters and EMG)	Hospital
Type 2	PSG (EEG + 4 + respiratory parameters and EMG)	Ambulatory
Type 3	PG with 4 + parameters: 2 respiratory variables (e.g. effort to breathe, airflow), oxygen saturation, and a cardiac variable (e.g. heart rate or electrocardiogram)	Ambulatory
Type 4	1 + parameters, typically oxygen saturation and heart rate, or in some cases just air flow	Ambulatory

Abbreviations: EEG, electroencephalography; EMG, electromyography; PG, polygraphy; PSG, polysomnography.

Equipment must be age appropriate: if PG or PSG is performed on children, respiratory captors (e.g. belts, nasal flow devices and oximetry) must be adapted to children.

The MSLT evaluates the tendency to fall asleep and the latency of rapid eye movement sleep. The MSLT must be performed and interpreted following AASM guidelines (AASM Scoring Manual 2022). The MSLT should always be preceded by a PSG (Krahn et al., 2021; Maski et al., 2023).

The MWT evaluates the capacity to remain awake. The MWT must be performed and interpreted following AASM guidelines (Krahn et al., 2021; Maski et al., 2023).

3.7 | Inpatient facilities

Sleep centre inpatient and outpatient facilities must comply with local health authority guidelines.

3.8 | Level 3 centres performing inpatient PSG

Sleep studies should be performed in single bedrooms. Beds for parents or carers must be provided if sleep studies are performed in children or in handicapped adults.

Rooms must be of adequate size following national guidelines: a minimum of 12 m^2 is suggested. Each room should be equipped with adequate sanitary facilities in or near the room, light-excluding blinds and adequate sound proofing (< 30 A-weighted decibels dB(A) at night and during the day as recommended by WHO guidelines), temperature control, adequate ventilation, a two-way communication system and a call system for emergencies.

The equipment should deliver simultaneous video recording, and electrical and biological calibration.

It is recommended that continuous monitoring of signal quality during the night from a separate room of adequate size is performed by trained staff.

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An emergency trolley with essential resuscitation equipment for adults (and children if necessary) must be available close to the rooms: equipment provided should follow local guidelines.

Activity (number of PSG per year) depends on the number of inpatient beds, but should be adequate to ensure staff competence with a minimum of one PSG per night.

3.9 | Level 1 and 2 centres performing PSG, MSLT and MWT

Sleep studies should be performed in single bedrooms. Beds for parents or carers must be provided if sleep studies are performed on children or in handicapped adults with facilities for parents/carers to wait close to the room if necessary during daytime vigilance tests.

Rooms must be of adequate size following national guidelines: a minimum of 12 m^2 is suggested. Each room should be equipped with adequate sanitary facilities in or near the room, light-excluding blinds and adequate sound proofing (< 30 A-weighted decibels dB(A) at night and during the day as recommended by WHO guidelines), temperature control, adequate ventilation, a two-way communication system (for MSLT and MWT) and a call system for emergencies.

The equipment should deliver simultaneous video recording, and electrical and biological calibration.

Trained staff must be present day and night to monitor PSG and to perform vigilance tests.

An emergency trolley with essential resuscitation equipment for adults (and children if necessary) must be available close to the rooms: equipment provided should follow local guidelines.

Activity (number of PSG, MSLT and MWT per year) should be adequate to ensure staff competence.

3.10 | Patient care pathways

The following points apply to all centres.

Patients should be evaluated prior to sleep studies (by the referring physician, by the sleep centre either via an in-person consultation or by questionnaire) in order to identify the most appropriate management (outpatient consultation or sleep study). After sleep studies, patients should be offered follow-up with an appropriately trained sleep physician.

All centres should follow national recommendations for the care of patients with sleep pathologies. In the absence of national recommendations, European or American recommendations should be followed (Penzel, 2022).

A sleep centre should be able to offer complete care from diagnosis to follow-up. This depends on their level and competencies: a level 3 or 4 centre should promptly refer patients who require PSG + MSLT/MWT. Centres should have rapid referral to specialists if necessary (e.g. maxillo-facial surgeons or psychiatrists).

3.11 | Patient reports, documentation and archiving

The following points apply to all centres.

Sleep disorders must be classified according the ICSD-3 (AASM, 2014).

Sleep study reports must be the result of visual analysis of signals by a trained sleep study technician or medical staff. All reports must be validated by a sleep physician.

The report in the patient records must be comprehensive and include the patient's sleep history, as well as a description of relevant sleep and/or respiratory parameters. Graphical summaries of relevant data are encouraged, as are screen shots of relevant electroencephalogram (EEG) or respiratory events. Reports must be prepared within a reasonable time delay. If the patient has been hospitalised, a brief discharge summary is recommended.

