

Mini-review

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Experiences with the accreditation of the Institute for Medical Research and Occupational Health, Zagreb, Croatia

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Accreditation in accordance with the international General Requirements for the Competence of Testing and Calibration Laboratories (HRN EN ISO/IEC 17025 standard) has become a widely accepted method of quality management and objective evidence of technical competence, knowledge, and skills of testing and calibration laboratories. In 2010, the Institute for Medical Research and Occupational Health (IMROH) had its management system accredited against the HRN EN ISO/IEC 17025 standard for the following scopes: determination of radioactivity, testing of ambient air quality, and testing in the scope of ionising radiation protection. This accreditation encompassed three laboratories: Radiation Protection Unit, Environmental Hygiene Unit, and the Radiation Dosimetry and Radiobiology Unit. In accordance with the rules of the Croatian Accreditation Agency, the second re-accreditation is due in 2020. This paper describes and discusses the quality management system at IMROH over the ten years of its implementation. We share our experiences about non-conformities discovered during regular work, internal audits, and external audits performed by the Croatian Accreditation Agency. The accredited management system significantly improved the performance of the accredited units, and the Institute increased its visibility and marketing advantage, consequently improving its market position.

KEY WORDS: ISO norms; measurement traceability; quality management; testing laboratories

According to the United Nations Industrial Development Organization (1) quality infrastructure is the totality of public and private institutional framework required to establish and implement standardisation, metrology (scientific, industrial, and legal), accreditation, and conformity assessment services (inspection, testing, and product and system certification) necessary to provide acceptable objective evidence that products and services meet defined requirements set by either authorities or the market. Quality infrastructure must ensure: elaboration and implementation of technical regulations for products and passage from compulsory standards to voluntary ones; application of good practice codes; and elimination of all measures that pose trade barriers, especially customs, taxes, and quantitative restrictions, but also all other measures with equivalent (protective) effects (2).

Accreditation is the key part of quality infrastructure and is defined as a process by which an independent and authorised accreditation body officially accredits the quality system and competence of: testing and calibration laboratories; legal or physical entities that perform certification of products, management systems and persons; inspection bodies; verification bodies; and legal or physical

entities that perform technical monitoring and similar activities to perform certain activities on the basis of some pre-defined standards.

The above-mentioned entities are referred to as conformity assessment bodies (CABs). Accreditation certificate is a document issued by a national accreditation body as an acknowledged body competent to carry out conformity assessment, test and certify third parties, behave ethically, and employ suitable quality assurance. Therefore, accreditation and possession of accreditation certificate are important for validation of data and quality and customer satisfaction assurance. It is a voluntary, third party-reviewed process.

However, in Croatia accreditation of testing laboratories in many fields is stipulated by law, such as those for dosimetric surveillance, monitoring of radioactive contamination in the environment, testing of ambient air quality, and noise protection (3–16). In these cases accreditation is a legal requirement for marketing as well as for applying to various research projects.

The quality management system in testing and calibration laboratories is implemented by the application of international standard EN ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories (17). However, laboratories often have to comply with both quality standards and (national

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and/or international) regulations at the same time. In that case, such regulations become normative documents.

THE ROLE OF THE CROATIAN ACCREDITATION AGENCY IN QUALITY INFRASTRUCTURE IN CROATIA

A quality infrastructure system (QIS) includes a national quality policy, regulatory framework, and institutions which provide standardisation, metrology (scientific, industrial, and legal), accreditation, and conformity assessment services (inspection, testing and certification) necessary to guarantee that products and services provided by accredited institutions meet specific legal and/or consumer requirements.

The key pillar of QIS is accreditation. In Croatia, the national accreditation body is the Croatian Accreditation Agency (HAA). CABs regularly submit themselves and their own quality management systems to peer review. In Europe, such peer review is performed through European Co-operation for Accreditation (EA). HAA is a full EA member since 2005, and in 2010 it signed a multilateral agreement with EA (EAMLA) after successful peer review. With this agreement it has received a recognition of equivalence, reliability, and acceptance by the European market “of certification, verification, inspection and calibration certificates and test reports issued by accredited conformity assessment bodies” (18, 19). In other words, the market can have confidence in the activities of EAMLA signatories and CABs they accredit. This contributes to the freedom of trade by eliminating technical barriers.

