

The Quality Management System of the Robert Koch Institute

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Abstract – The Robert Koch Institute (RKI) is Germany’s leading governmental scientific institution in the field of biomedicine and moreover one of the most essential bodies for the safeguarding of public health. It issues independent recommendations for medical specialists, state and local health authorities and the federal government. Furthermore, there is a brisk exchange of information and advice with its partner countries, for instance to improve preparing disease outbreaks and health crises. In conclusion the Robert Koch Institute contributes to health protection not only in Germany, but across the world. Citizens, medical specialists, state and local health authorities as well as the federal government and partner countries need to rely on it.

This paper shall give an overview of the quality management (QM) and its features at the RKI as a federal institution as well as of the latest crucial issues and achievements. It is supposed to give an insight and stress the importance of quality and its assurance in a national research and health institute. It explains how the institute gains reliability and credibility for its services and recommendations of national and even global significance.

Keywords – IMEKO, TC10, Robert Koch Institute; quality management system; flexible scope of accreditation

I. INTRODUCTION

“The degree to which a set of inherent characteristics fulfills requirements” – that is how quality is defined according to DIN EN ISO 9000:2015; in short: quality means fulfillment of customer requirements. To the RKI quality assurance is an essential part of everyday work in its diagnostic laboratories; quality guarantees the fulfillment of highest standards. This paper introduces the

quality management system (QMS) of the RKI, which contributes to its credibility and reputation.

First, there will be a short introduction of the Robert Koch Institute itself and secondly an introduction of its quality management. The RKIs’ unusual feature to integrate three ISO standards into one QMS is specified. In the following the importance of accreditation is pointed out and finally there is a report on flexible scopes and their benefits, especially in times of biological threats, like the COVID-19-crisis.

II. RELATED RESULTS IN THE LITERATURE

There are no comparable results in literature, which explain the QMS of the Robert Koch Institute.

III. DESCRIPTION OF THE METHOD

THE ROBERT KOCH INSTITUTE

Being one of the oldest institutes for public health across the world, the Robert Koch Institute did not just gain publicity during the SARS-CoV-2 crises in 2020 but long before that. The RKI is an international hub for health protection networks. It cooperates with many international partners like the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) and is part of various international research projects. Furthermore, it is a WHO Collaborating Centre for Emerging Infectious and Biological Threats and partner of the Global Outbreak Alert and Response Network. Amongst others it operates three regional reference laboratories of the WHO/Europe and holds various national reference centers and consultant laboratories. Likewise, the RKI cooperates with many national partners for instance INSTAND e.V., which is a not-for-profit, scientific medical society, organizing external quality assessments through ring trials.

The RKI was founded in 1891 and was named after

Robert Koch, who was a physician, researcher and the first head of the institute. Robert Koch's investigations were the first showing the relation between infectious agent and disease. Moreover, he was awarded the Nobel Prize in Medicine 1905 for discovering the tuberculosis pathogen. The core activities of the Robert Koch Institute are research, prevention and combating of infectious diseases as well as the analysis of long-term public health trends. It monitors and investigates at various levels including infectious diseases and biological threats besides non-infective diseases like diabetes, cancer and obesity. The RKI issues independent recommendations for medical specialists, state and local health authorities and the federal government. Additionally, there is a brisk exchange of information and advice with its foreign partner institutions, for instance to improve preparing disease outbreaks and health crises like the West African Ebola outbreak 2014-2016 and the latest global pandemic, SARS-CoV-2.

The Robert Koch Institute employs highly-motivated and qualified staff operates a modern research infrastructure, in a flexible organizational structures and an efficient administration, everything contributing to its eminence and success.

QUALITY MANAGEMENT

For a federal institution, that performs specialized diagnostics, a QMS is of significant importance. A QMS will be even more essential if the institute manages tasks being involved with the defense of biological hazards, outbreaks of highly pathogenic or bio terroristic agents. Especially in those cases an efficient and comprehensive QMS, which supports and fosters the diagnostics, is indispensable. Consequently, the RKI takes top priority on the quality assurance of its virological, bacteriological, parasitological laboratories as well as the toxin analysis with a focus on national reference centers and consulting laboratories.

