European Association of
Research and Technology Organisations

GENERAL GUIDELINES FOR

THE OPERATION OF RESEARCH AND

TECHNOLOGY ORGANISATIONS

EARTO

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GENERAL GUIDELINES FOR THE OPERATION OF RESEARCH AND TECHNOLOGY ORGANISATIONS

Contents

FOREWORD

Aim

These guidelines should be used as an aide-mémoire from which research and technology organisations (RTOs) can select and reformulate the requirements that are relevant to their operations. It is important to realise that every RTO has an individual profile, scope and operational strategy. Consequently this document has no mandatory status. The document should also be seen in a larger perspective in which the RTOs can try to improve their services to their clients as well as their competitiveness. The principles of continuous improvement, effective management, benchmarking and assessment are elements that RTOs have to tackle. The European Association of Research and Technology Organisations (EARTO) is also addressing all these issues with the aim of giving further guidance for RTOs.

Certain RTOs may want to accredit or certify part of, or the entire operation. This document is not intended to be used for accreditation or certification purposes, although many clauses could be used after necessary rewording. This document is a proactive approach by EARTO to state the RTOs' views on the practical work.

Background

There is a general trend towards a more systematic approach regarding quality assurance and conformity assessment operations. This can be seen from the widespread use of the ISO 9000 series, especially in industry. Third-party assessment of the compliance of quality systems and products to relevant standards is made through a certification process.

Testing, including measurements and chemical analyses as well as calibration, are covered by a new standard, ISO/IEC 17025 which has greatly influenced some of the sections in this document. The assessment of technical competence is made through an accreditation process, which also encompasses the quality system for the testing and calibration operations.

The OECD has developed the principles of good laboratory practice (GLP) for the non-clinical safety testing of items contained in, for example, pharmaceutical products, pesticide products, cosmetics products, veterinary drugs, food additives, feed additives and industrial chemicals. The GLP practice focuses on the quality of non-clinical health and environmental safety studies.

There are some national standards applicable to basic and applied research, e.g., NEN 3417 in the Netherlands and ANSI Z1.13 and DE92-016352 in the USA. In addition, accreditation bodies have issued criteria to be used when accrediting organisations that perform research and development work. There is also much public literature available providing guidance on the operation of research organisations.

Sectorial organisations have also developed their own rules and guidelines for their members. For example, Eurachem and CITAC have prepared a comprehensive document on quality assurance for research and non-routine chemical analysis. Some paragraphs in the following text have been borrowed from that document.

EARTO members possess long experience and comprehensive documentation of the processes related to their research activities. General terms of contract, model contracts, project guides, quality manuals, technical procedures, administrative rules, etc. exist in many RTOs. EACRO published a Code of Conduct in 1992.

All the above-mentioned documents have been used in collecting the contents for these general guidelines and the main emphasis has been on industrial and applied research.

RTOs, their clients and the public sector all have an interest in developing the operations of RTOs. One aim of the present work is to promote confidence in the RTOs' operations and to facilitate co-operation between the RTO and its clients. Certain industrial and public clients prescribe in great detail the way the RTO should operate, whereas others do not place any requirements or constraints on the operations. Although the market will dominate the development, there is already a trend towards a more systematic assessment of the competence of RTOs.

In the present guidelines the word 'project' has been used for all types of assignments, i.e. both large multidisciplinary tasks as well as small, straightforward measurements.

Contents

The general guidelines have been divided into five sections:

Section 1 outlines the code of conduct for RTOs as well as some ethical issues.

In Section 2 contractual and legal aspects are discussed. Contractual procedures and intellectual property rights are the focal points.

Section 3 outlines the issues related to the quality system. It covers the quality management, organisation, documentation and information control, sub-contracting, procurement, client relationship, non-conforming work, corrective and preventive actions, control of records, etc.

Section 4 on technical capabilities deals with questions related to the competence of personnel, facilities, experimental methods, equipment, measurement traceability, sampling, handling of research items, etc.

Finally, in Section 5 the project management and professional judgement issues are described. The responsibility for quality in particular in project work and in the reporting of results is discussed.

Key words have been written in bold characters in the text.

Summary

This document establishes the general guidelines a research and technology organisation (RTO) should follow in its practical work. It covers all types of research using methodologies that have been published, methodologies that an RTO uses and methodologies that it has to develop. The guidelines are applicable to all research organisations regardless of the number of personnel or the extent of the scope of the activities.

It is recognised that several of the clauses may not apply to all RTOs. Each RTO should comply with those clauses that enable it to perform the intended research in a competent and effective way. It is the responsibility of the RTO to carry out its activities in such a way as to satisfy the needs of the clients irrespective of the guidance given in this document. It is also the responsibility of the RTO to comply with the relevant regulatory health and safety legislation and requirements. The RTO shall also minimise the risk it may cause to personnel and the environment, as well as handle and dispose of hazardous, toxic and dangerous substances and wastes in a safe way, etc. These requirements are, however, outside the scope of this document.

Section 1: CODE OF CONDUCT

The RTO should impose **behaviour rules** upon relationships with clients and also observe particular fairness, social and environmental values in carrying out its assignments. Whenever **ethic codes** cover all or parts of the RTO's operations, the RTO shall follow the procedures laid out in these codes.

The RTO must abide by behaviour rules that leave necessary freedom of action, permit **free market competition** and impose bonds of propriety and uprightness of conduct.

No discredit or blame should be put on competitors nor improper use be made of the information regarding them. Rather than emphasising the "weak" points or stressing the unfair or poor performances of competitors, ethics suggest educating the market to distinguish, by itself, between reliable and unreliable RTOs.

RTOs must apply fair **employment rules** to their employees to avoid any kind of discrimination. RTO employees must be rendered proud of their organisation and their creative attitude and capabilities must be encouraged and valued.

The RTO shall continuously strive to **improve the quality** of its activities. Different approaches, such as **total quality management**, **benchmarking,** etc. can be used for continuous quality improvement. The process is a continuous interaction between top-down activities (e.g., RTO policies) and bottom-up approaches and the experience gained from performed projects.

RTOs shall abide by **good scientific practice**. Fabrication and/or falsification of results as well as plagiarism are unacceptable. Citation without clearly revealing the source shall not be done. If found and/or misconduct is observed or presumed, the RTO must take prompt actions to resolve the problem and implement disciplinary actions when needed.

The RTO shall have a policy on how to deal with projects involving great risks to humans, flora and fauna and the environment. The RTO shall especially define how to deal with issues endangering human life and/or in grave contradiction to legislation. An area, in which special precautions might be needed, is gene technology. The RTO should have a clear policy on how to deal with genetically modified organisms (GMOs) observing current legislation and societal values.

The RTO should also have a policy how to handle **environmental issues**. It is recommendable to follow the **principles of sustainable development** and to establish a programme to diminish the use of resources and the impact on the environment.
In order to achieve these objectives the RTO should, amongst other things

- strive to accomplish the research objectives with the lowest possible consumption of raw materials and energy and the lowest production of wastes and any kind of pollution;

- discuss in particular the consequences of the results, proposals and actions, direct or indirect, immediate or long-term, upon the health of people and social equity;

- study the environment that will be affected, assess the impacts that might arise, and select the best alternative for environmentally sound and sustainable development;

- promote a clear understanding of the actions required to restore and, if possible, to improve the environment that may de disturbed;

- reject any kind of commitment that involves unfair damage to human surroundings and nature.