The number of accredited CABs in Croatia had constantly been rising ever since the first official accreditation certificate issued in 1998 (Figure 1) until 2017, when it reached its peak of 434. Since 2017, it slightly decreased with prolonged economic crisis, as shrinking economy demanded fewer services provided by accredited CABs.

INSTITUTE FOR MEDICAL RESEARCH AND OCCUPATIONAL HEALTH

The Institute was founded as the Institute of Occupational Hygiene by the Yugoslav Academy of Sciences and Arts (Croatian Academy of Sciences and Arts since 1992) in 1947 and started with research in 1949. In 1958, it became independent of the Academy, and in 1959, changed name to Institute for Medical Research and Occupational Health (IMROH). Today, as the second largest Croatian research institution it reports to the Croatian Ministry of Science and Education.

As a scientific branch of the public health doctrine, IMROH studies various anthropogenic factors, pollutants, and noxae that affect health and the environment to perform

risk assessments essential for preventive and remedial actions. The bulk of its ongoing multidisciplinary research involves physical and biological aspects of occupational health, environmental hygiene and pollution, and man-made as well as natural radioactive contamination of the environment.

Quality management system at IMROH

In order to provide validated high-quality results IMROH has been implementing measures to improve the quality of its performance from the very beginning. This resulted in full readiness for acceptance of a quality management system in line with the (17) standard as the only internationally accepted standard for laboratory quality systems that provides globally accepted testing and calibration reports.

In 2010, IMROH was accredited by HAA for the following scopes: “determination of radioactivity”; “testing of ambient air quality”; and “testing in the scope of ionizing radiation protection”. This accreditation encompassed three laboratories: Radiation Protection Unit, Environmental Hygiene Unit, and the Radiation Dosimetry and Radiobiology Unit. In 2015, IMROH was duly re-accredited, and the second re-accreditation is planned for the end of 2020. Accredited materials, products, types of tests, and methods are listed in the Accreditation Certificate No. 1288, publicly available at the web site of HAA (20).

The quality management system operating at IMROH has the following characteristics:

- Single Quality manual and generic documentation for all accredited organizational units;
- Quality manual follows the structure of the HRN EN ISO/IEC 17025 standard;
- Only documentation that is published at IMROH Intranet is valid, i.e., printed documentation becomes obsolete by the act of printing. The signed and approved original is kept by Quality manager;
- Working instructions for testing methods are prepared by respective organizational units;
- Every method is validated, whether they are standardised or not (in-house);
- Internal audits are performed every year by all units against all standard requirements and normative documents, if applicable;
- Results of internal audits provide input for management review in each accredited unit;
- Management reviews by each unit provide input for top management review.

Laboratory diaries have been replaced by checklists to minimise error (skipping or incorrectly applying required procedures) and to keep a thorough record of all data and samples (aka test items) needed for calculations.

After regular HAA audit in February 2020, IMROH made a successful transition from HRN EN ISO/IEC 17025:2007 to the new 2017 edition of the ISO standard,