Competent and powerful medical laboratory diagnostics make a significant contribution to the combat of a pandemic with a new pathogen. Likewise, a high-quality diagnostic supports patient protection, since medical decisions are based on reliable test results of laboratory medicine.

The RKI has established its quality management system for more than ten years. It was initiated due to economic and technological developments and new regulatory requirements in the healthcare sector. Adopting a QMS was a strategic decision that is still improving the overall performance. It is based on the fundamental QM principles:

- customer focus
- leadership
- engagement of people
- process approach
- improvement
- evidence-based decision making
- relationship management.

The RKI created a special unit for developing and maintaining its QM system: unit ZV 6.2 "Quality Management".

ZV 6.2 is part of the department ZV 6: Organization (ZV 6.1) and Quality Management (ZV 6.2). Both units pursue the same objective: targeted organizational development. The merger creates a profitable benefit. ZV 6.1 is in responsibility for the RKI's general organizational remits while ZV 6.2 focuses on the laboratories.

ZV 6.2 is the central coordinating part of the QMS. Furthermore, there are quality assurance representatives in every unit of the RKI, which belong to the QMS.

The responsibilities of ZV 6.2 range from accreditations of laboratories according to DIN guidelines to satisfaction analyses for ongoing evaluation and improvement of the effectiveness and efficiency of the QM system. In detail ZV 6.2 has the following tasks:

- establishment and further development of the quality management system at the RKI and accreditation of laboratories according to DIN EN ISO 15189, DIN EN ISO/IEC 17025 and 17043
- participation in the elaboration of the RKI's quality policy
- participation in the elaboration of quality goals and their implementation by means of suitable quality measures in the departments and specialist areas of the RKI
- overall coordination of the control of quality-relevant documents of the RKI in accordance with the relevant standards and legal provisions, including the creation and maintenance of the RKI's QM-manual
- coordination of the communication of all QM-relevant aspects within the RKI
- organization and implementation, as well as documentation of internal audits
- monitoring of corrective and preventive measures as well as measures for the continuous improvement of the RKI's QM system
- preparation of the annual management review
- coordination of QM events
- advice and support from the quality assurance representatives
- participation in the improvement of QM-relevant processes, integration of further areas into the QM system
- coordination of internal processes such as sample receipt / transport
- project management and controlling within the framework of external assessments
- coordination of test equipment monitoring

The quality system of the RKI is based on the following norms (Tab. 1):

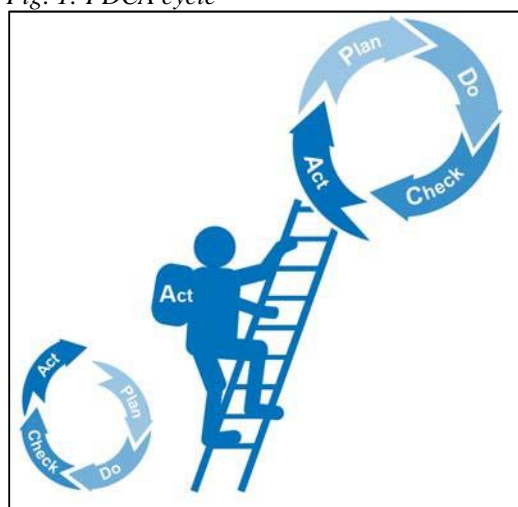
Tab. 1: norms concerning QMS at RKI

DIN EN ISO 9001	Quality management systems – Requirements
DIN EN ISO 15189	Medical laboratories - Requirements for quality and competence
DIN EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
DIN EN ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing
RiliBÄK	Guideline for quality assurance of laboratory medical tests issued by the German Medical Association

The RKI’s QMS is guided by the PDCA cycle - plan, do, act, check (fig.1). It enables continuous improvement. First processes are planned thoroughly and implemented. The processes are always according to the RKI’s mission: “Generate evidence - share knowledge - protect and improve health”. In the following the processes are monitored and checked against former objectives and the RKI’s policy. If necessary, they will be corrected and updated. The optimizations taken will become new standards and furthermore will be the basis of the next cycle.

The PDCA cycle enables the RKI to perform a process adequately and efficiently. Through risk-based thinking while planning a process, the RKI determines factors that could deviate from the intended objectives. Preventive controls will be put in place to minimize negative outcomes.

