BAM
Bundesanstalt für
Materialforschung
und -prüfung

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# Management Handbook of BAM

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# 1 Bundesanstalt für Materialforschung und -prüfung (BAM)

## 1.1 Description

The Bundesanstalt für Materialforschung und -prüfung (BAM) is a senior scientific and technical Federal Institute with responsibility to the Federal Ministry for Economic Affairs and Climate Action (BMWK). We test, research, and advise on the protection of people, the environment, and material goods. Our legal status and tasks result from the Decree on BAM as well as the Legal Bases.

In performing our tasks, we pursue the goal of ensuring and further developing safety in the fields of technology and chemistry. We have defined this goal more clearly in our Mission Statement.

Our key target groups are:

- Federal ministries, the European Commission, and international organizations
- Trade associations, industrial companies, especially small and medium-sized enterprises
- Universities, non-university research institutions, scientific organizations, scientific associations
- Standardization bodies and rule-making institutions
- Authorities, courts, and statutory bodies
- Consumer organizations

Our employees find themselves with their tasks in the three sight axes of BAM (see Fig. 1): customer perspective (business fields), professional perspective (focus areas), and organizational perspective (organization).

In the customer perspective, we have described the services we provide in four Business Fields: Research and Development, Sovereign and Public Services, Scientific and Technical Services, and Knowledge and Technology Transfer. The business fields structure our diverse services and make it possible to describe the nature of our widely differentiated service provision in terms of products.

Research and development are a key focus here. As an instrument of research planning, our Research Program serves as a link between strategy development and implementation. It provides an overview of current research work and sets the framework for future research tasks. Science is based on honesty, which is one of the essential principles of good scientific practice. BAM and its employees are therefore committed to adhering to Good Scientific Practice.

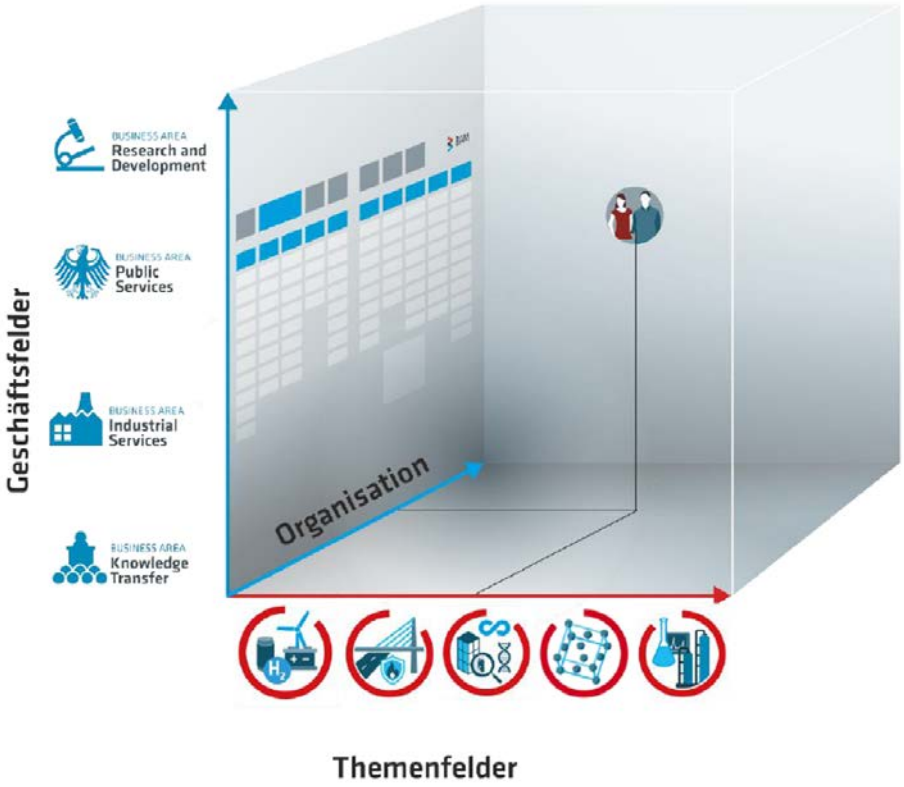


Fig. 1: The three sight axes of BAM

The technical perspective of our work includes the five cross-departmental Focus Areas: Energy, Infrastructure, Environment, Materials, and Chemistry and process engineering. They are of essential importance for BAM's research and are both drivers for innovations and the basis for new products, processes, and services. As thematic platforms, the five focus areas structure our work. At the same time, they serve to make BAM's contribution to politically, socially, and scientifically important topics visible. The focus areas are underpinned by fields of activity and subject tasks.

From an organizational perspective, BAM is divided into Departments and Divisions or Sections. This is shown in an Organizational Chart. BAM is headed by the President, who is supported in his tasks by the Board of Directors. Details are laid down in a Business Distribution Plan.

