INRA Quality Guidelines for the research and experimental units

Version 2

March 2013

Contents

Introduction

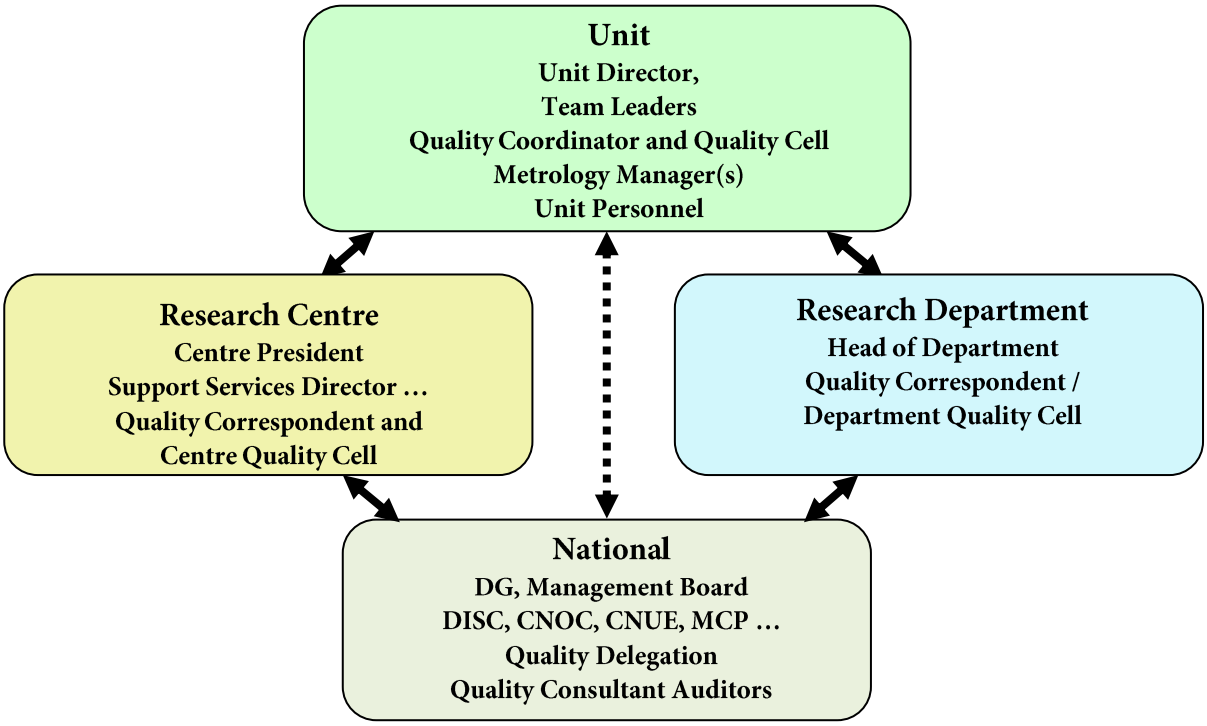
The INRA initiated quality measures in the late 1990s. An initial quality policy was defined in March 2000, with as its objectives the reliability of measurable results and the traceability of research work. To provide a framework for the operational implementation of its policy, in 2005 the INRA constructed quality guidelines for the research and experimentation units, accompanied by a self-assessment tool.

This new version takes into account the experience gained from the implementation of the quality policy.

The INRA has redefined its policy for the 2012-2016 period.

The purpose of this second version of the INRA guidelines is to set out this policy for the research and experimentation units which are the main quality actors in the institute.

INRA Quality Actors



1 Scope of application

This document specifies:

- **the requirements of the common set of standards needed to meet the objectives of the INRA's quality policy, marked by the symbol** AQR
- **as well as recommendations, that the units are free to adopt or otherwise, based on the feedback of the INRA's quality measures.**

These actions are complementary to the applicable contractual legal and regulatory requirements, but do not replace them.

Similarly, these guidelines are complementary to the requirements of good "professional" practice" defined by the relevant structures and collective bodies.
Most of the requirements or recommendations relate to principles or results to be achieved, and entrust to the unit the task of defining the actual arrangements adapted in particular, in terms of resources.

Like its 2005 version, the INRA's quality guidelines version 2 do not relate to the assessment of the scientific excellence of the research work, which is covered by specific measures (internal to the INRA, reading committees, assessment committees etc.).

All the actions of the quality guidelines are applicable to all units, whether they are INRA research units (UR), joint research units (UMR), experimental units (UE) or service units (U(M)S).

The research quality measures cover all research activities, including modelling, bioinformatics, surveys, etc., from the questioning of the research to its publication, taking in all the stages on the way and, in particular, the research and/or experimental protocols.

Where one or more actions in these quality guidelines does not concern the unit, it is possible to exclude them. The unit then justifies this exclusion in its self-assessment.

2 Quality Management and Responsibilities

The unit implements a quality management system in accordance with these quality guidelines and continuously improves its efficiency through the use of indicators, self-assessments and audits.