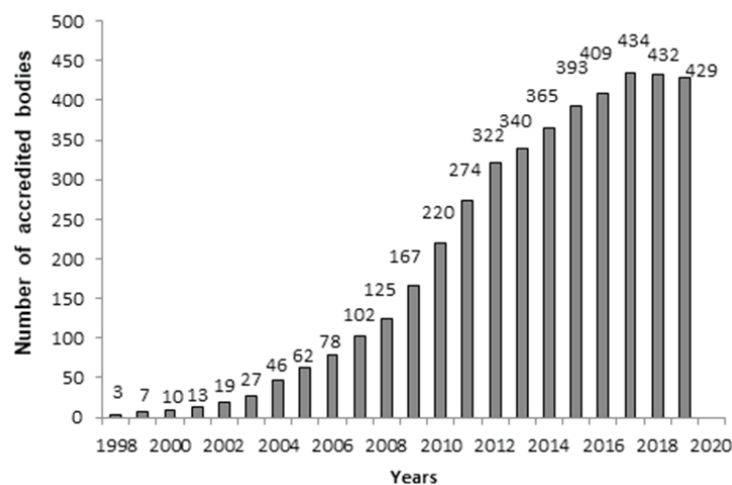


Figure 1 Number of accredited bodies in Croatia after the establishment of the accreditation system

i.e., HRN EN ISO/IEC 17025:2017. The transition went smoothly, and external auditors found only two non-conformities, the first one dealing with new requirements for monitoring competences and authorisation of personnel and the other one dealing with quality assurance, as the exact dates for calibration were not properly documented.

Documentation did not change, but a new procedure for risk management and related forms were developed, quality policy was improved, and several forms were upgraded.

As required by standard, all three accredited laboratory units assure metrological traceability of their testing results by unbroken and documented chain of calibrations. Each of these calibrations contribute to the overall measurement uncertainty. Measurement uncertainties of methods are evaluated following the principles set out in the HAA document “Evaluation of measurement uncertainty” (21) and guidelines set by European Accreditation Cooperation (22), International Laboratory Accreditation Cooperation (23 and EURACHEM/CITAC (24).

Among the three accredited units, the Environmental Hygiene Unit issues a statement of conformity. It is a binary statement that accepts or rejects measurement results and describes the decision rule that is applied, i.e., how measurement uncertainty is evaluated and accounted for (25).

Quality objectives

Quality objectives of the IMROH quality policy are as follows:

- Customer satisfaction - to deliver evaluation services that meet agreed customer requirements, timescales, and expectations regarding value and service;
- Commitment to the implementation of the ISO 17025 standard;
- Effectiveness - to ensure effective application of data security and testing methodologies in order to produce

decisive results and high standards of excellence creating new value in research;

- Efficiency - to continually improve all processes to deliver services more efficiently, avoiding wasting time and effort and maximising output values;
- Impartiality - to deliver services in an impartial and unhindered manner;
- Objectivity - to obtain evaluation results with a minimum of subjective judgment or opinion;
- Repeatability and reproducibility - to retain sufficient and accurate records to enable evaluations to be repeated and results to be reproduced.

Structure of documentation

A laboratory must clearly define its structure and activities and describe them in its documentation which is compliant with quality policy. Quality policy statement is a strategic document developed by unit management in line with top management quality directive(s). The policy should demonstrate laboratory’s commitment to implementation of the ISO/IEC 17025 standard and to continuous improvement.

Management system documentation includes a set of documents (quality policy, quality manual, procedures, working instructions, regulations, standards, and other normative documents) organised in a so called documentation pyramid. Quality manual is the top tier document, which describes organisation’s quality management system and approaches to achieve quality data. It also specifies the adopted and implemented competence, impartiality, and operational requirements. The new, 2017 version of the HRN EN ISO/IEC 17025 standard does not require a quality manual, but most accredited laboratories worldwide have retained it, including our laboratories at IMROH.

The next, second tier, if we look from the top down, are standard operating procedures (SOPs) – generic instructions for how to perform a specific task, such as personnel

management, documentation management, internal auditing, or reporting of results.

The third tier are working instructions – step-by-step instructions that clearly and precisely describe the correct way to perform certain tasks such as specific testing methods or calibration of a specific instrument.

The fourth tier consists of records generated on a day-to-day basis, such as checklists, forms, calibration and analytical results, as well as various other maintenance, testing, and training records.

Finally, the last tier consists of various external documents such as standards, regulations, instructions for instrument use and maintenance, manuals, HAA accreditation documents (26), and other rules.