## 1.2 Impartiality

We are committed to providing all our services in an objective, transparent and impartial manner. The Rules on Integrity of the Federal Ministry of the Interior form the basis for our internal rules.

Regulations on corruption prevention and sponsoring have been established. Corruption prevention and sponsorship officers have been appointed to support the management.

The Internal Audit Unit supports the President in his obligation to ensure regularity and legality as well as efficiency in all business processes.

External persons are employed within BAM only in compliance with the regulations as set out in the "General Administrative Regulation on the Use of Persons Not Employed in the Public Service (External Persons) in the Federal Administration of July 17, 2008".

Our employees declare their compliance with BAM's External Funding Code as part of the application process for externally funded R&D projects, according to the External Funding Guideline.

Our employees are obligated to disclose any conflicts of interest, e.g., due to relationship, membership, or cooperation. They are sensitized to act with integrity by their superiors during their induction and in regular briefings, following their functions and relationships within the framework of service provision.

Impartiality is an integral part of the risk assessment following BAM's Risk Policy.

## 1.3 Independence

As a Federal Higher Authority, we receive our basic funding from the federal budget and are therefore economically independent. Earnings of scientific and technical services are transferred according to budgetary regulations. BAM is subject to financial control of the Bundesrechnungshof (Financial Audit Office).

Our employees provide their services free from undue internal and external commercial, financial, and other influences.

## 1.4 Confidentiality

We ensure that information and data of customers or third parties, which are dealt with in the course of our service provision, are handled confidentially and securely. Precautions have been taken within the organization to counteract any loss or misuse of data.

Regulations on data privacy, IT security, and the handling of facts requiring secrecy in the public interest (classified information) are in place. Officers for data protection, IT security, and protection against the disclosure of confidential information and sabotage have been appointed to support the management.

If confidential information is exchanged with third parties in research projects, the aim is to conclude a Non-Disclosure Agreement.

In the case of services based on a contract, these contain confidentiality agreements with the customer.

Our employees are bound by their duty of professional secrecy following § 61 BBG (Official secrecy), § 3 (1) TVöD (Official duty of confidentiality), and § 353 b StGB (Violation of official secrecy). They are sensitized to the topic of confidentiality by their superiors as part of their induction and in regular briefings.

# 2 BAM QM System

## 2.1 Quality mission statement

The basis of our QM system is the Quality Mission Statement, which defines our strategic quality objectives. All employees are obligated to act in accordance with these principles.

## 2.2 Control

The President, together with the Board of Directors, determines BAM's strategic quality objectives as outlined in the Quality Mission Statement. To support him, he appoints the Quality Management Representative of BAM (QMB-BAM) and sets up the Quality Management Committee (AQM).

The Quality Management Representative of BAM (QMB-BAM) is responsible for the further development of the QM system. Their tasks include the management of the AQM, the revision of the central QM documentation, advising the President, the Board of Directors, and the Departments, the training of the employees as well as the external representation of the QM system. The QMB-BAM is supported in their tasks by employees in the central QM team.

The Quality Management Committee (AQM) is composed of the chair, manager, and the quality management representatives of the Departments. The chair is appointed by the President. The AQM supports the Board of Directors in implementing the quality mission statement, develops central QM documents and processes, and serves as an exchange between the Departments on QM issues. The minutes of the AQM are published.

The heads of the Departments, Divisions, and Sections are responsible for the implementation and application of the QM system in their working areas and the associated proper and safe execution of the processes. They ensure that the necessary resources are made available and that employees are competent and familiar with the processes and standard operating procedures relevant to them. To support them, the managements appoint QM Representatives for the Departments and Divisions. These representatives can be dismissed informally.

The QM representatives of the Departments are responsible for the further development and ongoing support of the QM system in their Departments as well as for updating the Departments' QM documentation. They are the central contact persons for QM relevant issues both for their management and the other employees. The QM representatives of the Departments manage those working groups of the Departments in which the exchange with the QM representatives of the Divisions is ensured. Their further tasks result from the QM processes.

The QM representatives of the Divisions support the work of the QM representative of the Department and perform individual tasks of theirs as required. An overview of the Quality Management Representatives is published.

All employees are responsible for the quality of their work and at the same time are required to observe and apply the specifications of the quality management system and to actively participate in its further development.

### 2.3 QM documentation

The aim of the QM documentation is to describe our QM system and make it transparent, to clearly define tasks and competencies, to present work processes in a logical sequence, to define interfaces and clearly delineate responsibilities at the interfaces, to ensure traceability and reproducibility in all work steps, and to document scientific, technical, and administrative knowledge. It is created and maintained in the levels shown in Figure 2.

