Hands-On Experience: Accreditation of Pathology Laboratories according to ISO 15189

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Key Words

Pathology · Accreditation · ISO 15189

Abstract

Accreditation is a procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks according to certain standards. Accreditation of pathology laboratories according to ISO 15189 is now becoming more and more a matter of course in continental Europe. This review describes some practical experience aspects with our own pathology laboratory accreditation according to ISO 15189, and outlines the advantages, addresses critical points, and discusses certain caveats of this process.

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Introduction

Accreditation of pathology laboratories was introduced almost two and a half decades ago in the UK [1–3] as well as in the USA and Canada [4, 6], and is now a matter of course in most of the industrialized world. Initially focused on the need for reliable pathology services for

physicians, the current trend towards establishing organ-based comprehensive specialty centers, particularly cancer centers, has provided resurgence towards the accreditation of pathology labs to broaden the scope, ensure trustworthy results and thus optimize patient management [7, 8].

Earlier pilot studies suggested that auditing labs applying standards established by trial-and-error, textbook knowledge, other evidence or tradition, 55% would be accredited with only a moderate effort of the staff, while 10% would fail and 35% would require significant efforts to meet accreditation requirements [9]. Meanwhile, the International Organization for Standardization (ISO) established, and has since twice revised the 15189 norm applicable to medical labs in Europe [10], which is, to the largest extent, applicable to pathology labs. Reports of the introduction and auditing of conformity according to this norm have already been published [2, 11–13] and, more specifically, sense and nonsense aspects were recently excellently addressed in a provocative review [14].

This review describes some practical experience aspects with our own pathology lab accreditation according to ISO 15189, and outlines the advantages, addresses critical points and discusses certain caveats of this process.

What Is (the Purpose of) Accreditation?

The ISO defines accreditation as a procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks. It includes a standardized and regular, i.e. according to the ISO 15189 Standard for European Countries [10], external audit every 18 months by authorized experts of the applicant's lab facilities and of the management and quality assurance programs. A central issue in accreditation is the benefit to patients in assuring a lab's commitment to diagnostic excellence by maintaining good professional practices and performing analyses under optimal conditions as defined by the accreditation authority. By defining and documenting the best standards of practice, which are subjected to peer review by the authorized experts, accredited departments can assure users/customers/clients and patients that critical procedures influencing the diagnostic and therapeutic methodologies are conducted in a standardized and proven manner that is safe and minimally error-prone. Moreover, if deviations or errors occur, they will be recognized, tracked and fixed, which should result in improvements to minimize such deviations. Thus, compared to certification, summarized as a confirmation that lab processes conform to a certain standard, accreditation (1) attests that the respective lab is comprehensively competent to maintain quality along the entire diagnostic chain including personnel, equipment, reagents and techniques, and (2) confirms the dedication of the staff to facilitate continuous improvement. As such, accreditation provides a hallmark of performance and competence that is lacking in nonaccredited labs.

Accreditation, of course, cannot substitute professional competence, especially that of the academic staff, as is strikingly illustrated by following example. An internationally recognized expert in uropathology diagnosed International Society of Urological Pathology (ISUP) grade group 4 prostate cancer [15] in one of several biopsies that were supposed to belong to patient A, but, due to the lack of standards in probe handling in the respective lab, the tumor-affected biopsy actually belonged to patient B and was mislabeled at the embedding stage. This kind of error would be unlikely in an accredited lab, where mechanisms are in place to prevent this occurring. However, a general surgical pathologist in an accredited pathology department might overlook an analogous small ISUP grade group 4 prostate cancer in a properly oriented biopsy of patient A. This is an error accreditation cannot prevent, but the guaranteed existence of continuous im-

provement mechanisms in accredited institutions means that such errors will be quickly recognized and procedures implemented that will prevent repeating this mistake (e.g. implementation of internal review of all negative prostate screening biopsies).