The information given by the RTO shall be factual and relevant and not wilfully misleading or capable of misinterpretation. Advertising and promotion activities shall also be aligned with the above requirement.

2. CONTRACTUAL AND LEGAL ASPECT

An RTO shall take on board only such assignments for which it is adequately qualified to undertake and shall ensure that adequate resources are available to complete the work. Project work shall be carried out with appropriate professional expertise and scientific care. RTOs shall strive to produce scientifically and technically **sound results**.

RTOs shall exercise their best effort to define the **scope of R&D projects** with the client in order to identify the client's actual needs and fields of application. RTOs shall take particular care to clarify the client's needs in the case of SMEs or other clients not having experience in R&D work.

The RTO shall take necessary measures to ensure that there is a clear **mutual understanding** formulated in a contract between the client and the RTO. That contract shall, in addition to the technical contents, also cover financial arrangements, liabilities, ways to solve disputes, etc.

The RTO shall hold all client details strictly confidential unless they are already publicly released or the client gives specific permission for their release.

The RTO shall review its policies and procedures also from the point of view that it has to follow certain **contractual and legal rules** imposed by the RTO itself or agreed with the client. Such rules may relate to **confidentiality**, **secrecy arrangements**, **retention times,** etc. The RTO shall also bear in mind that certain documentation or information may be needed in the event of a dispute.

The RTO should define the rules that govern the client's rights to use the name of the RTO and the results of the project for **advertising purposes**.

The RTO shall use personnel with the required formal competence in activities covered by mandatory **competence requirements**. Such requirements exist in certain disciplines, e.g., non-destructive testing, welding, etc.

The RTO shall have a consistent **pricing policy** for all the work it performs. RTOs normally charge the clients at least the actual total cost of the project, except in special cases, which may include nationally or publicly funded projects, European Community programmes, development of the RTO's own capabilities etc.

In order to cover **liabilities**, the RTO should take necessary measures to cover them by insurance unless other arrangements are available.

2.1. Project contract

It is strongly recommended that the contract is a written agreement to provide a client with research, testing and/or calibration services. A contract can also be considered formed if the client accepts the RTO's tender or the RTO informs the client that it has accepted the client's specific request.

The RTO shall have **general terms of contract** and establish a **contract** with the client for all projects. The contract cannot be transferred to a third party unless the other party has

accepted the transfer. Any **modifications or additions to the contract** shall be agreed upon in writing between the contracting parties.

The RTO might find it useful to establish **model contracts** covering the major types of projects. For small or routine projects a simplified contract procedure should be used.

The RTO should have a procedure on how to maintain a predetermined **confidentiality level** for all the work carried out for its clients. If the degree of confidentiality is more stringent than usual, the measures required shall be defined in the contract or in a separate agreement. In addition, extraordinary activities related to the dissemination and exploitation of results shall be agreed upon in the contract.

The objective is that the projects shall be performed correctly at the first attempt in a cost-effective manner and that the results are applicable for exploitation as soon as possible. The RTO should

a) perform the project according to the scope, budget and timetable agreed upon in the contract;
b) give correct, reliable, concise and unambiguous results obtained from studies and investigations of appropriate depth and scope;
c) fully exploit multidisciplinary expertise when the project so requires.

The **deliverables,** including the content and format of the research report, should be specified as clearly as possible in the contract in order to avoid misunderstanding of the expected end result.

The RTO should be **liable** for carrying out the work as stipulated in the contract and for exercising reasonable skill, care and diligence. However, the RTO should be wary of **limiting its liability** appropriately in the contract. If not otherwise agreed, the liability should be limited to the price payable for the project. The RTO should avoid liability for indirect damage or consequential losses as well as product liability. Limitation should also be set related to the time aspect. It may be agreed that the **liability expires** after a certain period. A certain time limit should also be set for presenting **claims**.

Each **request**, **tender** and **contract** for research projects shall be reviewed by the RTO to ensure that:

a) the requirements, including the research methods to be used, are adequately defined, documented and understood;
b) the RTO has the capability and resources to meet the requirements; capability means that the RTO possesses the necessary physical, intellectual and information resources, and that the RTO's personnel have the skills, expertise and equipment necessary for the performance of the research project;
c) the contract is acceptable to the RTO and is in accordance with the original version(s) of the request and/or tender that was reviewed as in (a) and (b) above.

The request, tender and contract review should be conducted in a practical and efficient manner, and the financial, legal and time schedule aspects should be taken into account (see also Section 5.2). Any differences between the request or tender and the contract shall be

resolved before the work commences. For routine and other simple tasks the date and the initials of the person in the RTO responsible for the project are considered adequate for a request or contract review. For repetitive tasks, the review need only be made at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced research projects a more comprehensive review should be made.

Records of request, tender and contract reviews including any changes shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The review shall include any work that has to be sub-contracted by the RTO.

RTOs shall do their best to minimise the **risks of a mismatch** between clients' expectations or objectives and the final results of the research work. Taking into account technical and economic risks, the work programme for larger projects should be defined with intermediate checkpoints so as to allow the parties, especially in the case of unexpected results, to modify or discontinue the work according to relevant contractual terms.

There are always **technical risks in R&D activities**. The RTO must inform the client and especially SMEs that the project will not necessarily produce the anticipated results and safeguard itself against that possibility in the contract.

The RTO shall advise and seek the approval of the client in writing when it intends to **sub-contract specific parts** of the project to a third party, e.g., to another RTO or a testing and calibration laboratory. A written contract with the subcontractor defining the scope, tasks and responsibilities shall be established. The RTO is responsible for ensuring that the sub-contractor is competent.

If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

2.2 Intellectual property rights

In this document, **intellectual property** covers patents, copyrights, trade marks, utility models, designs and other similar statutory rights. Apart from the specific conditions dealing with **intellectual property rights** (IPR) established in the contracts with the client, the general principles laid down in this clause are meant to ensure the satisfactory handling of issues related to IPR.

The output of R&D activities performed for clients consists of general information (general knowledge) and specific information (results). The general information can be used freely by the RTO. The specific information should be dealt with so as to protect the client's relevant intellectual property rights. The documents received from the client as well as the reports, expositions and other results related to the project shall be the property of the client if not otherwise agreed.

When the client pays the full cost of the project, the intellectual property rights of specific information and the results obtained by an RTO in the frame of the R&D contract are

normally attributed to the client. In such a case the RTO should obtain a **non-exclusive free licence** for its own use.

When the client does not pay the full cost of the project (e.g., **jointly funded project**), the intellectual property rights of specific information and results as well as rights to inventions should be decided upon in the contract or in an additional agreement reached before finishing the project. In such a case, the client is normally awarded a non-exclusive licence to use the results within his own sector of activity.

The RTO may want to safeguard its **core technologies** so that they do not become the property of the client. In such cases, special clauses should be incorporated into the contract so that no misunderstanding between the client and the RTO arises.

When **background information** belonging to an RTO is used to start an R&D project for a client, the RTO is entitled to claim to be specifically rewarded for such a use.

In the event an RTO agrees with an industrial partner to jointly exploit the results of R&D projects performed by the RTO, an agreement defining the distribution of the costs and intellectual property rights shall be signed.

Software and design (e.g., layout of an integrated circuit) developed in connection with a project shall be the property of the RTO. However, if the aim was to develop, e.g., specific software, the client shall have all rights to the software. Rights and liabilities in respect of software and designs should be covered in more detail in the specific contract as the subject is difficult and may be a cause of conflict.