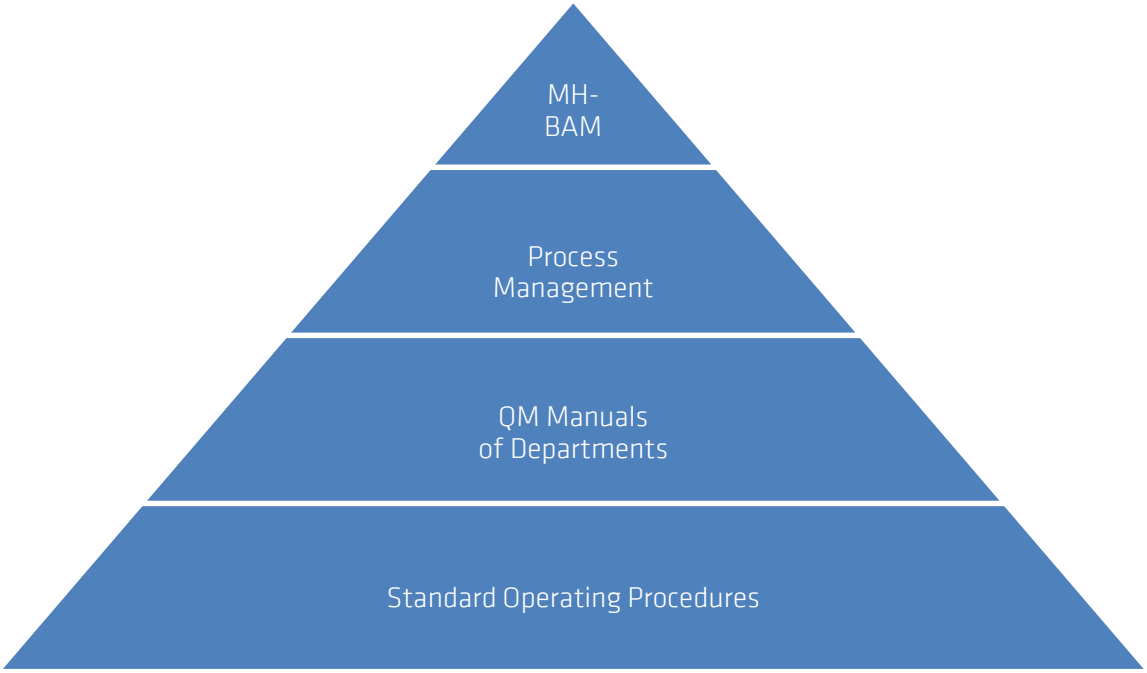


Fig. 2: QM documentation of BAM

The control of QM documentation is regulated in a process. Document Templates are available for a uniform appearance. The QM documents are clearly identified and reviewed regularly, at least annually, and updated as necessary. Changes to QM documents can be identified appropriately. Outdated documents are marked "invalid".

The Management Handbook (MH-BAM) includes the basic regulations of our QM system. It is available to the employees together with its Guidelines and Forms. They have a binding character regulating the entire organization. The QM Guidelines and Forms are released by the chair of AQM.

BAM's process management is governed by an In-house Regulation. Our management, core, and support processes are shown in a process map (Fig. 3). It is accessible to all employees via the BIC Portal. A Process for handling processes is published.