Definitions

Pathology labs are, on the one hand, medical labs, performing diagnostic tests (a staining is seen as a 'test' according to ISO 15189). On the other hand, they also perform diagnostic activities by step-wise examination and interpretation of such tests, which result in a report that, per se, is very difficult to accredit. This is why the standards used for accreditation vary even among different European countries. The 'core requests' of the different standards are, however, comparable, although somewhat different in their formulation (see below). In Ireland and the UK, ISO 15189 (attesting that medical labs fulfil requirements for quality and competence) (<http://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/>, <http://www.inab.ie/About-Accreditation/Accreditation-Schemes/Laboratory-Accreditation/Medical-Testing/>) is mandatory also for histopathology labs, which are usually subdivisions of clinical pathology departments. In Finland and Switzerland, pathology labs are forced to get accreditation according to both ISO 17025 (attesting competence of testing and calibration labs) and ISO 15189. In Germany, ISO 17020 (attesting competence of the bodies performing inspections) is regarded as the accreditation standard for pathology labs. This reflects the 'borderline' situation of pathology as a bridging discipline between clinical and medico-laboratory specialties. The following example may illustrate the situation.

A physician mandates a clinical chemistry lab to determine (test) a patient's potassium level and expects a result within a well-known level range; the required examination needs no further interpretation and can be carried out in a calibration lab. However, if a physician excises a skin tumor from a patient and sends the specimen for pathologic examination, he/she expects comprehensive assertions on the histogenesis of the tumor, the resection margins and, if needed, assessment of prognostic, predictive or theranostic markers. This examination requires a step-wise process that includes macroscopic, microscopic, histochemical (e.g. hematoxylin and eosin and Masson-Fontana stains), immunohistochemical (e.g. S100, HMB45, A103 and SOX10 stains), molecular (e.g. *BRAF*,

KRAS, *NRAS* and *CKIT* mutational testing) analyses that result in a comprehensive final interpretation; such procedures should be carried out within a body performing inspections. While the above calibration lab will be accredited according to ISO 17025 and the inspection body according to ISO 17020, the medico-laboratory processes of both must be conform to ISO 15189, and this is why the latter standard is most broadly used in pathology labs. While, at a first glance, the different ISO norms address different aspects of the activities taking place in a pathology lab, some basic requirements that are extensively inherent to ISO 17020 are also required by ISO 15189, i.e. (1) all personnel making judgements and examinations shall have the applicable experience and act in accordance to professional guidelines, (2) there should be continuing education and professional development of the staff (including diagnostic pathologists), (3) certain aspects of the reports' attributes like interpretative comments are to be considered and (4) external technical quality control, which cannot, for obvious reasons, be separated from the diagnostic performance, shall exist (e.g. if improper tissues or entities have been chosen for external quality control, respective poor annotations from the reviewers are to be expected).

ISO defines a *process* as a set of interrelated or interacting activities (procedures) that transform inputs into outputs. *Procedure* is a specific manner of carrying out an activity that is documented, implemented and maintained. A *laboratory examination* is a set of operations focused on the goal of determining the value (quantitative examinations) or characteristics of a property (qualitative examinations).

According to the ISO accreditation guidelines, all processes, procedures and examinations related to pathologic diagnostics must be documented as standard operating procedures (SOP) or working instructions that are current and accessible to the lab staff. This has several practical advantages. Initial documentation of these processes, procedures and examinations allows the lab head, manager and staff to perform internal evaluations of the indispensability and performance of processes, procedures and examinations, their norm conformity as well as their efficiency; such initial evaluations can, as we have experienced, eliminate up to 10% of unnecessary steps and improve efficiency and accuracy in another 20% of processes, procedures and examinations. These collected records (SOP and working instructions) comprise an enduring intellectual property of the lab, guaranteeing that experientially gained technical knowledge will be maintained without regard to personnel changes. Finally, they create

a basis for a standardized rather than experiential introduction for new employees into the work process.