Fig. 1: PDCA cycle



The quality management contributes to the RKI’s effectiveness and efficiency in achieving its intended results thus the overall performance of the institute can be enhanced. Furthermore, there are various more benefits of an elaborated QMS for diagnostic laboratories like:

- clear responsibilities (plan of authorization)
- up-to-date operating instructions (SOPs) for methods, techniques and devices
- procedures are clearly determined and written down thus there is a document to look them up that makes the work uniform for everybody
- the precise way of a clinical sample from receipt to report is known and can be traced
- facilitated initial training of new employees
- assays are validated
- devices are maintained at regular intervals

Undoubtedly there are a lot of prejudices associated with QM. For instance, a lot of time is spent introducing the QM to an organization, but once done the effort pays off. Moreover, certification and accreditation are arising costs. Nevertheless, there are customer demands that must be fulfilled. On one hand this requires extra effort to maintain the documents and increases the level of bureaucracy, but the payback on the other hand is a competent quality assurance and legal security, for instance through the sample traceability. All in all, once implemented, a QMS will facilitate and promote organizational work.

The advantages of a QMS and an accreditation are closely related. Thus, you find more benefits below in the section – The impact of accreditation (p. 4).

The RKI sees itself as a provider of quality-assured services, thus quality assurance is a crucial topic in every day work at the institute and vital for the laboratories.

The principles and thereby the fundament of the QMS are laid down in the quality management manual. Also, the continually evaluation and improvement of effectiveness and efficiency of the QMS is rooted deeply within the quality policy of the institute. The QMS comprises quality planning, quality inspection, quality assurance and arrangements for steady improvement.

Without limitation it includes procedures for periodically self-assessment of every section with the objective of continuously advancement. Apart from that, it assures consistent validation of applicability and sufficiency. In addition to superior national proceedings of assessment there are individual specific methods.

In the following three methods, used by the RKI for quality assurance through assessment of efficiency, are listed and described.

- **Proficiency testing:**
Proficiency tests are periodically performed to safeguard the quality of the work in favor of public health. They review capability and consistency of methods and test systems as well as they determine the performance of the laboratories involved. The national reference centers of the RKI participate in organization and performance of international proficiency test besides collaboration with reference centers of other countries and collaboration centers of the WHO. If there is an entrenched assay with no proficiency test available, neither national nor international, the RKI will perform a laboratory benchmarking test.
- **Internal quality audits:**
Monitoring of the congruency between specified condition and actual state. Due to internal audits, sticking to statutory and normative requirements is simplified. Audits are methodical and independent observations and assessments of the QMS and of the processes at the accredited units. Audits are guided by DIN EN ISO 19011.
Internal audits are not regarded as inspection or trial; they are considered as useful support. The effectiveness of the QM activities is specified, always with regard to the RKI's quality policy and the quality goals of the individual units. Furthermore, internal audits initiate corrective and preventive measures and moreover determine the effectiveness of those. All in all, internal audits prepare for external audits.
- **Annual management review (MR):**
The QMS of the RKI has to meet severe requirements. Therefore, comprehensive and methodical MR are performed in regular intervals. First the particular unit reviews itself and determines key figures and data. Those will be passed to the department ZV6.2 QM central, which evaluates it together with the head of institute and department. The outcome is written down in the annual management report. In the end the head of institute present it to the employees. The MR consists of key figures, making it calculable. Conclusions can be drawn whether set goals of the past year were achieved or not. Based on that, goals for the next year can be determined. It is possible to get a long-term improvement on a basis of calculable trends.

THE IMPACT OF ACCREDITATION

A further essential part of the RKI's QMS is accreditation.

The explicit definition of accreditation is given in ISO/IEC 17011: "Accreditation refers to third-party attestation related to a conformity assessment body

conveying formal demonstration of its competence to carry out specific conformity assessment tasks".

In many cases, laboratories provide evidence of their competence through accreditation. Accreditations are carried out by independent accreditation bodies. They assess and monitor the competence of the laboratories' staff and of the management system. They verify that laboratories possess technical competence in compliance with prevailing statutory requirements and international standards.

The official recognition of the RKI's competence happens through regular external assessments by the DAkkS ("Deutsche Akkreditierungsstelle" - national accreditation body of Germany).