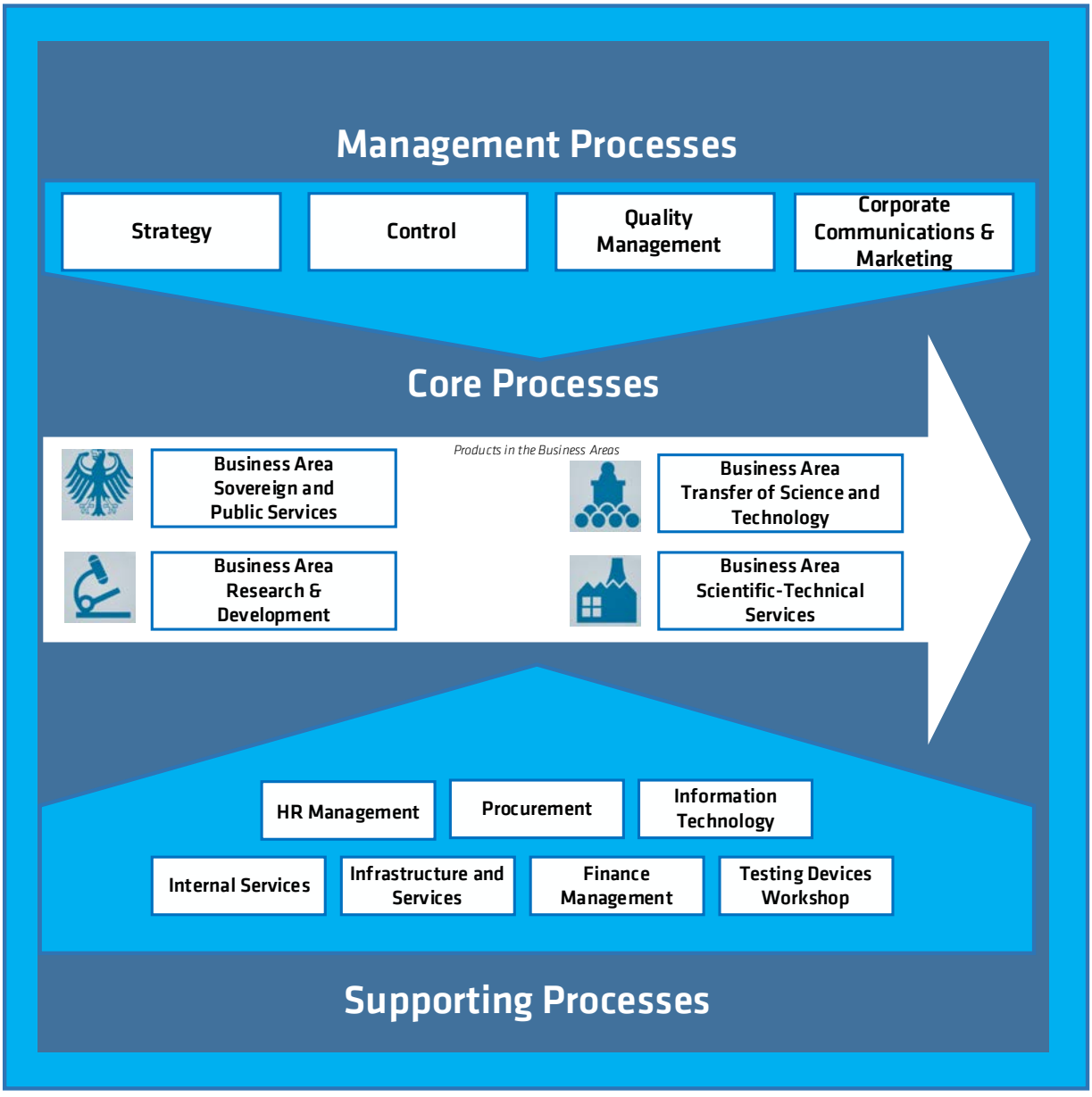


Fig. 3 BAM process map

Regulations on specific requirements that are placed on the services of the Departments and that go beyond the regulations of the MH-BAM or process management are documented in the Departments' QM Handbooks. These are released by the heads of the Departments.

Standard Operating Procedures (SOPs) describe the performance of recurring activities, such as the performance of tests or the handling of test equipment. Overviews of available SOPs are provided in the Departments' QM documentation by the QM Representatives (QMB).

The QM documentation is mapped and maintained in the document management system E-Akte in an audit-proof manner. All employees who have a role in the QM system are given write access within their area of responsibility, and all other employees are given read access. The release regulations are implemented in electronic workflows. Further regulations are set out in the guideline "Document control in the E-Akte".

There is a process in place to ensure that BAM is informed about the laws and regulations to be observed. This provides for the maintenance of overviews of the relevant regulations and an annual update check as part of the management review.

The e-Norm system is available for obtaining and monitoring the up-to-dateness of standards and informs employees of any changes. If new versions of standards are published, the Department or Section checks whether the procedures in place are affected by these changes. A documented evidence is created for the comparison and acted upon according to the process for Release of Standards. The employees affected are informed about the relevant changes.

## 2.4 Internal audits

The aim of internal audits is to check compliance with requirements in a systematic manner and to record errors and possible mistakes to avoid them in the future. With their help, the strengths and potentials of the organization can be identified, and improvements can be stimulated.

The central QM team prepares an audit program that defines the internal audits for the current year. BAM's Audit Program takes into account the main services of BAM and the requirements placed on these services (e. g. Good Scientific Practice or ISO/IEC 17025).

Internal audits are conducted by qualified internal auditors. They conduct audits in all Departments of BAM according to their professional expertise, thus stimulating the interdisciplinary exchange.

The procedure for conducting internal audits is defined in a Process.

## 2.5 External assessments

Wherever it is necessary for our tasks, if customer requirements exist, or if it seems sensible to build trust, we use external assessments.

As a departmental research organization, BAM is evaluated for its R&D operations by the German Science and Humanities Council.

For our industrial services, we use an accreditation performed by the German Accreditation Body (DAkkS). For this purpose, we have published the process „DAkkS Assessment". The technical management of our accredited testing laboratories is carried out by the responsible department heads. The implementation of requirements resulting from the accreditation is realised by the responsible managers.

For further services, the fulfillment of further requirements is supervised externally, e.g. the supervision of administrative actions.

Regular peer reviews and re-evaluations are carried out by EURAMET within the framework of the Mutual Recognition Agreement between national metrology institutes (CIPM-MRA). Further details can be found in the QM Guide „Metrological State Tasks of BAM".

The Attestations of Competence are published on our website.