Compared to other lab disciplines, pathology labs have more limited access to certified or validated commercial procedures (e.g. ready-to-use diagnostic kits). Thus, a significant percentage of nonstandardized, inhouse methods must be implemented to meet the respective diagnostic requirements. Such methods are permitted by ISO, provided they are verified, validated and qualitative. For the purposes of accreditation, *verification* is defined as confirmation, by providing objective evidence, that specified requirements have been fulfilled, e.g. that a Ziehl-Neelsen stain undoubtedly identifies acid-fast bacteria (i.e. adequate positive-control staining). *Validation* is confirmation, by providing objective evidence, that the requirements for a specific intended use or application have been fulfilled, e.g. that the same stain does not cross-react with non-acid-fast bacteria or other compounds (i.e. adequate negative-control staining). Finally, *quality* is defined as the degree to which a set of inherent characteristics fulfils requirements. This is the requisite, which is the most difficult to objectify. In cases of available external quality control circles, certification of successful respective runs provides an indicator of quality. Relative to pathology labs, the UK National External Quality Assessment Service (UKNEQAS) [16], the incentive of the German Society of Pathology for Quality Assurance (QuIP) [17], the Swiss Society of Histotechnicians (Swiss HistoTec) [18], the European Quality Assurance programs (EQA) [e.g. 19] and the Nordic Immunohistochemical Quality Control (NordiQC) [20] are good examples of platforms providing a broad spectrum of possibilities for the external quality control of histochemical, immunohistochemical and molecular methods. Quality can also be measured by how well an organization meets the needs and requirements of users or the benchmarks of defined operational processes. Thus, user surveys and regular organization-defined quality indicators can be utilized as quality verifications. Good illustrations of the latter are the ongoing internal assessments of results and trends by means of continuous internal technical quality control analyses of tissue floaters/contaminations, continuous internal diagnostic review of all negative prostate and breast screening biopsies (see the above example of missed prostate cancer), monitoring and improvement measures resulting from corrected reports, turn-around times (TAT) and false-positive/-negative frozen-section diagnoses. As an example, adherence to a certain TAT of <20 min for frozen-section examination is a prerequisite of comprehensive cancer center certification, so our pa-

thology lab was required to monitor this parameter. The data analysis was surprising and showed a broad variance of 7–72 min (mean: 22 min) that was more individual examiner-related than entity- or query-related. This required us to discuss these perceptions with the respective examiners, and resulted in a measurable improvement of the TAT, i.e. 7–31 min (mean: 19 min).

What Are the Subjects for Accreditation in Pathology Laboratories?

The quality management system and specific professional, methodical and technical requirements are all subjects that must be accredited. This quality management system should be a useful tool to outline the lab's organization, its managerial accountability and formal responsibilities and the flow of information and goods along the chain that transforms inputs (probes) into outputs (results). Specific (professional, methodical and technical) issues must be documented and organized in an understandable and transparent way. Pathology labs generate interpretative reports by means of a multistep process utilizing different investigational procedures such as macroscopic and microscopic analyses, immunohistochemical and immunocytochemical examinations and molecular testing. Thus, both the processes and each individual investigative procedure applied to a specific analysis must be documented properly, following clearly defined procedural and methodological instructions. One common misunderstanding is that the quality of documentation of these instructions is reflected by their quantity or length. This is not the case. Indeed, documentation should be as concise and understandable as possible. Here is an example. A lab performs its Fite staining exactly as suggested by the Manual of Histologic Staining Methods of the Armed Forces Institute of Pathology [21]; there is no need here to retype the respective prescription in the quality management system as the respective document 'Fite staining' should refer to the manual, which the lab manager must ensure is quickly and consistently available to the involved staff.