The RTO shall not have the right to give a third party the results of the project without written consent from the client. An RTO wishing to **publish results** and findings of purely scientific value must obtain the prior consent of the client to publish results and findings when obtained in the frame of the contract for the latter. When the RTO participates in the financing of the project, it could as a benefit of the project, for example, require in the contract that it has the right to publish the results.

The RTO shall, even after **termination or expiry of the contract**, keep confidential any confidential information and trade secrets obtained from its clients. The retention time shall preferably be agreed upon with the client, but if that is not done the recommended retention time is three years, unless national legislation or other arrangements impose other requirements.

RTOs can, in addition to the general secrecy requirements in the employment contract, require from their employees a special **commitment to secrecy** regarding information received from and produced for their clients. This requirement of secrecy should extend beyond the expiration or termination of the employment contract. The client can decide that the information related to the project will become public during the time the secrecy clause is operational. In such a case, the secrecy requirements imposed on the employees are considered to be terminated.

The client shall have the right to **inventions** generated as a direct result of a project. The inventor in the RTO shall notify his employer in writing of the invention. The RTO shall without delay notify the client in writing of the invention. The client shall notify the RTO in writing of his claim to the invention. The claim shall be made within a certain period from

the date the client came to know about the invention, or he may risk losing all his rights to the invention. The inventor shall always be accredited to have generated the invention and be entitled to a fair compensation. The costs for patent application and compensation for the inventor shall be paid by the party who has the right to the invention. The RTO must determine the timing and contents of the above actions in relation to the appropriate national legislation.

Section 3: MANAGEMENT REQUIREMENTS

The RTO shall be managed in an appropriate way and shall establish, implement and maintain a **quality system** appropriate to the scope of its activities. The RTO shall document its policies, procedures and instructions to the extent necessary to enable the RTO to assure the quality of the results it generates. The documentation used in the quality system shall be communicated to, available to, understood by, and implemented by the appropriate personnel.

3.1 Organisation

The RTO shall be legally identifiable. The RTO shall be organised and shall operate in such a way that it can carry out work adequately in its permanent facilities, at sites away from its permanent facilities, or in associated, temporary or mobile facilities.

The RTO shall have an **organisational chart** and define the tasks (responsibilities) of both permanently and temporarily employed staff.

The RTO shall

a) have managerial and technical personnel with the authority and resources needed to carry out their duties, to identify the occurrence of departures from the quality system and to initiate actions to prevent or minimise such departures;

b) have arrangements to ensure that its management and personnel are free from any undue internal or external commercial, financial and other pressures or influences that may adversely affect the quality of their work;

c) have policies to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define the organisation and management structure of the RTO and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work effecting the quality of the results;

g) provide adequate supervision of staff, including trainees by persons familiar with the research methods, experimental procedures and the assessment of the research results;

h) have technical management with the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of the RTO operations;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times. The **quality manager** shall have direct access to the highest level of management at which decisions are taken on the RTO's policies or resources;

j) appoint deputies for key managerial personnel. Especially in RTOs with a small number of personnel, individuals may have more than one function and it may be impractical to appoint deputies for every function.

The **responsibility for quality** in an RTO shall be defined. A part of that responsibility should be placed on individuals to control the quality of their own work. Project managers must ensure that the quality requirements for their projects are met. Immediate superiors shall ensure that subordinates understand their responsibilities, and that they are provided with the basic information necessary for the accomplishment of their tasks. Complaints and proposals concerning quality shall be brought to the attention of the person responsible for quality in the RTO.

3.2 Quality system

The RTO shall identify the policies and objectives to be achieved by implementing the **quality system**. The RTO management shall ensure that these policies and objectives are documented in a **quality manual**. The overall objectives shall be documented in a **quality policy statement.** The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) the management's statement of the RTO's standard of service;
b) the purpose of the quality system;
c) a requirement that all personnel concerned with research and other experimental activities within the RTO familiarise themselves with the quality documentation and implement the policies and procedures in their work;
d) the management's commitment to good professional practice and quality in servicing clients.

The RTO shall have written procedures for the major processes to ensure quality and integrity of the data generated and to be able to repeat if necessary the research, experiments and measurements under identical conditions.

The quality manual should include or make reference to technical procedures and outline the structure of the documentation used in the quality system. The quality manual shall be maintained current.

3.3 Document control

In this context, **document** means any procedure, specification, instruction, chart, textbook, poster, notice, memorandum, software, drawing, plan, etc. These may be in various media, whether hard copy or electronic, and they may be digital, analogue, photographic or written.

RTOs should attempt to keep documentation simple and easy to understand for its target audience. The RTO shall establish and maintain procedures to **control all documents** that form part of its quality documentation. This includes documents of external origin, such as regulations, standards, research methodologies, test and/or calibration methods and other normative documents, as well as drawings, specifications, instructions and manuals related to the projects. Internally generated documents must also be controlled.

All documents issued to personnel in the RTO as part of the quality system shall be reviewed and approved for use by authorised personnel prior to issue. A master list or an equivalent **document control procedure** identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

The procedure(s) adopted shall also ensure that

a) authorised editions of appropriate documents are available at locations where the operations essential to the effective functioning of the RTO are performed;
b) documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with the applicable requirements or guidelines;
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise ensured against unintended use;
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Quality system documents generated by the RTO shall be uniquely identified. Such identification should include the date of issue and/or the revision identification, page numbering, the total number of pages or a mark to signify the end of the document and the issuing authority.

Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval. Where practicable, the altered or new text shall be identified in the document or appropriate attachments. Documents amended by hand shall be marked, signed and dated and shall be formally reissued as soon as practicable.

Procedures shall be established to describe how changes to documents maintained in computerised systems are made and controlled.

3.4 Sub-contracting of parts of the project

When an RTO sub-contracts work whether because for unforeseen reasons, (e.g., workload, need for further expertise or temporary incapacity), or on a continuing basis (e.g., through permanent sub-contracting, agency or franchising arrangements) this work shall be placed with a **competent sub-contractor**. The RTO shall ensure that its sub-contractor is competent to perform the activities in question and complies with the same guidelines as the RTO itself with respect to the work being sub-contracted. Testing and calibration laboratories should comply with the requirements in ISO/IEC 17025.

The RTO shall maintain a register of all the main sub-contractors that it uses and a record of the evidence that they are competent.

3.5 Procurement of services and supplies

The RTO shall use only such external services and supplies that are of adequate quality to sustain confidence in its results. The RTO shall ensure that purchased materials and services comply with applicable requirements or its own specifications.

Procedures should exist for the purchase, reception and storage of consumables that may considerably affect the quality of the results. The RTO shall ensure that **purchased supplies and consumables** are not used until they have been inspected, calibrated or otherwise verified as complying with standards, specifications or requirements. The RTO should maintain records of the main suppliers from whom it obtains services and supplies that affect the quality of the results.

3.6 Service to and feedback from the client

The RTO shall afford clients or their representatives co-operation to clarify the client's request and to monitor the RTO's performance in relation to the work performed and to the extent to which the RTO can ensure confidentiality to its clients. Such co-operation may include:

a) allowing the client or his representative **access to relevant areas** of the RTO, for witnessing experiments, calculations, etc. performed for the client;
b) preparation, packaging, and dispatch of items needed by the client for verification purposes.

Continual contact with the client, especially in large research projects, should be maintained throughout the project. The RTO should inform the client of any **delays or major deviations** in the performance of the project.

