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О РЕНТАБЕЛЬНОСТИ ВАЛИДАЦИИ И АККРЕДИТАЦИИ

В статье говорится, что в связи с нынешним экономическим кризисом европейские правительства пытаются сокращать расходы на государственные услуги, включая и финансирование лабораторий судебных экспертиз, хотя в реальности расходы на проведение экспертиз постоянно возрастают, что создает необходимость искать дополнительные инвестиции.

В судебно-экспертной деятельности можно выделить два типа затрат. Первое, это инвестиции в разработку научных методов, применяемых в ходе проведения экспертиз, повышение компетенции людей, вовлеченных в работу на всех этапах анализа, качество применяемой техники и инструментов. Второе, - совершенствование самой системы аккредитации, которая требует большого количества документации, соответствующей стандартам при проведении различных экспертиз. Важным элементом, включающим дополнительные расходы на проведение экспертиз, является внешний аудит, который необходим для каждого направления судебно-экспертной работы.

Недостаток финансирования лабораторий судебных экспертиз создает риски снижения качества экспертиз, которые трудно оценить, потому что за каждой из них стоят судьбы конкретных людей. Полученные результаты порой не проверяются должным образом. Возможна интерпретация результатов анализов различными должностными лицами при сдаче дел в прокуратуру или полицейский участок, что в некоторых случаях ставит под сомнение выводы экспертов. Тем не менее, в сложившихся условиях следует совершенствовать формы и методы организационной деятельности, повышать престиж организаций, эффективность и надежность работы экспертов, расширять взаимное доверие к судебной системе, и содействовать формированию культуры внедрения инноваций и постоянного совершенствования.

Кроме того, лабораториям необходимо иметь постоянный доступ к информационным материалам различных коммерческих учреждений, которые производят оборудование и расходные материалы для проведения исследований в ходе валидаций. Открытость и транспарентность этих материалов, обмен опытом между производителями техники и лабораториями судебных экспертиз – важные составляющие для качественного и эффективного проведения экспертиз. В целом, снижение затрат и повышение эффективности работы лабораторий судебных экспертиз являются ключевыми элементами всей системы качества в судебно-экспертном сообществе.

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COSTS OF VALIDATION AND ACCREDITATION

Undergoing the current economic crisis, the European governments experience a reduced income from taxes, while they recognize the need to make investments in order to boost the national economy. The governments try to achieve this by reducing the operational cost of the public services and consequently the amount of means available for the public forensic laboratories is reduced. During this period of austerity, forensic service providers are confronted with an increase in incoming case work which is triggered by a number of factors such as forensic awareness, changes in legislation (just to mention one: the Salduz ruling) and an increasing importance of material evidence in court cases. The bottom line is that the forensic institutes will have more work to do with less money. "More with less" seem to be the magic phrase for the political world.

Hence, one can ask oneself the question: Is the time right to invest money in becoming accredited according to an international standard? What are costs involved for moving into this direction? Is it

Rudimentally, one can distinguish two contributions to the cost for accreditation: The first source of costs is due to the fact that the operational bar is put to a higher level for the forensic laboratory. Additional investments may be required to put the standard of operation according to the scientific accepted and state-of-art standards for a number of forensic disciplines. This includes the investment in the scientific techniques applied, the instruments used, the competency of the people involved in all steps of the analysis, the environment in which the analysis is performed, the traceability of the evidence material throughout the forensic chain,... to name a the most important ones.

The second source of costs is due to the putting into place of the accreditation system itself, which requires a lot of documentation to assure that the different elements of the standard are satisfied. Quality documents have to be established, a document management system needs to be in place. An additional and important cost implies the external audit, where a technical auditor is needed for each forensic field. Linguistic requirements as well as the search for scarce specialist in each narrow field of forensics may require the travel of auditors from another country.

Is it an option to have no quality system in place? Does this simply imply that the resources for putting a quality system

into place will become available? No, the laboratory risks encountering costs which are difficult to estimate. The scientific bases of the obtained results are not validated and the individual collaborators in the laboratory do not necessarily perform the forensic analysis in the same, coherent way. Reporting officers may be interpreting analytical results in a different way and may be disagreeing on the expert opinion to be given to the prosecutor or to the police station, dealing with this case.