This quality management system is a tool for controlling and guiding the unit's activities. It allows the operation of the unit to be improved and also its organisational and professional practices.

The quality measures concern and involve all the unit's personnel.

2.1 Responsibilities of the Unit Director

AQR **The Unit Director:**

- **defines the unit's quality policy: directions and priorities, in line with those of the Institute, the supervisory research department, its research centre and for the UMRs, its other supervisory bodies;**
- **appoints a quality coordinator and a quality cell responsible for organising and coordinating the implementation of the unit's quality measures, drafts their mission statement and assesses their contribution;**
- **organises the metrological function; this organisation (metrology manager(s), metrology group or cell, equipment or materials managers, references per type of quantities etc.) is formalised by mission statements;**
- **validates and prioritises the actions to be performed;**
- **allocates the resources needed for implementing its quality policy, in particular for the training of the Quality Coordinators and Metrology Managers;**
- **examines, at a specified frequency, the outcome of the activities undertaken and assesses their effectiveness, on the basis of self-assessments, indicators and audits, and defines accordingly the new objectives to be attained and actions to be undertaken (quality review, see 6.5);**
- **formalises the outcome and the prospects of the quality approach in the unit's assessment report (AERES for the research units / INRA assessment for the experimental units);**
- **supports the measures in the unit and promotes it in and outside the unit, communicates, within the unit, its quality policy: objectives, accomplishments ...**
- **is responsible for identifying the rules applicable to the unit's activities and ensures that they are applied.**

Recommendations:

- *Create a quality cell with participants representing the unit's various teams or activities, and including scientists.*
- *To develop an integrated approach to quality aspects, prevention and sustainable development, create a joint quality – prevention – environment cell. For the prevention areas, the resources that the unit may use are the prevention centre delegate, the specialised bodies (bio-safety committee & cell, animal testing office etc.) and the central prevention mission.*

- *Attach to the unit's collective assessment report, the audit report, the action plan which has followed it, as well as the results of the action plan follow-up and the quality indicators that the unit has chosen.*

More generally, the Unit Director is responsible for organising and assigning responsibilities within the unit.

These responsibilities and organisations are communicated within the unit.

The organisation and responsibilities are formalised (flowchart, mission statements).

2.2 Quality Coordinator Responsibilities

The Unit's Quality Coordinator:

- **defines and schedules with the Unit Director the quality actions to be undertaken;**
- **organises the implementation of the quality actions and communicates about these;**
- **self-assesses the unit's quality system according to the set frequency, gives an account of the operation of the quality system to the Unit Director, and communicates the self-assessment to the department(s) to which the unit is attached and to the centre;**
- **is the interlocutor in respect of the quality measures with the unit's personnel, the department, the centre and the quality delegation.**

Recommendations:

- *Associate the members of the unit's quality cell with these activities, and, in particular, the unit's team leaders with the self-assessment.*
- *Associate as many of the unit's people with the measures: shared coordination, working groups ...*
- *Seek the contribution of actors from outside the unit and participate in exchanges, events and training offered by the departments, the centres, the professional networks, the quality delegation and the unit's other supervisory bodies.*

3 Conducting Research

3.1 Research Process

Starting from a research question, the person in charge of conducting this research develops hypotheses, drafts the protocols for testing them, coordinates sampling / analysis / simulations, and interprets the data and promote them.