RTOs should seek both positive and negative **feedback from their clients**, preferably in a systematic way to improve the quality system, technical activities and client service.

3.7 Complaints

The RTO shall have a policy for the resolution of **complaints** received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the RTO.

3.8 Control of non-conformances

The identification of **non-conformances** in the quality system, in research methodologies, in the technical operations and in the project work can occur at various stages. The identification can come from customer complaints, quality control, instrument calibration, checking of consumables, staff observations, report checking, internal or external audits, management reviews, etc.

The RTO shall have a policy to be implemented when any aspect of its research work, or the results of this work, do not conform with its own procedures or the contract with the client. The policy shall ensure that:

a) responsibilities and authorities for management of non-conformances are designated and actions (including halting of work) are defined and taken when non-conformance is identified;
b) an evaluation of the significance of the non-conformances work is made;
c) **remedial actions** are taken immediately, together with any decisions about the acceptability of the non-conforming work;

d) where necessary, the client is notified and work is recalled;
e) the responsibility for authorisation of the resumption of work is defined.

Where the evaluation indicates that the non-conformance could recur, or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures as well as the contract, the corrective action procedures (see Section 3.9) shall be promptly followed.

3.9 Corrective action

The RTO shall establish a policy and shall designate appropriate authorities for implementing **corrective action** when non-conforming work or departures from the policies in the quality system, technical operations or project work have been identified. The aim should be to avoid recurrence. Any corrective action taken to eliminate the causes of non-conformances or other deviations shall be appropriate to the magnitude of the problems and commensurate with the risks encountered.

Corrective action shall include an investigation process to determine the **root cause(s)** of the problem. Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include, inter alia, client requirements, the samples, sample specifications, experimental or calculation methods and procedures, staff skills and training, consumables, as well as equipment and its calibration. The RTO shall select the action(s) most likely to eliminate the problem and to prevent it from recurring. The RTO shall document any required changes resulting from corrective action investigations.

After having implemented the corrective action plan, the RTO shall monitor the results to ensure that the actions taken have been effective in overcoming the problems originally identified. The results of corrective actions shall be submitted for management review (see Section 3.13).

3.10 Preventive action

Preventive action is a proactive process to **identify improvement opportunities**, rather than a reaction to the identification of problems or complaints. Apart from the review of the operational procedures, preventive action might involve the analysis of data, including trend analysis, risk assessments and the results of inter-laboratory comparisons. For example, the TQM process as well as brainstorming, flowcharting, mind mapping and Pareto charts can assist in this process.

Opportunities for needed improvement and the potential sources of non-conformances, either technical or with the quality system, or in the project work, shall be identified. If preventive action is required or decided, an action plan shall be developed, implemented and monitored, to reduce the likelihood of the occurrence of anticipated non-conformances and to take advantage of the improvement opportunities. The RTO shall take measures to improve the quality of its management. Input can be provided by, e.g., customer surveys, personnel satisfaction studies, benchmarking exercises, evaluations, participation in inter-comparisons and learning by doing.

The results of preventive actions shall be submitted for management review (Section 3.13).

3.11 Control of records

Quality records are records providing objective evidence of the extent of the fulfilment of the requirements for quality or the effectiveness of the operation of the quality system. They include, e.g., reports from internal audits and management reviews as well as corrective and preventive action records.

Technical records are accumulations of data and information that result from carrying out experiments and/or calculations and which indicate whether specified parameters are achieved. They include forms, work sheets, work books, work notes, experimental or test results, results of calculations, clients' notes, technical comments, reports, etc.

The RTO should establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality and technical records. Records may be in the form of any type of media, such as hard copy or electronic media. The RTO shall ensure that it has recorded information that might be needed when continuing the research, repeating the experiments or calculations or in a future dispute situation. All records shall be held secure and in confidence. The RTO shall have a procedure to protect and back-up data held on computers and to prevent unauthorised access to or amendment of data on computers.

Attention shall be paid to **the layout of records and reports**, especially with regard to the presentation of data and ease of assimilation by the reader. The format shall be designed to accommodate each type of record and to minimise the possibility of misunderstanding or misuse. The headings shall be standardised as far as possible.

All records should be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration, and loss. **Retention times of records** shall be established. In certain cases the retention time is determined by legislation or in the contract.

The RTO shall ensure that, where clients require **transmission of results** by telephone, telex, facsimile or other electronic or electromagnetic means, personnel follow such procedures that ensure that confidentiality is preserved. The RTO cannot take responsibility for any break in confidentiality that takes place at the locations of the client or during the transmission in public networks.

The RTO shall retain original observations, calculations and derived data, calibration records, staff records, quality records (e.g., audit and review record) and a copy of each report issued for a defined period. The records shall contain sufficient information to facilitate, if possible, the identification of factors affecting the uncertainty of the results and which will enable the work to be repeated under conditions as close as possible to the original. The records shall include the identity of the personnel responsible for sampling, performing experimental tasks and checking of results.

Observations, data and calculations shall be recorded and identifiable to the specific job at the time they are made. When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible nor deleted, and the correct value entered alongside.

In the case of computer-collected data, similar measures shall be taken to avoid the loss or change of original data. Attention shall also be paid to the safety (anti-fire, anti-fraud) of data as well as the possibility to revisit the data after longer time periods, during which the RTO's hardware and software configurations have been changed.

3.12 Internal audits

The RTO shall periodically and in accordance with a predetermined annual schedule, conduct **internal audits** of its activities to verify that its operations continue to comply with the requirements of the quality system. The internal audit programme shall address the major elements of the quality system. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by the management. Such audits shall be carried out by trained and qualified personnel who are, whenever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the RTO's results, the RTO shall take timely corrective action and shall notify clients in writing if investigations show that the RTO's results may have been affected.

Audit findings, and corrective actions that arise from them shall be recorded. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective actions taken.

3.13 Management reviews

By **management review** the organisation and operations of the RTO is surveyed. The review covers the RTO's overall objectives, business results and opportunities, quality systems and quality of operations, further development of technical competence and personnel, etc. The aim is to identify and implement measures needed for further improvement in and of the RTO. The results should be fed into the strategic development programme of the RTO and should include the goals as well as the objectives and action plans for the coming year(s).

The executive management of the RTO shall periodically conduct a review of the RTO's research activities and quality system to ensure their continuing suitability and effectiveness, and to introduce any necessary changes or improvements. The review shall take account of

- reports from managerial and supervisory personnel;
- the outcome of recent internal audits;
- corrective and preventive actions;
- assessments or evaluations by external experts or bodies;
- the results of inter-laboratory comparisons;
- changes in the volume and type of the work;
- client feedback;
- complaints;
- other relevant factors, such as quality control activities, new resources and staff competence.

The findings from the management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are implemented within an appropriate and agreed time-scale.

Section 4: TECHNICAL COMPETENCE

This section describes the guidelines an RTO should meet in order to be able to demonstrate that it is technically competent for the type of research projects it undertakes. Many factors determine the correctness and reliability of the results of the projects. These factors include contributions from human factors, accommodation and environmental conditions, research and experimental methods and their validation, equipment, sampling, etc. The extent to which they contribute to the results differs considerably from case to case. The RTO shall take account of these factors in developing research methodologies and procedures, in the training and qualification of personnel and in the selection of the equipment and computational programmes it uses.