Usually, professional, methodical and technical procedures are documented in a very detailed manner, while processes such as the establishment of novel diagnostic tools (new antibodies, new sequencing panels, etc.) are more poorly described. A structured approach to the description of such a process, including clearly written and easy-to-understand definitions, a breakdown into single phases, with the designation of responsibilities for

decision-making and instructions for trouble-shooting, will promote the quality of the respective SOP and also increase its usability. These compiled documentations comprise the management manual of the lab. In addition to descriptions and prescriptions, all request forms, complaint forms, machine and device maintenance lists and quality control references (e.g. reference microphotographs defining proper staining) can and should be an integral part of the management manual of the lab.

An often misunderstood and underrated obligation of pathology labs is the need for the calibration, gauging and verification of measurements. While this can be easily applied, e.g. to temperature measurements in refrigerators, PCR machines or immunohistochemical devices by a gauged thermometer or a gauged-thermometer-verified conventional thermometer, the requirement for this norm is more difficult to implement in other activities in pathology labs. The following 2 examples illustrate the potential far-reaching consequences of uncalibrated measurements, however.

(1) If a scale in the grossing room is somehow warped and has a deviation of 0.5 mm, and (due to a tradition of not gauging or there being no gauging requirement in the lab's SOP) this irregularity goes unnoticed and the gross examiner blindly trusts the measurements yielded by the scale, a considerable number of tumors will be either understaged or overstaged according to T-stage. Clearly, this would impact the integrative decisions regarding the treatment of patients, and, ultimately, in addition to badly influencing the performance of the medical center, harm the patients. (2) A tissue-slide thickness of at least 6 µm is essential to reliably detect amyloid deposition in tissues by means of Congo red staining, while other thicknesses are needed when combining this staining with immunohistochemistry for amyloid subtyping [e.g. 22]. If these requirements are not met at the cutting station and slides of unstandardized and varying thicknesses are passed over for staining, amyloid detection or subtyping would not always be possible, which would obviously have significant morbidity consequences for the patients. By requiring compliance to standard calibration and gauging and verifying measurement procedures, accreditation ensures that labs have the appropriate mechanisms and SOP to guarantee precision and to avoid mistakes such as those noted above.

The norm requires full traceability of probes and analyses. The probes must be unequivocally identifiable at any time along the analytical process. At the time the probes are stored in containers and in cassettes so this requirement is constantly met, but there are several critical steps

at which probes and identification marks are spatially disconnected that must be considered: (1) during the description and gross analysis of tissue, and when (2) embedding tissue, (3) cutting tissue, (4) transferring tissue isolates, e.g. DNA, into respective tubes, and (5) allocating automated results generated by machines (e.g. genetic analyzers or automated immunostainers without connectivity) that are not equipped to sustain traceability by the lab informatics system (LIS). Modern, commercially available, LSI add-ons can support labs to meet the ISO prerequisites by tracking single analytical steps. To avoid the accumulation of tremendous amounts of electronic data, it is stipulated that lab officers are to properly design such tracking software and consider optimal hardware support. Our experience is that one should pay special attention to these 5 critical steps, and the SOP for these steps should ensure that each is performed in as verifiable a manner as possible, e.g. password-authorized access to the embedding station, opening only 1 cassette per embedding procedure, providing metadata such as number of tissue fragments and gross description at the embedding station, using prescribed methods to handle thermoforceps, following instructions regarding how to deal with additional tissue encountered in baskets or cassettes, etc. Excellent help is provided by certain hardware such as on-site cassette- and slide printers, especially those without transfer tapes that print as many cassettes and slides as needed on demand, and that are situated immediately next to the grossing or cutting station (fig. 1). In addition, from practical experience, we recommend that direct scanning of barcoded specimens, e.g. containers (at description/grossing), slides (at histological examination) or tubes (in the molecular lab), can significantly reduce errors, the only prerequisite being a uniform barcoding system and the proper workplace facilities. Traceability also applies to the reagents utilized, which can be easily achieved by comparing LIS data with the respective reagent management records (further implying how these records should be designed to guarantee respective feedback loops). After having addressed these points in our lab, we have been able to save approximately 30 working hours per month, simply by minimizing errors.