This means that the risks for having to re-do an analysis or to perform additional analyses are substantially high. In some cases, expert opinions will be questioned and second opinions from outside the forensic laboratory will be required. In this case, the confidence of the stakeholders will be damaged and they will be looking around for another, more relying partner for these services. Apart from additional costs, a decrease in case work and satisfaction about the services provided by the laboratory will result. The latter may, when forensic case work is billed, also lead to a reduced income for the laboratory.

In the forensic discipline, examinations are performed in a very cautious way in order to avoid at all costs the punishment and even the imprisonment of innocent people. Connected to this, is the risk that still dangerous criminals are around who are not stopped in their activities.

The costs related to this exceed the level of the laboratory and are situated on the society level.

Do one want to live in a society which the citizens experience as safe, fair and correct? As scientists we have the moral obligation to contribute to the experience of the citizens that justice exists.

Literature lists the advantages of quality systems. These include an improved organizational performance, an improvement of the organization's prestige and image, a stronger mutual trust, an enhanced credibility, more effective and transparent methods and communication, simpler and swifter procedures, the fostering of a culture of innovation and continuous improvement, lower costs and a greater efficiency. Lower costs and a greater efficiency are key elements for a quality system in place.

In the second part of this contribution, I will focus on the validation of methods as this represent a component of the accreditation process that requires an important investment of consumables and time of the laboratory

personnel. Moreover, each time a manufacturer comes with novelties, the validation of the corresponding technique will have to be repeated. This is currently the case for the forensic DNA analysis, where a number of new kits recently became available. A solution lies into moving towards "flexible scopes" in order to be able to respond quickly to a change in the working environment.

I would like to address two additional elements which will certainly be on the agenda tomorrow. Both of these ideas are already in application in the medical world which uses the ISO15189 standard instead of the commonly used ISO17025 standard in forensic laboratories.

Four crucial elements in the validation process can be identified: (1) Precision: how good is the repeatability of the technique? (2) Trueness: how accurate is the technique? (3) What is the measurement range (Limit of Detection, Limits of Quantification)? (4) Robustness: is the method dependent on external factors such as the person who executes the task or the temperature in the lab?

Firstly, the forensic community could benefit from the validation reports made publicly available by the commercial manufacturers of equipment and consumables. If their reports are made available to the worldwide forensic world, a single verification of the results in each laboratory would be sufficient for its validation. A full validation study according to the four criteria mentioned before would no longer be necessary. Two examples for this originate from the forensic DNA analysis: the commonly used kits, which are black boxes to be used in conjunction with the equipment provided by the same manufacturer and the presumptive testing (e.g. the PSA test used to detect sperm). In the latter case, the selectivity of the method could be determined by the manufacturer. In order to get hold of this information, the forensic world will have to speak with a single

voice to the manufacturers and express the demand that this information should be made available.

A second proposal lies in the validation of methods which are common to a number of laboratories.

If two laboratories perform a validation of a method using exactly the same materials and the results of these validation studies coincide, one can assume that this method is universally applicable. A verification of the results in a third laboratory is then sufficient instead of doing a complete validation. This way of working is already applied in the field of genetically modified organisms.

If either validation reports from the manufacturers or from two laboratories are available, we would only have to verify the precision and certain elements of the robustness to prove that the methods satisfy the validation requirement.

In a later stage, a database of validated methods would be needed. This would also represent an important step towards a harmonisation of methods between laboratories. By doing so, the exchangeability of the results will increase substantially and the storage of results in international databases for operational and statistical purposes is just a single step away. Within the European Union, this need has already been identified as the frontiers between countries are disappearing and the probability for cross-border crime is increasing. This results in a stronger need for exchanging evidence materials as well as expert opinions, as far as they are mutually recognized. An example of the international exchange of data which is now already a reality lies in the Prüm treaty which regulates the exchange of DNA-profiles within the European Union. The mutual trust between the member states is provided by the obligation for accreditation for DNA-analysis within the European Union.