4.1. Personnel

The RTO management shall ensure that all personnel performing research, operating specific equipment and making professional judgement are competent. When using staff undergoing training, appropriate supervision shall be provided. The RTO shall normally use personnel who are employed by, or under contract to the RTO. Where additional personnel are used, the RTO shall ensure that such personnel are supervised and competent and that they work in accordance with the RTO's quality system.

The management shall formulate the goals with respect to the education, training and the skills of the RTO personnel. The RTO shall have a policy for identifying training needs and providing **training of personnel**. The training programme shall be relevant to the present and anticipated tasks of the RTO. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or skills, as required. The type of training should reflect the fact that research and development work involve the collaboration effort of personnel, who have widely divergent levels of education, skills and experience.

Training by mentoring is crucial to the continued intellectual development of personnel. The RTO should utilise competent mentors to model the problem, plan the measures needed to achieve the project’s objectives and enhance the intellectual development of personnel.

All personnel with management responsibilities should receive training in managerial, communication and interpersonal skills that is appropriately tailored to the unit they supervise.

In some technical areas (e.g., non-destructive testing) it is necessary that the personnel performing certain tasks are certified. The RTO is responsible for fulfilling sectoral personnel certification requirements. The requirements for **personnel certification** might be regulatory, i.e. included in the standards for the specific technical field or imposed by the RTO or its clients. When appropriate the management shall authorise personnel to perform particular types of experiments and sampling, to use equipment, and to make professional judgement. The personnel responsible for the professional judgement included in the research reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of R&D, also have

- relevant knowledge of the technology used for the manufacturing of materials, products, items etc. studied, or the way they are used or intended to be used and of the defects or degradation which may occur during or in service;

- knowledge of the general requirements expressed in legislation and standards;

- an understanding of the significance of deviations found with regard to the normal use of the materials, products, items, etc. concerned.

The RTO shall maintain a **record of the qualification**, training, experience and job description for each managerial, professional and technical individual.

The RTO shall retain **job descriptions and CVs** for managerial personnel and technical personnel involved in the research activities.

4.2. Facilities and environmental conditions

In addition to the operations in permanent laboratory facilities, RTOs may also operate in mobile laboratories, at the sites of the clients or in the field. **Laboratory facilities**, including but not limited to energy sources, lighting and environmental conditions shall be such as to facilitate the correct performance of the research operations.

The environment in which the sampling, experiments and measurements are undertaken shall not invalidate the results or adversely affect them. Particular care shall be taken when these activities are undertaken at sites other than the RTO's permanent facilities.

The RTO shall monitor, control and record **environmental conditions** as required by relevant specifications and research methods or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Research activities shall be stopped when the environmental conditions jeopardise the results of the research.

Newly received living biological material, plants or animals should be isolated before their condition (health, status) has been evaluated. When the research begins they should be free of any disease or condition that might interfere with the purpose or conduct of the research. **Acclimatisation** to the research environment should be allowed if considered necessary.

There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent **cross-contamination**.

Access to and use of areas affecting the quality of the results shall be controlled. Measures shall be taken to ensure **good housekeeping** in the laboratory.

4.3 Experimental and calculational methods

The RTO shall use appropriate **experimental and calculational methods** for all activities within its scope, including the sampling, handling, transport, storage and preparation of research items.

The RTO shall have instructions on the use and operation of all relevant **equipment and software** where the absence of such instructions could jeopardise the results. Instructions, standards, manuals and reference data relevant to the work of the RTO shall be maintained current and be made readily available to the personnel concerned.

The RTO shall use **research methodologies** that meet the needs of the client and which are scientifically appropriate for the projects it undertakes. International, regional or national **standards or other recognised specifications** that contain sufficient and concise information for performing the experiments and calculations should be used, if these standards or specifications are written in a way that can be used by the personnel. The RTO shall ensure that it uses the latest edition of the standards unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application. Deviations from research methods should occur only if the deviation has been documented, technically justified and accepted by the client.

When the client does not specify the research methodology to be used, the RTO shall select appropriate research methodologies or methods that have been published in international, regional or national standards, or by reputable technical organisations, or in relevant scientific texts or journals, or as specified by the equipment manufacturer. **RTO developed methods** or methods adopted by the RTO may also be used if they are appropriate for the intended use and validated.

The RTO shall check that it can properly operate standard methods before carrying out such work for clients.

The RTO shall inform the client when the method proposed by the client is considered to be inappropriate or out-of-date.

When it is necessary to employ research methods or methodologies not covered by standards, these shall be subject to agreement with the client and shall include a specification of the requirements and the objectives. The research methods or methodologies developed shall be validated appropriately before use, and be available for examination by the client.

New research methods or methodologies should normally be developed prior to the research being performed and should contain at least the following information:

- scope;
- parameters, properties and/or ranges to be studied;
- the apparatus, equipment, software, reference standards and reference materials required;
- the environmental conditions required and any stabilisation period needed;
- description of the procedure, including
  - affixing identification marks, handling, transporting, storing and preparing items;
  - checks to be made before the experimental work or calculations are started;
  - checking that the equipment and/or software is working properly and, where required, calibrating and adjusting the equipment before use;
  - method of recording the observations and results;
  - safety measures to be observed;
- data to be recorded and method of analysis and presentation;
- procedure for estimating uncertainty.

Validation is the confirmation by examination and provision of objective evidence that the particular requirements for the intended use of the research method are fulfilled. The aim of the **validation of methods** should be to demonstrate that the method is fit for its intended purpose and that the results have an acceptable uncertainty. The validation should, when required, provide information about the representativeness, repeatability and reproducibility as well as of the influence of instrumental, human and environmental factors on the uncertainty of the results.

The techniques used for the validation of a research method or methodology should be one or a combination of the following: calibration using reference standards or reference materials, comparison of results achieved with other methods, inter-laboratory comparisons, systematic assessment of the factors influencing the results, assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method, and practical experience.

The RTO shall validate non-standard methods, RTO designed/developed methods, standard methods used outside their intended use and amplifications or modifications of standard methods to confirm that they are suitable for the intended use. The validation shall be as extensive as is necessary to meet the needs in the given application or field of application. The RTO shall record the results including the procedure used for the validation.

The suitability of the non-standard research methods or methodologies may be checked and confirmed by comparing the method with specified requirements typical for the intended use. The range and accuracy of the values obtainable with this method (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/research object) as assessed for the intended use shall be relevant to the customers' needs.

In research work it is not unusual to make ad-hoc deviations from procedures. These may adversely influence the hardware and software performance, data collection, calculations, and interpretation of results. A simple system recording deviations as they occur and confirming that consequences have been evaluated and where appropriate corrective action has been taken should ensure that there is no inadvertent loss of quality arising from the deviations.

The depth by which validation is carried out is always a balance between costs, risks and technical possibilities. A validation should be completed by a statement from the RTO management that the method is fit for the intended use.

Calculations and data transfers shall be subject to appropriate checks in a systematic manner. When computers or automated equipment are used for the capture, processing, recording, reporting, storage or retrieval of data, the RTO shall ensure that:

a) the computer software, including any software built into the equipment, is documented in sufficient detail and suitably validated or otherwise checked as adequate for use;
b) procedures are established and implemented for **protecting the data**; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
c) automated equipment and computers are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of data.

Commercial off-the-shelf software (e.g., word processing, database and statistical programmes) in general use within its designed application range is considered sufficiently validated by the manufacturer. However, software configurations/modifications should be validated by the RTO.

