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ACCREDITATION REQUIREMENTS FOR DIAGNOSTIC LABORATORIES

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A laboratory applying for the accreditation has to implement a management system conformable both to the requirements of the standard PN-ISO/ IEC 17025:2005 – "General requirements for the competence of testing and calibration laboratories" and to some elements of the standard PN-EN ISO 15189:2008 – "Medical laboratories. Detailed requirements on quality and competence". Currently there are no legal regulations ordering diagnostic laboratories to obtain the accreditation, but there are legal regulations on the quality standards in medical diagnostic laboratories (Ordinance of Ministry of Health dated 26 March 2006 Law Journal 06.61.435); the deadline for laboratories to conform with the mentioned regulations was set up for the 31 March 2009.

As it involves financial expenditures, it is the laboratory management which is expected to make the decision on creating a management system. The management have to prove and ensure their involvement in building and implementing the management system as well as to continuously improve their efficiency. The management system should cover all the laboratory staff having the required and certified qualifications and authorizations and they must be subordinated to the definite requirements; at the same time they must observe the bounding procedures and progress instructions.

The most important factor to achieve a success is motivation of all people participating in the process of building the system, the managing director as well as the executive and technical staff. Firstly, the process of building the system ought to start from establishing the quality policy, short-distance and long-distance targets and defining the document hierarchy.

Secondly, the quality manager should be nominated and the following actions should be undertaken:

- staff members responsible for elaborating respective procedures should be appointed and adequate staff training should be carried out.
- the laboratory must have a required premises and the equipment, complying with the respective technical requirements.

- continual monitoring to guarantee the execution of the set up diagnostic tests in circumstance under constant control should be provided.
- the staff should be authorized to collect samples, operating all kinds of the necessary equipment and submit test reports.
- all diagnostic tests applied in the laboratory should be documented and validated in the required scope, according to the demand of the order of the client.
- implementation of the system should be evaluated during internal audits covering all the areas of the laboratory activities as well as the carried out management reviews.
- while building and supervising the management system, the requirements specified in the documents of the Polish Centre of Accreditation (DA-05, DA-06, DAB-07 EA 04/10) should be taken into the consideration as well as requirements of standards, settlements and regulations covering the scope of the laboratory activities.
- as it is indicated in the document DA-05, the laboratory must prove its proficiency by participating in at least one round of proficiency tests/interlaboratory comparison for the technique in question.

Implementation and maintenance of the system allows laboratories to apply for the accreditation, which is an objective confirmation of the technical competence to carry out respective sorts of tests. In Poland the Polish Centre for Accreditation is authorized to carry out evaluation, to confirm the competence and finally to grant the actual accreditation. The PCA functions on the basis of the Act dated 30 August 2002, on conformity evaluation system.

Lastly, after having received the accreditation, the laboratory may use the accreditation symbol of the PCA. Examinations on virology are carried out by the Laboratory of the Virology Department of the National Institute of Public Health – National Institute of Hygiene (AB 509).

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WYMAGANIA DO AKREDYTACJI LABORATORIÓW

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