Special attention is needed for preanalytics. The ISO defines *preanalytics* as a chronological process initiated at the clinician's request and it includes the examination, application, preparation and identification of the patient, collection of the primary sample(s) as well as transportation to and within the lab, and it concludes when the analytical examination begins. The importance of preanalytics for the quality of the final result has, historically,

Fig. 1. The slide printer is situated immediately next to the cutting station and prints the necessary slides on demand in real time. Note that not only the ID number but also the 2-dimensional bar-code has been successfully transferred from the tissue block to the glass slide. By means of this equipment, mislabeling errors can be eliminated.

been underrated, and has only recently become the subject of more intensive consideration (perhaps due to evolving ISO requirements), since a clear convention on whether this is the responsibility of the requesting physicians or of the pathology lab staff was lacking. Because many hospitals are being pressured to accredit their organ system-based (tumor) centers, this issue has assumed significant importance. Given the tremendous effects of preanalytics such as cold ischemia time, the concentration and pH value of the formalin solution, the duration of fixation, etc. on the subsequent pathologic diagnostic processes, and the plethora of required methodologies for tissue examinations, e.g. direct immunofluorescence, electron microscopy and RNA extractions, to name a few, it is clear that the lab professional (in this case, pathologist) should be responsible for preanalytics. This can be achieved by distributing the proper solutions in tissue-collection devices to the respective customers and providing written instructions on the homepage, in addition to direct communication and hands-on instruction provided by the lab [23–26]. This will fulfil the ISO requirements and, in our experience, even after a few months, this approach pays worthy dividends of greater error-free performance.

On the opposite end of the spectrum, the responsibility for *postanalytics*, defined as processes following the examinations of a sample, including review of results, re-

Fig. 2. Time lines of different types of misidentification errors in the histopathology lab at the University Hospital Basel before and after the implementation of accreditation standards in June 2013.

tention and storage of clinical material, sample (and waste) disposal, as well as the formatting, releasing, reporting and retention of the examination results, has been relegated to the pathology institutions as a matter of course, according to tradition or even legislation, and mostly conforms to the norm.

The Major Advantages of Accreditation

By analyzing, describing and critically questioning the processes and procedures of a pathology lab, these will be intuitively subjected to improvement, even in the first run of accreditation. As mentioned, our experience shows that 10% of 'traditional' processes and procedures are a waste of resources and could actually be eliminated, and another 20% could be considerably improved upon. Eliminating waste, reducing unnecessary interfaces and intermediate steps, and improving processes and procedures, automatically reduces TAT and considerably reduces, if not eliminates, the number of technical errors.

For example, before our lab committed to accreditation, we meticulously documented the number of critical errors caused by improperly hand-written probe identification numbers, which averaged 40 per month from a total of 7,900 probes processed monthly. All these errors were detected at distinct points in the diagnostic process, e.g. realizing that one was looking at the wrong tissue un-

der the microscope, and were subsequently analyzed, communicated to the involved staff and finally corrected, all of which required approximately 20 additional monthly work hours by the staff. Clearly, the process had to be improved to become an error-safe process with as few interfaces as possible. With the implementation of pre-designed barcode-readable labels, cassette- and slide printers and process redesign with full traceability, this type of error has been almost eliminated, thus significantly increasing the safety of patients, minimizing the time required to reconstruct the faults, reducing unproductive personnel deployment and, finally, achieving significant financial savings (fig. 2).