## 2.6 Correction management

In dealing with nonconformities and errors, we strive for an open error culture. Nonconformities obtained from internal and external audits, complaints, and internal errors are collated and documented in centrally kept collective lists in the frame of the Correction Management process. In addition, the Corrective Action Sheet can be used for documentation.

## 2.7 Management review

Each technical Department conducts an annual Management Review. The heads of the Departments are supported by the Departments' QM representatives. The Heads of Departments and Divisions evaluate the status, appropriateness, and effectiveness of the QM

system in terms of the fulfillment of requirements and operational quality objectives, as well as the implementation of measures and opportunities for improving the QM system. New operational quality objectives are defined, measures are scheduled, and responsibilities are defined.

Departments 'risks and opportunities are also recorded and updated as part of the management review. Risks are assessed following BAM's Risk Guideline.

BAM's QM representative is responsible for the annual presentation on the status, adequacy, and effectiveness of the QM system to the Board of Directors. The Presentation is based on the reports from the Departments collated in the so-called Q-Report, which provides information on the achievement of quality objectives, innovations in the QM system, the conductance and results of internal audits and external assessments, customer feedback, and QM events. The Board of Directors evaluates the Q-Report and sets new operational quality objectives.

The procedure for conducting the management review is shown in a process.

## 2.8 Internal communication

We maintain an open communication culture. This takes place at all and across all levels. Various communication channels and media are used for this purpose.

Extensive information about the organization, the rules and regulations, and central projects of BAM are published in the Infoportal. Employees regularly use the Infoportal to find out about new developments at the institute.

Regular exchanges take place at various levels on specialist topics and quality management. The relevant contents are documented and made available to all employees. This ensures that all employees receive the information they need to perform their tasks.

# 3 Resource Requirements

## 3.1 Personnel

In order to live up with the diverse and demanding tasks of safety in technology and chemistry, we ensure the competence and qualification of our employees.

Requirements for the competence and qualification of employees are documented for defined roles within the process management and for specific technical requirements in the Standard Operating Procedures. All requirements flow into the personnel recruitment process described in the „Personnel Recruitment Process“. Personnel is selected in accordance with the guideline „Personnel Recruitment Process“.

The induction of new employees into the organizational and technical principles of working at BAM is based on the Induction Plan and described in a Process. The induction by experienced employees is a basis for good scientific work.

The regulations for the supervision of young scientists pursuing a doctorate are laid down in the Framework for PhD students of BAM and their supervisors. This stipulates the conclusion of a supervision agreement.

Upon completion of the induction process, the employee fulfills the competence requirements for the activities to be performed. The direct superior confirms the fulfillment in the induction plan and assigns and communicates the corresponding responsibilities and authorities to the employee.

The Departments maintain overviews showing the transfer of responsibilities.

Qualification measures are part of the individual professional development and are made possible for employees in dependence on the annual allocations. In the Annual Meeting for Employees, the need for qualification is recorded and transferred to the Qualification Lists.

To implement the qualification measures, BAM makes use of internal and external expert offers. Participation in training courses is documented and evaluated. Evidence of participation in qualification measures is handled in accordance with the procedural instructions for qualification measures.

Where necessary, management uses Personnel Competence Sheets to monitor the competence of personnel and document corresponding evidence, when new responsibilities and authorities are transferred to an employee, especially concerning the products „Testing/Analysis“,

„Calibration“, and „Reference Materials“. Personnel Competence Sheets are updated annually. Role-specific authorities are documented within the process management.

When an employee leaves BAM, the superior ensures that knowledge is secured and transferred with the help of the Knowledge Transfer Guideline. The transfer of knowledge is regulated in a Process.

Before an employee leaves, superiors are provided with a Checklist containing requirements for retaining knowledge and ensuring the traceability of data and records. Details are governed by a Process.

Further personnel management instruments are described in the Personnel Development Concept.

### 3.2 Premises and environmental conditions

Activities are carried out in premises with appropriate environmental conditions. It is ensured that results are not distorted or adversely affected in their quality. Effective separation is provided between areas where incompatible activities are performed. Where necessary, relevant influencing factors are monitored, regulated, and recorded. Such requirements are documented in the Standard Operating Procedures.

Access Regulations for the different areas of BAM are documented. In this context, all measures are considered which come into play in the case of confidentiality agreements.

The legal requirements covering Occupational Health and Safety are taken into account.

Room lists can be viewed by superiors and Department secretariats in IMSWARE.GO!. Location and Access Maps for all BAM sites are published.

The regulations of the QM system also apply if services are provided at locations or premises outside BAM.

### 3.3 Test and measurement equipment

To provide our services, test and measurement equipment shall be used that is suitable for the proper performance of the intended applications. They achieve the required measurement accuracy or uncertainty, thus meeting the specifications relevant to the applications concerned.