Patient records must be filed and raw data from sleep studies stored in accordance with NSS guidelines.

4 | IMPLEMENTATION OF ACCREDITATION

4.1 | Guidelines for NSS accreditation activities

Accreditation is organised under the auspices of local NSS based on the European accreditation criteria.

Each NSS is encouraged to set up an accreditation committee with experienced sleep clinicians.

It is anticipated that accreditation by levels will lead to an increase in the number of sleep centres that can be accredited, as prior to the revision only large hospital-based centres had the possibility of requesting accreditation from their NSS. The following accreditation process is suggested (Table 3), but the detailed implementation process at a national level is to be determined by each NSS based on local needs.

The accreditation process depends on the level of the centre, and can include an application form and a virtual or physical site visit.

4.2 | Sleep practice application forms

Application forms are completed by the sleep practice and reviewed by the NSS accreditation panel to identify the level of the sleep practice and to decide whether an expert visit is required.

The initial application form is available on the ESRS website: the elements are listed in Table 4.

4.3 | Expert site visit

Should a site visit be required, this must be performed by experienced sleep physicians/paramedical staff from the NSS. The size of the

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TABLE 3 Recommended process for the implementation of accreditation by levels.

	Application form	Expert visit	Reaccreditation
Level 1	Required	Mandatory in centres with inpatient beds	By application form and video conference[a]
Level 2	Required	Mandatory in centres with inpatient beds: video conference possible if the centre is geographically remote	By application form and video conference[a]
Level 3	Required	Recommended in centres with inpatient beds with the potential of video conference	By application form and video conference[a]
Level 4	Required	Not required	By application form

[a]In the case of a significant change in sleep facilities, a visit is recommended.

TABLE 4 Elements of the application form.

Management and medical staff	Centre manager	Name and qualifications, initial and continuing sleep education, membership of NSS/ESRS
	Medical staff	Names and qualifications, initial and continuing sleep education, membership of NSS/ESRS, amount of time dedicated to the sleep centre
	Medical cover	Organisation of medical cover for emergencies
Paramedical staff	Paramedical staff	Number of staff and qualifications, initial and continuing sleep education, membership of NSS/ESRS, amount of time dedicated to the sleep centre
	Overnight staff	Presence of overnight staff
Centre activity	Sleep studies	Sleep studies performed (PG, PSG, video PSG, MSLT and MWT)
	Equipment	Description of equipment (manufacturer, date)
	Home or hospital testing	Description of sleep studies (ambulatory or inpatient)
	Sleep study interpretation	Description of staff members involved in sleep study interpretation and validation
	Other investigations	Sleep diaries, actigraphy, capnography, oximetry, 24-hr EEG, etc.
	Investigation activity	Number of studies per year by type
	Diagnostic activity by pathology	Number of patients diagnosed per year by type of pathology (estimated)
	Follow-up activity by pathology	Number of patients seen as outpatients per year by pathology (estimated)
	Protocols	Written protocols for all sleep activities, description of patient care pathways for major sleep pathologies[a]
Sleep facilities	Inpatient beds	Number of recording rooms
		Description of recording rooms (size, proximity of bathrooms, presence of beds for parents/carers if appropriate, sound and light proofing, video, two-way communication for calibration)
	Monitoring rooms	Size and equipment in the monitoring room
	Emergency response	Presence of emergency trolley for resuscitation
Patient reports, documentation and archiving	Report quality	Sample anonymised PG/PSG/PSG + MSLT/MWT report
	Archiving	Description of archiving procedure for medical records and raw data from studies
Teaching and research	Research	University affiliation List of research projects (mono/multicentric) investigator role Description of research team
	Teaching	University affiliation Description of teaching activities undertaken by centre staff at undergraduate and postgraduate level

Abbreviations: EEG, electroencephalography; ESRS, European Sleep Research Society; MSLT, Mean Sleep Latency Test; MWT, Maintenance of Wakefulness Test; NSS, National Sleep Societies; PG, polygraphy; PSG, polysomnography.
[a]Patient care pathways (from initial patient contact to investigation, management and follow-up) should follow national recommendations. If national recommendations are not available, European guidelines should be referenced.

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visiting team is to be determined by each NSS, but for an initial visit a team of three experts is recommended. Follow-up visits can use a single expert. The NSS and local accreditation team can propose the use of video conference, especially if centres are remote.

During the site visit, a meeting with the medical, paramedical and administrative team to present the sleep centre should be followed by a visit to outpatient and inpatient facilities. Staff competence should be observed during PSG (hook-up), MSLT/MWT. Calibration and signal quality should be assessed during testing.