An RTO should have, and apply, a procedure for **estimating the uncertainty** of the results, measurements and calculations whenever the client requires uncertainties to be reported, or when the uncertainty is likely to adversely affect the results and compliance with a specification. When estimating the uncertainty of the measurements and calculations, the major uncertainty components, which are of importance in the given situation, should be taken into account.

4.4 Equipment

The RTO shall normally be furnished with all items of equipment required for the correct performance of the research (including sampling, preparation of items, processing and analysis of data). In those cases where the RTO needs to use equipment outside its permanent control, it shall ensure that the same requirements are met.

Before placed into service, the purchased equipment shall be checked against the purchase order to establish that it meets the specification requirements, complies with the relevant standard specifications, and is calibrated and/or verified. Each item of equipment shall, when appropriate, be uniquely labelled, marked or otherwise identified.

Equipment and its software, including that used for sampling, shall be capable of providing the accuracy required and shall comply with specifications relevant to the experiments or measurements concerned.

Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

Equipment shall be operated by competent and authorised personnel. Up-to-date instructions on the **use and maintenance of equipment** (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate personnel.

Records shall be maintained of each significant item of equipment and its software. The records should include at least:

a) the identity of the equipment and its software;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) date received and/or date placed in service;
d) checks that the equipment and its software comply with the specification;
e) current location, where appropriate;
f) the manufacturer's instructions, if available, or reference to their location,
g) dates, results and copies of reports and certificates of all calibrations and/or verifications, adjustments, the acceptance criteria, and due date of next calibration and/or verification;
h) maintenance plan where appropriate and maintenance carried out to date;
i) damage, malfunction, modification or repair to the equipment.

Equipment shall be protected from contamination, deterioration and abuse, and shall be maintained regularly to ensure proper functioning. The RTO should have procedures for the safe handling, transport, storage and use of experimental and measuring equipment in order to prevent damage, contamination or deterioration. Additional procedures may be necessary when experimental and measuring equipment is used outside the permanent RTO facilities.

Maintenance procedures shall be established. Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown by verification or use to be defective, or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use, or clearly labelled or marked as out of service until it has been repaired and shown by calibration, verification or other means to perform correctly. The laboratory shall examine the effect of the observed defect or departure from specified limits on previous works and when necessary take measures to correct wrong results and inform the clients in question.

Whenever practicable, equipment under the control of the RTO, and requiring calibration or verification shall be labelled, coded or otherwise identified to indicate the status of calibration or verification and the date when re-calibration or re-verification is due. When, for whatever reason, equipment goes outside the direct control of the RTO, the RTO shall ensure that the function and calibration status of the equipment and its software are checked and shown to be satisfactory before the equipment is returned to service.

When automated equipment or computers are used for the collection, processing, recording, reporting, storage or retrieval of data, the RTO shall ensure that also the guidelines in Section 4.3 are followed. Equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the results.

Where calibrations give rise to a set of correction factors, the RTO shall have procedures to ensure that any copies (e.g., in computer software) are correctly updated.

Research work may often involve the modification of existing equipment or the design of new equipment and related software. Accepted engineering and scientific practices should be applied to the design, construction and modification. Method validation procedures and the use of blanks, standards, old samples, and reference materials can be used as part of the commissioning process. The RTO should follow the procedure described above when equipment is developed or modified.

4.5 Reagents and laboratory consumables

The RTO shall ensure that the **reagents, laboratory consumables, reference materials and calibrants** conform to the purchase order and/or specified requirements, especially when their quality is expected to influence the results. Careless preparation or poor storage may result in inadvertent degradation. This is particularly important where chemical metabolites, or chemicals about which little is known, are involved. Sometimes, the use of added preservatives or storage under inert atmosphere (e.g., Ar or N_2) may be appropriate.

Reagents, laboratory consumables, reference materials and calibrants prepared for specific R&D applications should be appropriately labelled, and if necessary, their use restricted to prevent contamination through widespread use. Details of preparation etc. should be recorded when needed. If there is a risk that consumables (e.g., chemicals and reagents) may deteriorate during storage, **restrictions of use** and **date of expiry** shall be clearly marked. This is of special importance when dealing with, for example, living or degrading materials.

In research work, the RTO may encounter the situation where reagents, laboratory consumables, reference materials or calibrants are absent or, if available, are poorly characterised. For example, where the stoichiometry of the reagent or calibrant is not known, an approximate amount should be weighed and the exact amount of reagent or calibrant constituent determined with an absolute method. In addition, the level of purity of, for example, complex organic compounds or calibrants can be a problem. For example, purities of $\leq$ 95 % are not uncommon.

4.6 Measurement traceability

Equipment, including equipment for subsidiary measurements (for example for measuring environmental conditions), which has a significant effect on the accuracy or validity of the results, shall be calibrated or verified before being put into service. The RTO shall have a programme for the calibration and verification of its equipment, including the use of reference materials and reference standards.

Traceability of measurement shall be ensured by the use of calibration services from laboratories that can demonstrate traceability and competence. The extent to which this requirement should be followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is a dominant factor, the requirements should be strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used as given below:

a) participation in a suitable programme of inter-laboratory comparisons;
b) the use of suitable reference materials;
c) checking by another method;
d) mutual consent standards or methods that are specified and mutually agreed upon by all parties concerned.

The traceability of measurements should be made to SI units. However, this cannot always be strictly done.

The RTO shall have a programme for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability. Such reference

standards shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

4.7 Sampling

Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide a representative sample. Sampling is used for many purposes within and outside the RTO's facilities. Sampling can also be required by appropriate standards or specifications. Samples are needed for the characterisation of bulk of materials, manufactured products, the statistical control of processes, comparative testing and research, environmental monitoring, etc. The **sampling procedure** should describe the selection, the sampling plan, withdrawal and preparation of samples, etc., and be available at the location where the sampling is performed. In certain cases (e.g., forensic and damage analysis) the sample may not be representative but determined by availability.

Where the client requires deviations, additions or exclusions from the documented sampling procedure used by the RTO, these shall be recorded with the appropriate sampling data and included in all documents containing results. Special attention shall be paid when performing sampling for use in comparative research and studies on products.

Where a large number of samples are involved and only a few are expected to yield significant results, screening techniques may be used for eliminating the large numbers of insignificant samples. The significant samples can then be examined in more detail.

4.8 Handling of research items

The RTO should have practices for the transport, receipt, handling, protection, storage, retention and/or disposal of items, including provisions necessary to protect the integrity and interest of the RTO and the client.

The RTO shall have a system for **identifying research items**. The identification shall be retained throughout the life of the item in the RTO. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

Upon the receipt of research items, abnormalities or departures from normal or specified conditions shall be recorded. When there is doubt as to the suitability of an item, or when an item does not conform to the description provided, the RTO shall consult the client for further instruction before proceeding. The RTO shall establish whether the research item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the RTO.

The RTO shall have procedures and appropriate facilities for avoiding **deterioration, loss or damage to items** during storage, handling, preparation and experimental work; instructions provided with the item shall be followed. When items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained,

monitored and recorded. Where a research item or portion of an item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary experiments to be performed later), the RTO shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

Where research items are to be returned into service after experiments or measurements, special care is required to ensure that they are not damaged or injured during the handling, experiments or storing/waiting processes.

If not otherwise agreed, research items (e.g., products materials, samples, specimens) delivered by the client shall be kept for at least three months from the date the results were given to the client. For legal reasons, or in case of a dispute, it might be advisable for the RTO to keep the items for a longer time.