The facilities are supervised by equipment responsibles, who provide documented instructions for the users. For the proper use of the other facilities the employees inform themselves through current instructions for use and maintenance. All test and measurement equipment are therefore only operated by competent personnel.

Before they are used, test and measurement equipment are checked for their functionality. The use and handling of the equipment is documented in the lab and equipment books.

We ensure the metrological traceability through a documented, unbroken chain of calibrations, if the characteristic values have a significant influence on the test and measurement results. Whenever possible, traceability is to the International System of Units (SI). Calibrations can be performed internally or externally by competent suppliers. The requirements to be taken into account are documented in the Guide Metrological Traceability. Required intermediate checks to maintain confidence in the calibrations are performed out according to documented procedures.

Test and measurement equipment are clearly marked. Their hardware and software are secured against changes to the settings that could falsify the results. Test and measurement equipment shall have records in an equipment folder containing, as a minimum, the information specified in para. 6.4.13 of ISO/IEC 17025:2017.

Test or measurement equipment that operates incorrectly or provides questionable results is immediately taken out of service upon discovery and marked as unusable. Possible effects on previous investigations are dealt with using the Corrective Action Management process. Only when documented evidence has been provided that the equipment is producing satisfactory results it will be returned to service.

Test or measurement equipment which is developed at BAM and built up for permanent use of generally more than 3 years complies with the regulations of the Product Safety Act. Depending on the type of test or measurement equipment, a declaration of conformity based on other EU Directives (Machinery Directive, Pressure Equipment Directive, Low-Voltage Directive, etc.) may be issued. Further information can be found in the document „Construction of Scientific Instruments – Machinery Directive“. Information is available from Division 9.2 Testing Devices and Equipment.

In cases where Divisions use test or measurement equipment that are not under their constant control, it is ensured that the requirements described here are met.

Each Department maintains an overview of available equipment in their QM documentation. The overview is maintained by the respective QM representative.

## 3.4 Externally provided products and services

Specific requirements for products and services that have an influence on the test and measurement results are defined in the Standard Operating Procedures (SOPs). They are based on the competence and experience of the employees and are fit for purpose. The selection and evaluation criteria are included in the performance specification of the purchase order application.

The procurement of products and services is subject to national and European procurement legislation as well as BAM's Internal Procurement Rules. The procurement office's procedure is documented in the Procurement process.

A suitability assessment of the suppliers is carried out by the procurement office in accordance with the Procurement Ordinance (VgV), the Act against Restraints of Competition (GwB), and the Federal Budget Code (BHO). Due to procurement law, no supplier rating list shall be maintained. Concerning adherence to deadlines and diligence, the procurement office monitors suppliers and takes action in the event of overruns.

When subcontracting services, it is ensured and can be demonstrated that the subcontractors have the necessary expertise and meet the requirements placed on the service provision (e.g. compliance with the requirements for testing and calibration as specified in ISO/IEC 17025:2017). These requirements are also taken into account when subcontracting internally via the Subcontract form.

The Divisions inform the procurement office about the receipt and quality of the delivered products and services. In the positive case, the delivery bill is marked „Goods properly received" and forwarded to the procurement office.

The quality of the products and services is monitored and evaluated by appropriate quality assurance measures. Records of the implementation of these measures are kept in the laboratory or equipment books.

If quality deficiencies are found, the product is marked and handled in such a way that its further use is excluded. The Division informs the procurement office that acts in accordance with contract law.

# 4 Product Requirements

## 4.1 Customer focus

We strive to meet the requirements and expectations that our stakeholders place on our services. We, therefore, work closely with our customers as part of the service delivery process.

Through regular exchanges with the Federal Ministry for Economic Affairs and Climate Action (BMWK), the Advisory Council, and the Scientific Advisory Boards, we receive feedback from our stakeholders in science, business, politics, and society and can thus respond to their expectations in our strategic orientation.

Further requirements are determined in the form of Customer Surveys or customer discussions. Negative customer feedback is responded to professionally after an internal review.

The handling of complaints and appeals is presented in a Process that is made available to customers as required. Text Modules are available to employees for communication in complaint situations.

BAM's Rules of Procedures set out further regulations on communication and cooperation with customers and authorities.

## 4.2 BAM services

Our services are presented in a systemized form derived from the Decree on BAM, which is divided into three levels: Business Fields, Product Groups, and Products (Fig. 4). Each product is presented in the Process Map as a core process.

All Divisions and Sections maintain an overview of the services they currently offer, e.g. in the form of the list of Standard Operating Procedures.