At IMROH standard operating procedures include:

1. procedure for document and record control;
2. procedure for review of requests, tenders, and contracts;
3. procedure for risk management;
4. procedure for complaints management (description of the process for receiving, validating, and investigating a complaint and deciding what actions are to be taken in response to it, tracking and recording complaints, actions undertaken to resolve them);
5. purchasing procedure (defining, reviewing, and approving the laboratory's requirements for external products and services, criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers, ensuring that external products and services conform to the laboratory's requirements or, when applicable, to relevant requirements of normative documents);
6. procedure for management of nonconforming work (defining responsibilities and authorities, risk-based actions, evaluation of the significance of the nonconforming work, impact analysis and acceptability of the nonconforming work, notification of customers in cases when work is recalled, responsibility for authorising resumption of work);
7. personnel management procedures (determining competence requirements, selection of personnel, training, supervision, and authorisation of personnel, monitoring competences);
8. procedure for management of facilities and environmental conditions;
9. procedure for managing equipment (handling, transport, storage, use and planned maintenance of equipment)
10. Procedure for handling test or calibration items (transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items)
11. Procedure for ensuring the validity of results (monitoring the validity of results)

Regarding test methods, each method has a comprehensive and validated working instruction. If applicable, validation parameters are as follows (for definitions see ref. 27): working range in which the calibration equation applies (linearity of calibration); measuring interval; matrix effects; selectivity; sensitivity; accuracy; precision; repeatability; reproducibility; trueness; limit of detection; limit of quantitation; limit of reporting; ruggedness; and measurement uncertainty.

Validation records also include reports from quality assurance programmes and results of participation in proficiency testing and inter-laboratory comparison schemes. Validation is performed by professional staff in charge of respective methods.

Quality assurance

Every year, IMROH participates in more than ten national and international quality assurance programmes for various analytical methods organised by providers like the Joint Research Centre (JRC), International Atomic Energy Agency (IAEA), Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA), Institut national de l'environnement industriel et des risques (INERIS), LGC Group, Ekoneg, and others.

Equipment and measuring instruments are calibrated at appropriate, usually annual intervals. An important part of quality assurance is continuous investment in human resources in order to improve their competencies and level of expertise through international workshops, trainings, and courses).

How is quality assurance implemented in gamma-ray spectrometry at IMROH has been reported in more detail elsewhere (28).

Internal audits and management review

Internal audits verify compliance of laboratory's performance with the ISO/IEC 17025 requirements and company policies, processes, and procedures. At IMROH internal audits take place 1–2 months before external audits. All internal auditors have been trained for auditing. Over the last 10 years, internal auditors have reported 166 non-conformities (85 related to the management system

Table 1 Total number of non-conformities and recommendations recorded in internal audits in the 2010–2020 period

Scope of accreditation	Non-conformities	Recommendations
Determination of radioactivity	78	33
Determination of air quality and pollutants in the air	17	18
Testing in the scope of ionising radiation protection	71	30
Total	166	81

requirements and 81 to methods and technical requirements) and 81 recommendations (43 related to the management system requirements and 38 to methods and technical requirements). Thirty non-conformities concerned the performance of testing methods, 18 the management of personnel, and 13 quality assurance of results. A large number of non-conformities and recommendations found in management system helped to identify and minimise the risks associated with organisation and impartiality (Table 1).

External audits

The first (initial) accreditation audit of IMROH took place in 2010. Between 2010 and 2020, HAA carried out nine external audits and found a total of 22 non-conformities, only three of which concerned system management. It also issued 58 recommendations, 15 of which concerned system management. Most non-conformities and recommendations concerned testing methods (8 and 18, respectively).

Figure 2 compares the non-conformities found by external (HAA) and internal auditors to show how competent, impartial, and strict internal audits are at IMROH. Both auditing teams paid special attention to clause 5.4 of the EN ISO 17025:2017 standard (test and calibration methods and method validation). Internal auditors were also very strict regarding clause 5.9 of the EN ISO 17025:2017 standard (assuring the quality of test and calibration results). The ratio between the total number of non-conformities found by external and internal auditors is 13:100, respectively and clearly shows that internal audits were much more rigorous. Namely, very strict internal audits, designed and conducted much in the same way as external audits, proved to be beneficial in maintaining the high standard and robustness of the quality system at

IMROH. Consequently, non-conformities were successfully corrected before external audits.