An official accreditation verifies various parameters. The reviewed services, methods and systems are proven to be reliable with regards to their quality and safety. They conform to technical standards, guidelines and laws in compliance with diverse strict requirements. Moreover, assessment services depend on the competence of the person who performs it and not only on objective certificates, inspections or calibration standards. Therefore, it is possible to confirm the quality of one's own work and skill with an accreditation.

Accreditations offer many benefits for several parties. The accredited units will receive a better acceptance for the service and recommendation they are offering. Apart from that, it illustrates international comparability and the recognition of certificates and inspections. In addition, there will be an advantage over non-accredited market participants offering the same services. Also, there are advantages for clients, like a higher trust and acceptance in the quality of work and service in addition to fewer errors or recalls. As a federal institution the RKI proves reliability, credibility and skill to the German population through accreditations.

Undoubtedly there are benefits for the accredited unit as well. These advantages are listed below. They are the results of an internal workshop and from the laboratories' staff point of view:

- higher acceptance of examinations, services
- checked once, accepted everywhere: international comparability and recognition, including official ones
- saving additional costs through avoidance of multiple evaluations
- greater trust in the quality of the services from client/ patient/public side
- powerful tool to increasing quality
- fewer errors and easier troubleshooting
- objective evidence of the quality and competence of the work according to international standards

- better positioning in case of liability (evidence of compliance with due diligence, state of the art of science and technology)
- competitive advantages
- significant increase in the quality of the laboratories and their test procedures
- higher retention of knowledge even in the event of staff changes / absence
- increase in personnel qualifications
- increasing the exchange with other QM employees
- equipment in best condition- properly calibrated and maintained
- suitable and valid test procedures and methods
- regular external assessments by technical experts
- traceability of measurements to national standards
- procedures for accurate recording and reporting

To proof the RKI's expertise in other countries great importance is attributed to the use of the combined DAkks/ILAC-symbols on external reports (fig.2). Through the "ILAC Mutual Recognition Arrangement (MRA)", all listed accredited laboratories have proven their national and international recognition of their medical services in all ILAC member states. In short: the RKI's methods, being accredited, are recognized in every other ILAC member state, which facilitates the collaboration across borders.

Fig. 2: exemplary combined DAkks/ILAC-logo with a registration number of a medical (ML) and test (PL) laboratory and proficiency testing provider (EP) of the RKI



All four sites of the RKI own and operate accredited laboratories, each one different and unique. Every laboratory holds its own remits, pathogens and testing methods. There are epidemiological laboratories besides consultant laboratories. Each laboratory is accredited independently and according to different norms. The following national reference centers (NRZ), consultant laboratories (KL) and other laboratories have been successively accredited since 2010.

Tab 2. accredited laboratories

FG11	NRZ for salmonellae and other bacterial enteritis pathogens	ML/PL
FG12	NRZ for measles, mumps, German measles	ML/PL
FG13	NRZ for staphylococci and enterococci	ML/PL
FG14	central for nutrient media	PL
FG14	linen disinfection	PL
FG15	KL for noroviruses and KL for rotaviruses	ML/PL
FG15	NRZ for poliomyelitis and enteroviruses	ML/PL
FG16	KL for cryptococcosis and rare system mycosis	ML/PL
FG17	NRZ for influenza and KL for respiratory syncytial viruses (RSV), parainfluenza viruses (PIV) and human metapneumoviruses (HMPV)	ML/PL
FG 18	HIV Study Laboratory	ML/PL
FG 22	epidemiological central laboratory	ML/PL
ZBS 1	KL for smallpox viruses	ML/PL
ZBS 2	Bacillus anthracis and KL for tularemia	ML/PL/EP
ZBS 3	KL for neurotoxin-producing clostridia (botulism, tetanus)	ML/PL
MF2	genome sequencing	PL

ML = medical laboratory
 (accredited according DIN EN ISO 15189)
 PL = test laboratory
 (accredited according DIN EN ISO/IEC 17025)
 EP = proficiency testing provider
 (accredited according DIN EN ISO/IEC 17043) FG = unit (German "Fachgruppe")

There is a strong focus to accredit the RKI's national reference centers and consultant laboratories according to DIN EN ISO 15189 (Medical laboratories - Requirements for quality and competence) and DIN EN ISO /IEC 17025 (General requirements for the competence of testing and calibration laboratories). The central service facilities like the genome sequencing, laundry disinfection and centre for nutrient media are accredited according to DIN EN ISO/IEC 17025.

