BfR becomes first German federal scientific institute to be certified according to DIN EN ISO 9001

BfR Information Nr. 039/2010, 25 August 2010

Quality assurance and quality management of products and processes are not only of major importance in industry. Public authorities, especially scientific bodies such as laboratories and research institutes must provide confirmation that their work is carried out according to internationally recognised quality standards and ensure this through an effective quality management system (QMS).

Laboratories that carry out research must setup a QMS according to DIN EN ISO/IEC 17025 as a prerequisite for accreditation and recognition of their laboratory results. On the one hand this standard specifies all organisational and technical requirements that a laboratory must adhere to in its analyses and research. Furthermore, a transparent documentation of the results is required. During the accreditation process, the QMS is assessed by an external accreditation body. All laboratories of the Federal Institute for Risk Assessment (BfR) have been accredited since 2002. This was the precondition for the appointment of 14 national reference laboratories at BfR.

For those organisational sections that are not subject to the specifications particular to laboratories, the DIN EN ISO 9001 standard specifies requirements for certification. The standard specifies how business processes and responsibilities are to be organised in order to ensure that the products generated are of a high quality. Essentially, the aim is to certify that an organisation is systematically managed according to quality objectives, business processes are documented and implemented, and that improvements are continually sought out and realised. Methods, procedures and tools are to correspond to the current standard.

BfR has elected to establish a QMS for its entire organisational sector and presented this to TÜV Nord for certification. Based on a three-day audit, TÜV Nord has verified that the BfR QMS meets the requirements of the standard, and that it has been successfully implemented in all organisational sections. The existing laboratory accreditation also fulfils the requirements of DIN EN ISO 9001. BfR is thus the first federal German scientific institute to introduce a quality management system for laboratory work and for scientific assessment and administrative processes that meets international requirements.

DIN EN ISO 9001 ensures product quality by stating comprehensive business process specifications that contribute indirectly or directly to the production process. These include requirements for the documentation and transparency of processes as well as the qualifications of staff, quality controls of methods, procedures, tools, incorporation of stakeholder feedback as well as quality-driven management.

In the context of BfR, the term “products” in the sense of the DIN standard especially applies to science-based risk assessments of health hazards arising from food, consumer goods, products and substances (chemicals). Assessments are based on internationally recognised scientific assessment criteria. They are communicated in the form of reports and opinions or, in the case of authorisation procedures in which BfR is involved, are included in authorisation notices.

Quality objectives, responsibilities and competencies for processes at the Institute as well as fundamental conditions are documented in a quality management manual. Individual activities and tasks are defined in standard operating procedures (SOPs). The same applies to

corresponding management and support processes. Quality management representatives (QMRs) appointed in all sections ensure that changes and problems in individual processes are recognised quickly, and that SOPs are adjusted accordingly if necessary.

This warrants that especially the preparation of science-based risk assessments and the processes that lead up to a result remain generally transparent and can be critically reflected upon at any time.

With its henceforth certified QMS, BfR ensures that its in-house human and technical resources are applied as optimally as possible. Areas of responsibility are clearly defined; potential weaknesses in process organisation can be recognised and remedied more rapidly.

At the same time, existing BfR expertise is secured through the documentation of operational and decision-making processes and remains accessible once members of the staff as the keepers of expertise leave the Institute. The constant review of existing expertise as specified through the QMS also serves to promptly identify gaps in knowledge and generate new knowledge by initiating enquiries accordingly.

BfR quality policy is aimed at the following objectives: securing the highest possible quality of scientific research results; orientation on consumer protection; sustaining scientific independence; securing cost-effective performance; securing future stability through anticipatory planning and flexibility. Special care is taken to critically evaluate and review all results before they are released to the public or the enquiring institution. BfR uses confirmed data and verified and validated methods and models in accordance with the highest national and international standards. It discloses the limits and uncertainties of its results.

As part of the certification process, TÜV Nord in detail evaluated whether BfR processes and activities in the QMS are adequately mapped and documented. One or more random checks in all sections served to evaluate if processes were carried out according to SOPs, and whether the corresponding management and support processes function. Upon completion of the certification procedure, BfR was presented with a certification document.