By standardizing the established methodologies and technologies and continuously monitoring and improving lab techniques, such as histochemistry, immunohistochemistry and molecular testing, and the management of consumables, accreditation inevitably reduces the number of false results. As an example, unlike progesterone receptor testing, for which the external quality control results (UKNEQAS) of our lab (18–20/20 points) were constant and continuously excellent, estrogen receptor testing showed a broader variation with borderline-to-excellent results (12–20/20 points), since assessors claimed that staining intensity could be stronger and more nuclei could be stained in the intermediate expressors. Optimization of the results with the applied antibody clone SP1 did not lead to sustainable improvement

of the external quality control results until implementation of a cocktail of antiestrogen antibody clones (SP1 and 6F11) [27], and this potential methodologic shortcoming would likely have been missed as an opportunity for 'room for improvement' without the mechanisms established by the accreditation norms such as 'open issues' in the lab's management system.

Efforts to accredit a lab require team-work, and engaging all staff members in preparing, editing and proof-reading documents, conducting internal audits and being involved in processes of continuous improvement, and thus confers inclusive responsibility and increases staff communication and motivation.

The accreditation norm requires monitoring indicators of technical performance and quality to reduce the risk of errors or delay in information delivery [28]. Some rational benchmarks to be monitored are listed above (internal technical quality controls of tissue floaters/tissue contaminations, results of continuous internal diagnostic review of all negative prostate and breast screening biopsies, numbers of corrected reports, false-positive/-negative frozen-section diagnoses, distinct TAT, etc.), while some can be deduced to meet both patient expectations and diagnostic excellence from international experience [e.g. 29]. Such monitoring is very useful to the lab manager, not only to survey processes, but especially to identify critical fields throughout the diagnostic chain that require improvements. On top of increasing patients' safety, minimizing errors and delays, this automatically reduces waste of materials, reagents and time, and thus also costs.

In addition to compulsory external evaluation of quality, according to the accreditation norm, ensuring staff competence is also mandatory; this encompasses adequate educational eligibility and the maintenance and augmentation of competence, documented in the personnel files. Good examples are regular refresher courses on common subjects such as workplace and biosafety, or adequate application of WHO-conformed terminology, which is often prone to neglect if not stringently monitored.

An intuitive but not measureable accreditation effect, as previously mentioned, is the increased motivation of the lab staff that results from transferring responsibility for defined norm issues and continuous optimization to the respective members. This responsibility highlights the importance of each facet of the work in the chain and allows the individuals involved to directly influence, with a view to improving, the procedures of which they are in charge, and thus building a bridge towards lean management.

Caveats

Lab accreditation is not meant to be an end in itself, but is rather to improve the end results for patients. Processes unlikely to influence these results as well as those that are impossible to quantify or control should be described as briefly as possible to avoid unnecessary bureaucracy. Standards considered good medical practice, such as those already established in textbooks, and the best clinical practices should be accepted by the authorities as normative. There is no need, as exemplified by how to deal with the formal norms respecting the Fite stain, for excessive multiplication of written documents.

Since establishing and running an accreditation program is time-consuming, the respective allocation of human resources planning should be considered. Our experience as a lab that technically handles 95,000 specimens per year shows that these needs can be met by approximately 50% nonacademic/technical staff (i.e. 25% quality managers and 25% lab technicians) and 10% academic (medical lab-head) full-time equivalent staff to establish the program, and 15 and 5%, respectively, for running the program.

A particularly questionable practice is accreditation of only certain sections of a lab, especially molecular pathology facilities, which has been the subject of recent critical discussions [14]. In the context of comprehensive, patient-centered medicine as well as in the context of ISO 15189, which primarily aims to formally recognize an organization's competence to carry out specific tasks, it is indeed debatable whether singling out a specific procedure with minimal attention to upstream and downstream processes is justified.