Sample PSG recordings should be examined for signal quality, sleep stage scoring and interpretation. Randomly sampled patient records should be examined to evaluate the patient care pathway, and to confirm that diagnosis and management of sleep disorders follows national or European guidelines.

Following the visit, the experts will prepare a full report on the centre.

5 | RESULTS OF THE ACCREDITATION PROCESS

The accreditation committee should review the relevant information (application form and experts report if a visit has been performed) in order to determine the accreditation outcome.

Given the results of the application form and, if required, the experts' report, five major outcomes can be identified.

I. Recommendation to accredit the sleep practice at the requested level in its present form with no restrictions (A).
II. Recommendation to accredit the sleep practice at the requested level in its present form after correction of minimal deficiencies. The sleep practice must notify the Accreditation Committee in writing of the correction of the deficiencies (B).
III. Recommendation to accredit the sleep practice at a lower level with no restrictions (A).
IV. Recommendation to accredit the sleep practice at a lower level after correction of minimal deficiencies with a required time frame (B). The sleep practice must notify the Accreditation Committee in writing of the correction of the deficiencies.
V. No accreditation.

It is recommended that the NSS accreditation decision is communicated to the sleep practice in a report within a reasonable time frame. The report should contain the following information.

- Identification and description of the sleep practice.
- Accreditation decision (I-V): if decision IV or V is taken, the appropriate level should be identified and the practice offered the appropriate accreditation. For example, if a centre practising only PG asks for accreditation at level 3, but meets all the requirements for a level 4 centre with no restrictions, the decision is III in the list above and the practice should be offered accreditation at level 4 with no restrictions.
- Detailed report of the expert visit with key points pertinent to the assessment decision and recommendations.
- Recommendation of deadline for future reaccreditation and its modality (application form alone, application form + virtual visit, application form + visit) according to NSS guidelines.
- Signature of experts.

5.1 | Information about accredited practices

The NSS are encouraged to make the information about accredited practices publicly available, for example via the NSS website. Individual sleep practice information should include medical specialty and pathologies managed (for levels 3 and 4), the level and whether they are accredited without restrictions (A) or with restrictions (B). For example, a level 1 practice accredited without restrictions should be listed as 1A, and a level 3 practice accredited with restrictions as 3B. Once restrictions are lifted (after remediation has been successfully performed), the list should be revised: in the above example the practice listed as 3B should be listed as 3A.

5.2 | Responding to an accreditation report

If an accreditation report recommends correction of minimal deficiencies: the sleep practice should carry out remediation activities and inform the NSS accreditation committee within the required time frame providing appropriate evidence (photographs, screen copies to demonstrate improved signals, proof of further training, etc.). If these are acceptable to the NSS accreditation committee, a further accreditation report with the revised rating is sent to the sleep practice. If the evidence of remediation activity is insufficient, the NSS accreditation committee can either propose a further site visit or propose accreditation at a lower level.

It is recommended that the accreditation committee of the NSS keeps the NSS board informed of accreditation activities. If the sleep practice disagrees with the final accreditation outcome, they may appeal to the NSS board.

5.3 | Reaccreditation of sleep practices

Regular reaccreditation of sleep practices is encouraged. The frequency of reaccreditation should be fixed by individual NSS, but 2–5 years has been recommended by the ESRS and the AASM (AASM, 2022a; Pevernagie et al., 2009).

5.4 | Notification of changes

A sleep practice accreditation depends on the physical facilities and staff. If these change significantly, the accreditation committee of the NSS should be informed within 2 weeks.

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Change of personnel: to assure continuing quality, patient care personnel should be appropriately trained according to NSS requirements.

Change of facilities (moving laboratory and/or expansion): facilities should meet national health authority, NSS and ESRS requirements. A repeat site visit may be indicated in case of substantial change: the modalities of a repeat visit are to be fixed by the NSS.

6 | CONCLUSION

The revised European accreditation guidelines aim to assure high-quality diagnosis and management of sleep disorders. The introduction of accreditation by level aims to include sleep medicine practices that offer ambulatory PSG and PG. NSS are encouraged to adopt the new criteria within their accreditation frameworks.

AUTHOR CONTRIBUTIONS

Sarah Hartley: Conceptualization; writing – original draft; methodology; writing – review and editing; project administration. **Marta Goncalves** Methodology; investigation; writing – review and editing. **Thomas Penzel:** Methodology; investigation; writing – review and editing. **Johan Verbraecken:** Methodology; investigation; writing – review and editing. **Pitt Young:** Methodology; investigation; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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