Section 5: PROJECT MANAGEMENT

Where an RTO is carrying out a number of projects simultaneously, co-ordination of the projects also related to the use of the facilities is advised. Management needs to be aware of the different projects in progress in the RTO at a given time and the corresponding risks of one project affecting another both from a resource point of view but also from cross interaction. Similarly, where projects are spread across several units within an RTO, or involve input from external RTOs or laboratories, suitable co-ordination is necessary to ensure the coherent delivery of the work without any adverse effect on quality.

Professional judgement is a broad concept covering the technical understanding of the aims and contents of the project and associated operations in the RTO during all phases, i.e. project initiation, execution and finishing. It is particularly related to making correct conclusions out of sometimes 'fuzzy' material and information. The **professional judgement** can be expressed as opinions, interpretations, predictions, simulations, models, values, etc.

Professional judgements included in a research report may comprise:

- opinion on conformity with respect to general requirements, standards, specifications, etc.;
- fulfilment of contractual specifications and technical requirements;
- recommendations on how to use the results;
- validity of the results;
- guidance to be used for improvements (the RTO is not allowed to disclose confidential information obtained from, e.g. other clients).

5.1 Responsibility for quality

Research projects can be considered a collection of discrete tasks, each consisting of a number of unit processes, themselves composed of modules containing also routine unit operations. The unit processes are characterised as being separated by natural dividing lines. The benefit of this modular approach in defining projects is that new research work is likely to contain at least some components that are familiar to the RTO and may even be performed routinely. This approach offers benefits in terms of utilising staff competence and also in the documentation of procedures.

For each project, the RTO shall appoint a responsible person (**project manager**) with the appropriate qualifications. For large projects, it can be practical to appoint a deputy as well. For small routine projects, a simplified procedure may be applied.

The client and the RTO may set up a **steering committee** for the project. This group shall control and direct the execution of the project within the limits of the contract.

The project manager shall have the overall responsible for carrying out the project. He/she shall also direct the work of the members of the project team. The project manager shall report to the steering committee, if such a committee has been formed. The project manager must reach agreement with the line organisation on the human and experimental resources allocated to the project. The RTO must ensure that the interaction between the project manager and line organisation is fair and open.

Large or multidisciplinary projects may involve scientists from several units of the RTO and perhaps outside specialist sub-contractors. The role of project management is particularly important in order to ensure that the project team functions smoothly, with all members co-operating and aware of their roles and responsibilities. Particular attention should be given to:

- definition of the project management hierarchy, with leaders in particular areas, and defined authority and responsibility for all team members;

- involvement of all personnel pertinent to the project (including the client) in defining the task and assignments and in planning the project;

- setting clear tasks and goals that are challenging but achievable;

- early consultation with the management of other units or organisations involved in the project in order to resolve open questions concerning priorities and workload, and budget contributions, which often disrupt good team work;

- communication by holding meetings at appropriate intervals for the exchange of information, problem-solving, consultation, reporting, co-ordination and decision-making.

For small, straightforward projects, the same principles should be applied in a cut-down form.

The RTO should define the way projects are carried out within the organisation. This practice should preferably be documented in a **project guide or manual**.

Checklists may be used enabling the project leader to pay attention to all aspects of the project during the preparatory, realisation, and finishing stages.

The personnel making professional judgements shall have applicable theoretical and practical background and recent experience. They must have integrity and a good reputation.

5.2 Project work

In the initial phases of the project, it is recommended to collect the necessary basic information from earlier experience, public sources, data banks, etc.

Planning and preparation form a critical part of a research project, especially where new methods are generated or an extension of generic methods is made. The effort put into planning depends on the complexity and requirements of the work, previous experience, the extent to which the work is unfamiliar or novel in its character, the number of persons or organisations involved, the expenditure on new equipment, the consequences of wrong results, the duration of the work and deadlines, etc. A flowchart may assist in planning. Proportionally more planning is needed for high-risk work. It is important to correctly estimate the resources needed in all the project phases. The structure of the project should be flexible enough to allow creative problem-solving. The project manager, sometimes supported by a team, is responsible for planning activities within the project and for allocating resources to cover these activities.

Task definition is the first stage of planning and it should provide sufficient information to allow more detailed planning or indicate the viability of proceeding. Go/no-go decision criteria should be incorporated in the project structure at the earliest opportunity. It is vital to establish a good link with the client to ensure that work is defined adequately, thus maximising the chances of a productive outcome of the project. In **a research plan** one should, for example:

- set clear (and, if appropriate, intermediate) goals (measurable objectives including go/no-go decision points/acceptance criteria) and establish what questions need to be answered at each check-point and the corresponding results/data required to answer them;

- outline the strategy to be used for each phase and if necessary subdivide tasks into manageable, defined work packages with distinct goals;

- define the resources (personnel, equipment, facilities, consumables) needed for each phase;

- define the start and end of the project, the dead-lines for intermediate goals, and the minimum critical path for completing the work.

Research plans should contain as much detail as is necessary to define the tasks involved. For simple tasks the plan may simply be an entry in a notebook or a form. A more detailed plan is necessary for larger, more complex tasks or when time and cost constraints are to be closely controlled, or when high-risk or significant investments depend on the outcome of the work. If there is significant doubt as to whether the work can be completed successfully by a single route, then alternative plans should be defined.

In the preparatory phase of the project, attention should be paid to project marketing, content, financing and contract negotiations. It is recommended that the intended project manager participates in the preparatory phase. The RTO must check before signing the contract that it has the required equipment, competence and human resources to carry out the project.

In the realisation of the project, agreed research plans should be followed. If changes to the plans have to be made, they must be agreed upon at the same level as the original decision was made. The RTO should have a system to **monitor the progress,** including the completion grade of the project, and to follow the costs incurred. The progress and incurred costs should regularly be followed by the project manager and the line organisation.

When finishing the project, the project manager and a person from the RTO shall check before contacting the client that the conditions of the contract have been fulfilled. Thereafter, the results of the project shall be presented to the client for acceptance. Feedback from the personnel and the client should be collected. The necessary administrative measures shall also be taken to close the project. This includes final accounting, billing and closing of the archives.

The RTO must pay special attention to projects covering **comparative research** in which the properties or applications of two or more products are compared. The RTO must ensure that the research is impartial and that the results are objective and describe the product in a

justifiable way. The research plan should be established in such a way that no product is favoured by definition. Due care must also be taken when selecting samples to be studied. The RTO should report its findings in an objective way and avoid ranking of the products. The RTO has the right to refuse, without explanation, the performance of comparative research. The report must unambiguously define how the samples were selected, how the studies were carried out and give all the results.

Special attention should be paid to the **transfer of knowledge and technology** to the client during the project. The transfer can continue beyond the submission of a report and contract completion. The transfers should be planned, taking into account the client's material and immaterial capabilities.

5.3 Monitoring project progress

The progress of work and status of expenditure should be monitored by comparing achievements and use of resources against the planned budgets at convenient points within the work, typically at regular intervals or on the completion of milestones. Informal reviewing should be carried out by the RTO staff as work progresses. Unexpected difficulties or results, or major deviations from goals may call for extraordinary reviews and interim reports with re-planning of the work and re-allocation of resources as necessary.