Figure 3 shows a similar analysis for recommendations given by internal and external auditing teams. The HAA teams preferred to give recommendations rather than non-conformities regarding clause 5.4, which is yet another evidence that internal auditors were much more rigorous.

Generally, the analysis of the non-conformities is useful to assess quality assurance and risk analysis. Over the last ten years, the steady annual decrease in identified non-conformities by either internal or external auditors clearly suggests that the implementation of corrective and preventive actions has been successful. The good agreement between external and internal auditor findings indirectly validates the approach and competence of internal auditors.

In October 2019, the Radiation Protection Unit underwent a two-day external “verification of bodies having competence in the field of environmental radioactivity monitoring in Zagreb, Croatia” carried out by verifiers of the European Commission (Directorate-General for Energy - Directorate D for nuclear energy, safety and ITER) under the Euratom Treaty article 35 (29). This verification covered environmental radioactivity monitoring, radiological surveillance of foodstuffs and nuclear and radiological emergency preparedness.

No non-conformities were found. The verifiers concluded that the environmental radioactivity monitoring programmes in Zagreb complied with the requirements of the Euratom Treaty article 35 and reported that the “facilities needed to carry out continuous monitoring of levels of radioactivity in air, water and soil in Zagreb are adequate (29).

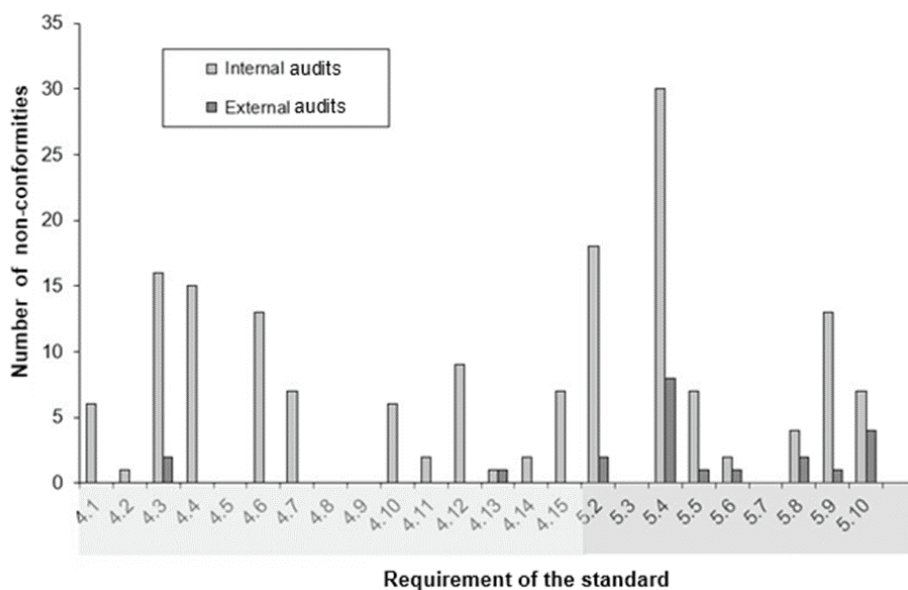


Figure 2 Non-conformities found by internal and external auditing teams in the 2010–2020 period. X-axis lists the requirements (by clauses) of the ISO IEC/17025:2007 standard (4.1–4.15 system management and 5.2–5.10 technical competences)