Therefore the RKI ensures that even the non-accredited research laboratories work on a basis of high quality standards. An exception of the QMS, which primarily focuses on diagnostic laboratories, is the quality management of the epidemiological central laboratory (FG 22) in Dept.2 "Epidemiology and Health Monitoring". Because of the involvement of FG 22 in the QMS the nationwide health monitoring studies are ensured to have high study and data quality. An outstanding achievement of the RKI is the

accreditation of department ZBS 2 "Highly pathogenic microorganisms" according to DIN EN ISO/IEC 17043 "Conformity assessment – General requirements for proficiency testing". The requirements of the DIN EN ISO/IEC 17025 and DIN EN ISO 15189 mentioned above are followed additionally.

As a result, the RKI is the only proficiency testing provider for highly pathogenic bacteria as well as living, inactivated and serologic samples world-wide.

Organization, arrangement and performance of those proficiency tests are standardized and comply with the respective regulations.

Furthermore, ZBS 2 is officially allowed to work with clinical, food and environmental samples. Initially, they were only permitted to handle clinical ones but they accomplished a scope extension.

It is planned to accredit more units according to DIN EN ISO/IEC 17043. That would expand the panel of the institute's work significantly. For instance the RKI could expand the scope of its accredited proficiency testing to highly pathogenic viruses.

The large scope of the RKI's services leads to another uniqueness of the QMS: Usually an organization matches with one division of the accreditation body perfectly whereas the RKI is supervised and assessed through three different divisions within the DAkkS:

- Division 1: Division Metrology | Construction | Transport | Renewable Energy:
 - Proficiency testing provider
- Division 3: Health | Forensics
 - Clinical samples
- Division 4: Consumer Protection | Agriculture | Chemistry and Environment
 - Food and environmental samples

ACCREDITATION WITH A FLEXIBLE SCOPE

The RKI focuses on a special version of accreditation: the accreditation with a flexible scope.

A flexible scope allows a laboratory to modify its own test methods, which are developed by itself, or use updated versions of standard test methods, that the laboratory is already accredited for. Furthermore it can be allowed to adopt similar standards or additional test methods, everything without the obligation to inform the DAkkS by forehand. Due to a flexible scope it is possible to use latest and updated methods under the official ambit of an accreditation.

Modifications and updated versions or new test methods must not include different measurement principles, being not covered by the former accreditation. It is not permitted to deviate from the original description of testing- and calibration scope.

All modified testing methods, which are operated with reference to accreditation, have to be verified or validated. The appropriate procedures of validation and verification must be in written form and provided

by the laboratory.

Naturally, there are limits of a possible flexible scope. According to the DAkkS guideline the flexibility of the scope can be granted up to the following possibilities:

- changes regarding matrix / sample / test item/ test object (e.g.: matrixes according to accreditation are throat and nasal swab; assay of influenza A virus in throat and nasal swab is extended to assays in autopsy material)
- changes regarding measuring / test parameter / analyte (e.g.: extending assay of Influenza A virus in throat and nasal swabs to SARS-CoV-2 cDNA always employing real- time PCR)
- changes in performance of the testing methods for a given scope and test parameters (e.g.: the change of the measuring range and the accessible measurement uncertainty)
- inclusion of methods, being equivalent to those which are already covered by the accreditation

If an existing accreditation shall be extended to one with a flexible scope, a formal application must be made to the DAkkS.

The assessors of the DAkkS are responsible to evaluate the possibility of an accreditation with flexible scope for a particular laboratory. Among others they will assess if all necessary requirements are given, for instance experience and skills in testing methods and techniques being used. Moreover, the laboratory has to document all rules and responsibilities for the development, implementation and validation of test methods. All modifications, including every result arising from validation and verification, must be fully recorded. The laboratory must maintain an updated a list of all testing methods, including the modified, revised or newly developed ones covered by the flexible scope of accreditation.