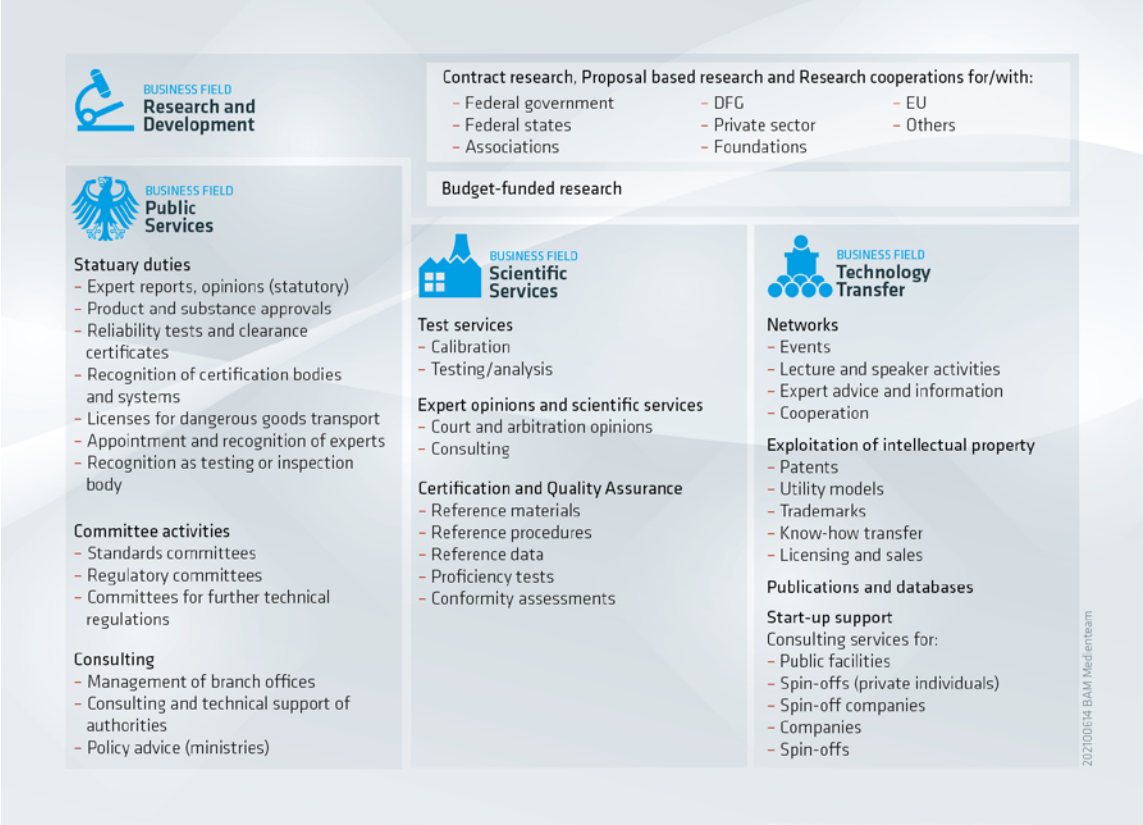


Fig. 4: BAM services

## 4.3 Research and development

Research and development form the basis for our scientific-technical, sovereign, and public services. This includes basic and applied research as well as the development of new products and processes.

Our research and development work is subject to the Code to ensure the Scientific Integrity of BAM which refers to the Code of the German Research Foundation (DFG) with the Guidelines for Safeguarding Good Scientific Practice. We have supplemented the BAM Code with a Data Policy, Open Access Policy and Open Source Policy.

Two ombudspersons of BAM have been named. They can be contacted in all questions of good scientific practice and in suspected cases of scientific misconduct. The handling of scientific misconduct is published in a process.

## 4.4 Sovereign and public services

Sovereign and public services are tasks assigned by law. This includes approvals and authorizations as well as policy advice and participation in national and international committees, especially for rule-making and standardization. All committee activities with an external effect are entered in the GRETAE database.

Our approval, certification, and expert activities are based on international conventions and standards, European directives, and national law.

Procedures and regulations for the implementation of sovereign and public services are published in the BIC portal or in the QM documentation of the responsible departments and in the organizational handbook (OHB).

## 4.5 Scientific and technical services

Scientific and technical services are remunerated services we offer based on proven knowledge and methods. In addition to performing tests and analyses and the preparation of expert reports, we also contribute to quality assurance through conformity assessments and the provision of reference materials, reference procedures, and reference data.

In this business field, we comply with the requirements set out in the international ISO 17000 series of standards. This concerns ISO/IEC 17025:2017 for testing and calibration activities, ISO 17034:2016 for the production of reference materials, ISO/IEC 17020:2012 for activities as an inspection body, and ISO/IEC 17065:2012 for activities as a certification body.

Procedures for the provision of our scientific and technical services are documented in the corresponding core processes in the BIC portal or in the QM documentation of the responsible departments.

## 4.6 Knowledge and technology transfer

Through knowledge and technology transfer, we make our findings and work results available to industry and the general public. The transfer takes place via various channels such as the licensing of patents or providing knowledge and expert platforms. A description of the transfer channels and transfer products can be found in the Transfer@BAM guidelines.

## 4.7 Quality assurance

The quality assurance measures listed below are used for a large part of our services.