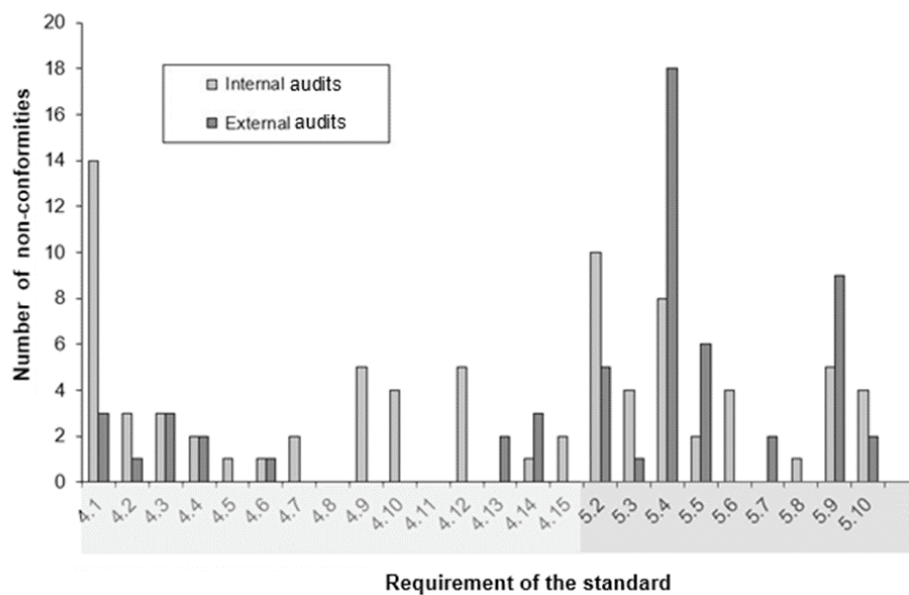


Figure 3 Recommendations given by internal and external auditing teams in the 2010–2020 period. X-axis lists the requirements (by clauses) of the ISO IEC/17025:2007 standard (4.1–4.15 system management and 5.2–5.10 technical competences)

Cost of quality management

The main purpose of quality assurance is to meet all customer expectations in terms of product quality at an acceptable cost. Quality assurance is therefore primarily focused on preventing any mistakes throughout the process of creating and using a product or service. Prevention involves planning, but successful planning is not possible without up-to-date information on quality costs. Quality management system costs include: administrative costs (accreditation, external audits, etc.); cost of process controls (actions taken for reduction of process, output variability); product quality-related costs (control, detection, prevention); poor quality costs / defect-related costs (failure, non-conformance, deficiencies); and other, hidden quality costs.

These costs are extra, on top of production costs, but ensure the quality end-product.

To minimise possible losses within the quality system it is important to monitor and control these costs.

After the initial high costs of implementing quality management, IMROH saw a steady decrease. In addition, accreditation and higher quality of laboratory activities have a direct impact on productivity and savings, although it is not always tangible. As we mentioned before, Croatian regulations stipulate that only accredited institutions can participate in certain activities and projects, including routine environmental monitoring. Accreditation therefore enabled IMROH to bid and win quite a number of national and international projects.

There are several commercial software tools available for quality cost management (30), but IMROH has developed its own, simple but effective tool based on the concept introduced by Feigenbaum (31), which also

includes risk analysis and actions to address risks and opportunities.

At IMROH, financial benefits of accreditation far outweigh the costs. Our accredited units have increased the number of contracts with external clients, the number of analysed samples also, and the number of implemented projects (Table 2).

Concluding remarks

In Croatia, environmental monitoring of radioactive contamination and air quality is mainly entrusted to scientific institutions. In return, they provide additional value to monitoring results. Instead of having binary approach to measurement results (contaminated/not contaminated, safe/unsafe, above/below specified limits) scientists strive to obtain real numbers, i.e. validated data that allow modelling and prediction of trends. This improves monitoring design and optimisation and facilitates decision-making and planning emergency response if necessary. Similar applies to dosimetric surveillance.

However, validated and internationally recognised data/testing results can be produced only by accredited laboratories. Reliability of test results leads to higher confidence of customers, which increases demand for such services.