The assessors focus particularly on:

- the ability to develop new test methods, to modify and validate them or to verify selected standard or equivalent testing methods
- the ability to technically implement methods and procedures with different issue dates
- necessary qualifications and experiences of the laboratories' staff
- testing and validation procedures and the technical equipment
- management system, in specific regarding validation and verification
- documentation of already performed validation or verification

The final report of the assessor must include a

recommendation for a flexible scope. It has to state which types of testing should be accredited and which test items, test objects, examination materials and matrices are included. In the end the successful laboratory gets an accreditation certificate with a description of the respective flexible scope. The annex must clearly state the sites of the laboratory for which the accreditation with flexible scope applies.

A flexible scope is facilitating research and consulting especially in crises like SARS-CoV-2. The laboratory of ZBS 1 - KL for smallpox viruses and the laboratory of Unit 17 NRZ for influenza and KL for respiratory syncytial viruses (RSV), parainfluenza viruses (PIV) and human metapneumoviruses (HMPV) own such accreditations with a flexible scope. Due to this property of the QMS the RKI was able to answer rapidly to the latest COVID-19 crises. After precise validation of the RT-PCR with SARS-CoV-2 cDNA, the diagnostics and microbiological studies could be performed quickly. Due to the accreditation with a flexible scope the laboratory was able to perform those studies covered by an official accreditation with all its benefits mentioned above. There was no need to inform the German accreditation body, which was extreme timesaving.

IV. RESULTS AND DISCUSSIONS

The QMS and its characteristics enable the RKI to hold some of the most reliable diagnostic laboratories around the world. The RKI is dealing with highly diverse samples of most various pathogens up to the most mortal ones. To assure the highest quality for working with these pathogens, the RKI holds three different standards for which it is also accredited. Through the accreditation by the DAkkS the offered services are recognized in every member state of the ILAC. Those states include a total of 70 countries. Furthermore the QMS makes it possible that even the non-accredited laboratories can work with a basis of high quality.

In addition to the maintenance and development of its own QMS the RKI is involved in the development of standards and in the general promotion of quality assurance in laboratories.

This includes international committee work and commitment to the promotion of exchange among laboratories. For instance, the RKI participated as a co-organizing scientific organization together with the Medical Care Center - Labor 28 Berlin GmbH and the DakkS for the annual conference of the Association of Accredited Laboratories (AAL) in September 2019.

The basic idea of this conference was: Exchange of experiences, ideas and information from accredited laboratories for accredited laboratories. The AAL is a working group that deals with all topics related to accredited laboratories and meets once a year to exchange current developments and information in this field and to invite to a dialogue.

Its quality management is one contribution to how the RKI meets the expectations of medical specialists, health authorities and the federal government and generates world-wide reliability.

V. CONCLUSIONS AND OUTLOOK

The RKI has achieved a lot in terms of quality assurance during the recent years but strives to achieve more. One of the latest highlight was the successful assessment by the DAkkS according to the revised DIN EN ISO / IEC 17025: 2018 of the units FG 11, FG 13 and FG 18 in November 2019. Because of this inspection the DakkS certified the successful conversion to all accredited units. Now the RKI is committed to prepare the future conversion of DIN EN ISO 15189, where it is involved via national and international committee work, additionally to the committee work of DIN EN ISO/IEC 17043 and the old DIN EN ISO/IEC 17025. Due to the fact, that the RKI is able to present its own developments to the international committee it can promote the revision in favor for global diagnostic laboratories significantly.

A comprehensive QM system supports the work of an institute. It adds benefits like clarified responsibilities, clearly determined and written procedures and a precise and retraceable way of clinical samples. An accreditation certifies quality to the clients and proofs it to the whole world, making the institute trustworthy and authoritative. Maintaining the confidence and credibility of the RKI's recommendation and proficiency takes top priority. The people, medical specialists, health authorities as well as the federal government and partner countries need to rely on it. Due to the elaborate QMS, involving self- assessments, reviews and accreditations, the RKI does a big step forward, towards the society and towards reliable public health.

VI. ACKNOWLEDGMENTS

We would like to take this opportunity to thank all employees, laboratories and units, being involved with the maintenance and development of our quality management system. The credit belongs to you that our national reference centers and consultant laboratories own such a great reputation.

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