Finally, certain aspects that are not covered by the accreditation norms are still important, including work safety, hygiene and the diagnostic expertise of the academic staff. While some of these are covered by local regulations, such as SUVA norms in Switzerland [30], hospital hygiene guidelines or legislation, diagnostic expertise based on a competence-oriented audit is not envisaged. Some rough requirements in this direction are being established, such as special training requirements for pathologists participating in, for example, breast cancer screening programs or evaluating particular biomarkers such as ALK, hormone receptors or KI67 (e.g. UKNEQAS, QuiP) [16, 17]. There are also schemes for diagnostic capacity assurance like those provided by UKNEQAS [31] and the Royal College of Pathologists (RCPATH) of Ireland [32] and the RCPATH of Australia [33]. This particular shortcoming of ISO 15189 could, to a significant extent,

be overcome by ISO 17020, which more specifically addresses the competence, particularly of medical staff, and confirms the diagnostic competence of the lab and the surgical pathologists. However, mainly because of reservations about accreditation of the medical diagnostic processes in pathology that are so difficult to standardize, aside from Germany, this norm has still not been broadly used in Europe [12, 13].

Shortlist and Critical Thoughts on Accreditation Procedures

(1) Document Control

A written, comprehensible and applicable system of document preparation, organization and accessibility to the relevant staff must exist as well as clear evidence of who is responsible for the documents.

(2) Control of Process and Quality Records

Departments must participate in appropriate external quality assessment programs and run pertinent internal quality platforms.

(3) Personnel Management

Sufficient and properly qualified staff with updated job descriptions must be employed. A continuous education program for all staff members must be implemented and monitored.

(4) Implementation of Health and Safety Measures (Not Specifically Required by ISO, but Auditors and Lab Officers are Advised to Implement Such Programs to Ensure Conformity to Both Legislation and Good Practice)

The auditor should, although not required by the norm, consult with the institutional safety officer and assess the department safety manual, since compliance with safety regulations reassures the staff members and allows them to perform more efficiently, which also increases patient/probe safety.

(5) Management of Facilities and Equipment

There must be appropriate and clean lab space as well as adequate, clean and well-maintained (routinely calibrated and gauged) equipment to perform the respective medical procedures.

(6) Management of Data and Information

Written descriptions of procedures and processes must be immediately available. Communication within the facility, in terms of the control of document streams (see 'Document control' above) and information delivery, and also outside the facility, in terms of the delivery of diagnostic records, must be adequately supported by technical and electronic devices; data storage and retrieval must be guaranteed. Diagnostic records must fulfil all minimal requirements of the norm (patient ID, date of collection, date of receipt, date of testing, date of reporting and ID of the testing staff member).

(7) Management of Reagents, Calibration and Materials

Written records on the respective materials and activities must be maintained to allow full traceability.

(8) Specimen Collection and Transportation

See the discussion on preanalytics.

(9) Receipt of Specimens

There must be appropriate space available for receiving specimens, with spatial separation from lab spaces where pathology-specific activities are performed. Comprehensive instructions to deal with nonconforming transmittals must be available.

(10) Examination Procedures

All actions that do not represent textbook knowledge as well as lab-specific procedures must be documented, verified, validated and tested for quality.

(11) Reporting of Results

Documents regulating the non-LIS-based transmission of results, such as oral reports and e-mails, must be considered, and instructions on how to document noninterpretative molecular results, such as those generated with massive parallel sequencing, must be provided.

(12) Evaluation and Improvement

There should be documentation of regular internal audits, actions undertaken as a consequence of results indicating the need for improvement of external quality assessment programs and pertinent internal quality platforms, and records of unresolved matters and final checks should be kept.

Conclusions

An accreditation seal certifies that processes and procedures in the respective labs are in compliance with norm standards and provide formal recognition that the lab is being run in a proper/right way, but this does not guarantee that the right things are being done. Therefore, accreditation cannot be thought of as a substitute for diagnostic quality, but only, at best, for lab and management process quality. Still, practical experience, as exemplified above, provides unequivocal evidence that standardized and continually optimized processes can tremendously influence diagnostic performance and thus be of great benefit to the patients. Improving the quality of the pathological

assessment process substantially reduces waste of resources and also systemic biases, and thus has the inherent potential to improve time management and resource allocation, to be able to increase diagnostic performance and consequently improve medical care. Finally, it is noteworthy that reducing waste usually results in savings more significant than the costs of accreditation.

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