The set-up and implementation of a functioning quality system based on the ISO 17025 standard at IMROH required coordination and collaboration of all involved organisational units and all of them demonstrated competence and skills. All personnel was trained to adopt changes that came with the new edition of the ISO 17025 standard. Implementation and maintenance of the quality system and accreditation helped personnel to get in touch with real-world economy and broaden their minds, which

Table 2 Number of projects, tested samples, inter-laboratory comparisons and collaborations in accredited Units

Unit	Projects	Samples	Inter-laboratory comparisons / proficiency tests	Collaborations
Radiation Protection Unit	30 (10 scientific and 20 professional projects)	4200	67	IAEA, JRC, WHO
Environmental Hygiene Unit	94 (15 scientific and 79 professional projects)	225259 (varies from 19500 to 26000 samples per year)	29	IAEA, JRC, WHO, University of Rijeka, Sarajevo University Faculty of Science, Ekoneg d.o.o.
Radiation Dosimetry and Radiobiology Unit	–	2400 thermoluminescent dosimeters (TLD): 5500 radiation sources	12	IAEA, EURADOS, Jožef Stefan Institute, Alara d.o.o., Hajkom d.o.o., Ekoteh dozimetrija d.o.o.

EURADOS – European Radiation Dosimetry Group; IAEA – International Atomic Energy Agency; JRC – Joint Research Centre, the European Commission’s science and knowledge service; WHO – World Health Organization

has had a lasting positive impact on research studies and academic production.

A functional and validated quality management system facilitates the introduction of other accreditation schemes, such as Good Laboratory Practice – GLP (32), the Federation of European Laboratory Animal Science Association - FELASA accreditation scheme (33) in laboratory animal science (LAS), and ISO 14000 series standards (34), which are often required for applying to various tenders and for various institutional collaborations.

In conclusion, the accredited management system at IMROH significantly improved the performance of the accredited units, and IMROH improved its visibility, customer loyalty, and market position.

UPDATE

On 26 and 27 October 2020, the auditing team of the Croatian Accreditation Agency conducted re-accreditation audit at IMROH and granted continuation of accreditation, as they found no non-conformities and concluded that all three laboratories had been implementing the management system effectively and in accordance with the requirements of the HRN EN ISO/IEC 17025:2017 standard.

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Iskustva akreditacije Instituta za medicinska istraživanja i medicinu rada

Akreditacija u skladu sa zahtjevima međunarodnog standarda HRN EN ISO / IEC 17025 (*Opći zahtjevi za osposobljenost ispitnih i umjernih laboratorija*) postala je praktična i široko prihvaćena metoda upravljanja kvalitetom i objektivni dokaz tehničke osposobljenosti, znanja i vještina u ispitnim i umjernih laboratorijima. Institut za medicinska istraživanja i medicinu rada (IMROH) akreditirao je 2010. godine svoj sustav upravljanja u skladu sa zahtjevima HRN EN ISO / IEC 17025 norme za sljedeća područja primjene: određivanje radioaktivnosti, ispitivanja kvalitete zraka te ispitivanja u području zaštite od ionizirajućega zračenja. Akreditacija je obuhvaćala tri laboratorija: Jedinicu za zaštitu od zračenja, Jedinicu za higijenu okoline i Jedinicu za dozimetriju zračenja i radiobiologiju. U skladu s pravilima Hrvatske akreditacijske agencije, u 2020. godini planira se druga reakreditacija Instituta. U radu je opisan sustav upravljanja kvalitetom u IMROH-u i iskustva stečena tijekom desetogodišnjeg razdoblja. Analizirane su nesukladnosti otkrivene tijekom redovitog rada, u internim auditima te u vanjskim auditima koje je provodila Hrvatska akreditacijska agencija, tj. nacionalno akreditacijsko tijelo u Hrvatskoj. Može se zaključiti da je akreditirani sustav upravljanja značajno poboljšao rad uključenih akreditiranih jedinica, a Institut je povećao vidljivost na tržištu i marketinšku prednost te posljedično poboljšao svoju tržišnu poziciju.

KLJUČNE RIJEČI: ISO norme; ispitni laboratoriji; mjerna sljedivost; upravljanje kvalitetom