Progress should be monitored in close co-operation with the client or steering committee, reported to the client, the steering committee and the RTO management in the format and at the time intervals agreed at the planning stage. Typically, such reports might cover a review of the project plans, information on whether the work is running to schedule and will achieve its objectives, an account of the technical progress with achievements and failures/setbacks and information on the resources used.

Where the progress review shows that a particular line of investigation is likely to be unsuccessful, the goals and/or chosen tactics and tasks may have to be changed. Such a change may already have been anticipated during planning. Changes should be made in consultation with the client where appropriate and justified in reports.

The client must provide the RTO with all the necessary data and information needed for carrying out the project. If work is carried out on the premises of the client, the client shall attend to health and safety at work for the employees of the RTO.

In addition to periodic internal audits of the RTO's procedures and quality system, the RTO shall ensure the **quality of outgoing results**. This may include but not be limited to

a) internal quality control schemes using statistical techniques;
b) participation in inter-laboratory comparison or proficiency testing programmes;
c) regular use of certified reference materials and/or in-house quality control using secondary reference materials;
d) replicate experiments using the same or different methods;
e) complementary experiments, measurements and calculations.

The selected methods should be appropriate for the type and volume of the work undertaken.

Statistical techniques may be a valuable tool in the design or use of research methods. During the lifetime of a research project, statistics can be used, for example, in the following areas:

- design of the research method and sampling procedure;
- characterisation of method performance and determination of uncertainty;
- supervision of the research and calculation method performance;
- interpretation of the results.

Statistical methods are important in the design of sampling schemes. If used properly they enable a representative characterisation to be obtained with the minimum of samples and subsequent analysis.

The RTO should check, inspect or verify the outcome of a contract to a level of detail that is commensurate with the scope, cost, complexity and risks of the project. When the draft research report is available, a **peer evaluation** or an independent check should be carried out in order to eliminate mistakes and wrong judgements.

The completed research work should be reviewed by the RTO management to evaluate the achievements. Experiences gained at all stages of the project may provide lessons for planning and carrying out similar work in the future. The review might typically cover:

- aspects of technical achievement, such as differences between goals and results, problems encountered and how they were solved, and overall usefulness of the results;
- compliance with budgeted costs and time schedules, with explanations for any deviations, expenditure overruns and unexpected technical results;
- quality of work of individual contributors;
- consequences of the project and the results to the RTO;
- satisfaction of the client.

5.4. Reporting the results

The results of projects carried out by the RTO shall be reported accurately, clearly, unambiguously and objectively, and in accordance with appropriate instructions.
The report must give the right impression of the results. Abnormalities related to the procedures and results should be reported.

The results of the research may be reported in various ways. Primarily a report should be made to the client in the format previously agreed and be written in a language that the client can readily understand. The report should provide sufficient information to enable the client, or any subsequent user, or assessor of the report to follow any arguments, and if required, to repeat any or all stages of the experimental work and obtain compatible results.

The report, whatever it is called, should include all the information requested by the client, and which is necessary for the interpretation of the results, together with the information required by the method used. The report may be issued as hard copy or by electronic data transfer. In the case of a written agreement with the client, the results may be reported in a simplified way. The information required in this clause, and not reported, shall be available in the RTO.

Each report shall normally include at least the following information:

a) a title describing also the character of the document, e.g. "Research Report", "Statement";
b) name and address of the RTO, and location where the work was carried out if different from the address of the RTO as well as the name of the researchers;
c) unique name or identification of the report (such as serial number) and on each page, an identification in order to ensure that the page is a recognised part of the report;
d) name and address of the client;
e) description and unambiguous identification of the task;
f) description and condition of the research items and the research method(s) applied;
g) date of receipt of item(s) and date(s) of performance of experiments, as appropriate;
h) sampling plan and procedures used by the RTO;
i) experimental and computational methods and results;
j) the name(s), title(s) and signature(s) or equivalent identification of person(s) authorising the report;
k) where relevant, a statement to the effect that the results relate only to the items studied;

RTOs are recommended to include a statement that the report shall not be published, reproduced, or distributed by the client except in full, without written approval of the RTO. It might be pertinent also to define the rules by which the client is entitled to use the name of the RTO for advertising purposes.

In addition to the requirements above, the report may include:

l) deviation from, additions to or exclusions from the normal research method or methodology and information on specific conditions, such as environmental conditions;
m) where relevant, a statement of compliance with design or performance specifications;
n) professional judgement based on the results;
o) additional information requested by the research method used or by the client;
p) references to pertinent documents;
q) executive summary.

Information on uncertainty is needed in the reports when it is relevant to the validity or application of the results, when a client’s instruction so requires or when uncertainty affects compliance to a specification limit.

When **professional judgements** are included in a report, they shall be clearly separated from the measured results. The RTO must be able to show that it has documented the basis upon which the professional judgement has been made, if such information is not included in the research report.

Where a research report contains results of experiments performed by sub-contractors, these results shall be clearly identified.

Material amendments to a report subsequent to issue shall only be made in the form of a further document, or data transfer, which includes the statement "Supplement to report, serial number ... (or as otherwise identified)", or an equivalent form of wording. Such amendments shall meet the relevant requirements as applied to the original report.
It may be appropriate to issue a completely new report. This report shall also be uniquely identified and normally contain a statement that it supersedes "Report no ...".

Section 6: BIBLIOGRAPHY

The general guidelines have been formulated so that they do not contradict the requirements that stem from other documents that the RTO may have to follow. Even direct quotations have been included from the following documents:

1. ISO/IEC FDIS, General requirements for the competence of testing and calibration laboratories (1999).

2. ISO 9001, Quality systems - Model for quality assurance in design, development, production, installation and servicing (1994).

3. ISO 9002, Quality systems - Model for quality assurance in production, installation and servicing (1994).

4. ISO Guide 25, General requirements for the competence of calibration and testing laboratories (1990).

5. EN 45001, General criteria for the operation of testing laboratories (1989).

6. Eurachem and CITAC, Quality assurance for research and development and non-routine analysis (1998).

7. EACRO, Code of conduct (1994).

8. World Federation of Engineering Organisations (WFEO), Code of environmental ethics for engineers (1986).

For more detailed information the following documents can be used:

9. Guide to the expression of uncertainty in measurement, issued by BIPM, IEC, IEC, IFCC, ISO, IUPAC, IUPAP and OIML (revised in 1995).

10. ISO 10011-1, Guidelines for auditing quality systems - Part 1: Auditing.

11. ISO/IEC Guide 43-1, Proficiency testing by interlaboratory comparisons - Part 1: Development and operation of proficiency testing schemes.

12. ASTM E 1579-93, Standard guide for ensuring data integrity in highly computerised laboratory operations (1993).

13. Eurachem Guide, The fitness for purpose of analytical methods - A laboratory guide to method validation and related topics (1998).

14. ASTM E 548-94, Standard guide for general criteria used for evaluating laboratory competence (1994).

15. EA and Eurolab, Validation of test methods. Published as EA-2/06 and Eurolab report 4/96, respectively (1997).

16. ISO 10006, Quality management - Guidelines to quality in project management (1997).

17. ANSI/ASQC Q2, Quality management and quality system elements for laboratories - Guidelines (1991).

18. Council decision 89/569/EEC, The acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice (1989).

19. Eurolab report 3/96, Quality assurance according to EN 45001 and OECD GLP-A guide to simultaneous implementation (1996).

20. US Department of Energy DE92-016352, Implementation guide for quality assurance programs for basic and applied research (1992).

21. RvA SC03, Supplementary criteria for research and development work (1996).