Test and measurement procedures applied or developed in the context of service provision are suitable for their intended purpose and generate valid data. This is evidenced by a description of the procedure (project documents, publication, standard operating procedures) and further documented evidence. The Guideline "Verification and Validation" supports the implementation of the topics.

Suitable quality assurance measures are selected and implemented for all test and measurement procedures. The results are checked for plausibility. The Guideline "Quality Assurance Measures" describes the most common methods.

Measurement results are traceable to a reference, preferably the International System of Units (SI). The Guideline "Metrological Traceability" describes how metrological traceability is ensured.

Evaluations and interpretations of the results are carried out according to the state of the art and take into account the measurement uncertainty. In research and development, this is part of our scientific self-understanding. Procedures for deriving measurement uncertainties are presented in the Guideline "Determination of Measurement uncertainties".

In the QM Toolbox, we have compiled further tips and links on these topics.

## 4.8 Publication of results

For the publication of research results, we use different refereed and non-refereed forms of publication, presentations, and research data sets. Our library provides hints for publishing. The Open Access Policy applies. All publications are published in the Publica database.

Results reports for scientific and technical services as well as for sovereign and public services are created based on central templates that are kept in BAM's corporate design (BAM-CD). They are suitable for shipment in paper form as well as for electronic shipment.

## 4.9 Signing and sealing

The signing of letters to customers and authorities is regulated in BAM's Rules of Procedure. Moreover applies, unless otherwise specified in processes:

Order processing letters are signed by the responsible employee involved. Results reports are signed on the right by the responsible employee involved and on the left by the responsible manager. In the absence of authorized signatories, a substitute is named in the QM documentation.

The „Regulation on Electronic Signing of Documents“ applies to the signing of electronic documents.

Documents are sealed following the Official Seal Guideline.

### 4.10 Records and data

We ensure that records are kept for all relevant activities that lead to the provision of services or serve to ensure the QM system. These records contain sufficient information to make it as easy as possible to identify factors that affect results and to allow repetition under the documented conditions. Original observations, data, and calculations are recorded at the time they are made and attributed to the specific task. Records include the date and identity of the individuals responsible for each activity and result.

For research work, records are documented in a lab-book.

Changes to records can be traced back to previous versions or original observations. Both the original and modified data and files are retained, along with the date of the modification, an indication of what was modified, and the person responsible for the modification.

All employees who generate data are responsible for backing up this data. The basis for this is the Data Backup Concept.

The structure of the data folder is designed logically and in a way that is comprehensible to third parties. After completion of the processes, the data folders are backed up in such a way that they are protected against unintentional modification. In addition, documentation is kept which allows clear assignment of the respective raw data to the corresponding metadata and samples.

All those involved in the process, including the superior, have access to the data folders. Access by unauthorized persons is precluded, especially in the case of data requiring protection (e.g., General Data Protection Regulation [DSGVO] or non-disclosure agreements).

In principle, the Guidelines for electronic document management apply to the processing of business transactions

For research work, the BAM Data Policy applies, which defines the handling of research data within BAM and in cooperation with partners. The Data Policy is supported by further recommendations for action.

### 4.11 Software handling

Self-developed or modified software, templates or macros are validated before they are used. The aim of validation is to prove that the software works without errors. The procedure is described in a process. Commercial software that is used in its intended area of application is considered to be sufficiently validated.

As part of BAM's Open Source Strategy, the extent to which software created in-house can be made available to the general public is examined, provided there are no legal obligations or reasonable grounds to the contrary.

### 4.12 Archiving

All records and data created in connection with the provision of services and the QM system are kept for at least 10 years. Longer periods may result from legal or contractual requirements.

The provisions of the Data protection management system are taken into account.

Archived records and data are indexed to allow for proper retention and quick retrieval. They are annotated with the specified retention period, protected from unauthorized access, secured against tampering and loss, and stored in an environment that ensures their preservation during the retention period.

Sample materials are stored under comparable requirements, considering their stability and shelf life.

# 5 Applicable Documents

- QM Guidelines
- QM Forms
- Glossary

# 6 Amendments

| Date | Amendment |
|---|---|
| April 2021 | Transfer of the MH-BAM into its new structure as well as into QM and core processes in the process tool BIC portal |
| April 2022 | References to new regulations of the organization handbook (R&D policies, data protection, document management), update in sections 3.3 and 4.7, editorial adjustments |
| April 2023 | Additions and changes in Sections 1.3 Independence, 2.4 Internal Audits, 2.5 External Assessments, 4.3 Research and Development and 4.8 Publication of Results; plus editorial adjustments |
| June 2024 | Additions and amendments to sections 2.3 QM documentation (QM documentation process, E-Akte guideline, laws and regulations process), 2.5 External assessments (management of accredited bodies) and 4.11 Handling of software (software validation); editorial adjustments |