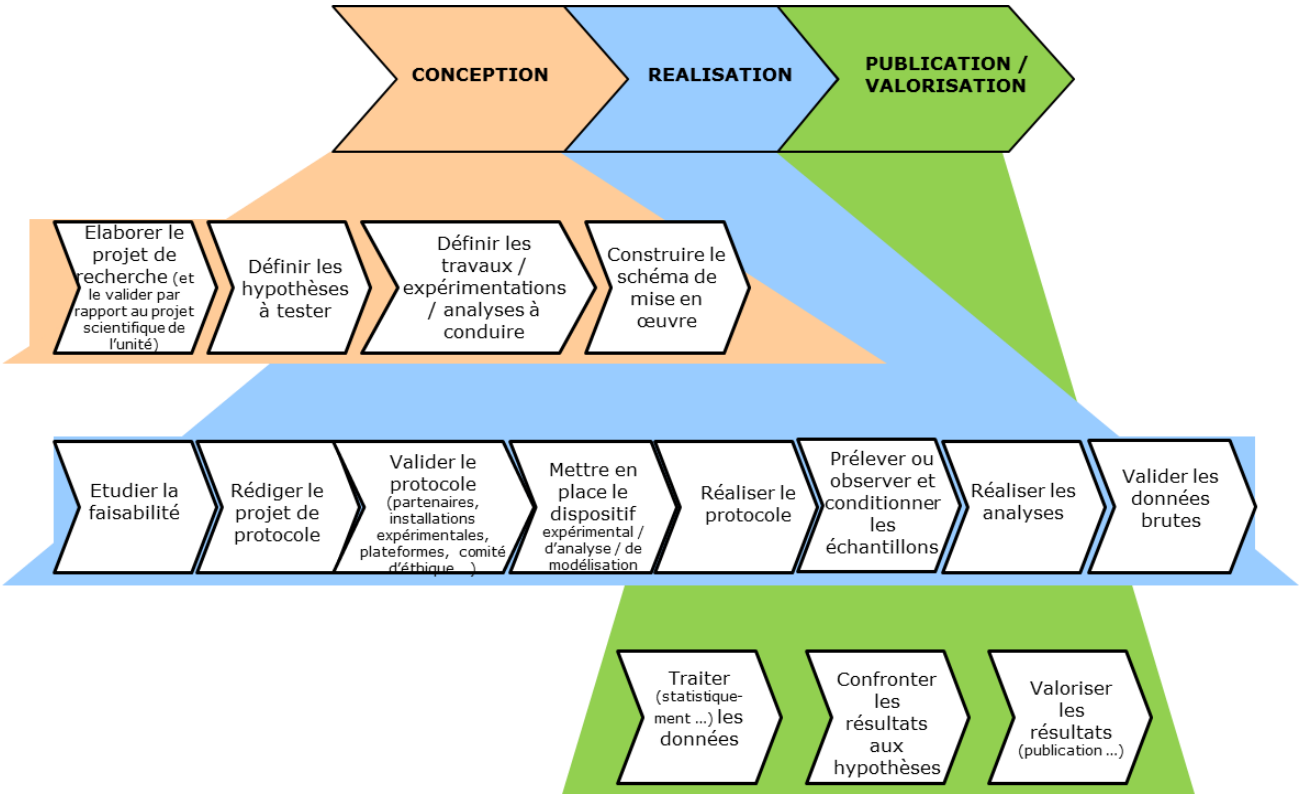
The research activities therefore use a set of correlated activities, called a process, having input and output elements, to create value-added.

The "process approach" consists of identifying the processes and their interactions and to manage them in order to attain set objectives.

The unit describes, controls and manages its processes for conducting research and experimentation.

Recommendation: The unit may also adopt the process approach for all other activities for which it believes that this approach will be beneficial.

Example of research process



3.2 Planning and Organisation

AQR **The unit identifies the research projects it undertakes.**

AQR **The unit identifies and implements the methods and tools for conducting a project (stages, deliverables, milestones, planning, etc.) applicable to the various types of research projects that it carries out, taking into account the commitments contracted with partners (PCRD, ANR, socio-economic partners etc.) and the requirements of its supervisory bodies (scientific departments, institutions etc.) in relation to the research questions.**

AQR **It retains the records arising from the use of these methods and tools for the projects concerned.**

Recommendation: Elicit feedback on projects that the unit has submitted to calls for projects (ANR, PCRD …), including for non-selected projects.

3.3 Research and/or Experimental Protocols

Starting from research questions and scientific hypotheses, a set of activities is carried out, the most often involving several actors.

These activities (experiments, tests, experiments, analyses etc.) are carried out using a research and/or experimental protocol which is guiding thread and the backbone of the workflow of the activities.

Note: The research projects or programmes (European projects, ANR projects etc.) most often require the preparation of several research and/or experimental protocols.

AQR **The research and/or experimental protocol includes:**

- **the objectives of the protocol in relation to the research project;**

- and the resources that are needed to achieve them:
  - the methods used, including for the modelling, planned statistical analyses, specific instructions,
  - materials and/or resources and facilities used,
  - the intervening entities and the persons or particular skills used,
  - the provisional timetable,
  - the points of vigilance and the arrangement for information feedback in the event of a change in the implementation of the protocol that may have an impact on the result,
  - the planned promotion,
  - the retention period for samples and data, or even specific arrangements for storing and backing up the data,
  - the specific constraints of confidentiality if relevant.

AQR The unit defines and uses a standard format for research and/or experimental protocols.

AQR The scientist, or the person in charge of the research to be undertaken, drafts the research and/or experimental protocol, presents it to the different actors who will contribute to it, which allows its feasibility to be checked collectively, to take into account the different actors' comments and proposals, to validate the actions to be performed and the way they should be performed as well as the timetable.

AQR The reference person for the research and/or experimental protocol (the person from whom it originates) and the responsibilities at each stage are identified.

AQR Each actor of the research and/or experimental protocol monitors its preparation, ensures its traceability and is accountable to the other actors of its implementation particularly in the case of a modification. In this case, the changes are logged and if necessary a new schedule is defined.

AQR Once the research and/or experimental protocol has been prepared, the person in charge of the protocol organises information feedback on the results and experience feedback on its implementation with the stakeholders.

3.4 Control of Samples

A sample is a piece of biological and/or mineral material which undergoes research or experimentation in the INRA's units. A sample may be observed, measured, sub-sampled, etc.

Examples of samples: animals, organs, hair, blood, faeces, urine, semen, various tissues, various cells, DNA, RNA, serum, soil, water, whole plant, seed, leaf, flower, parasite, pathogen, virus, bacterium, etc.

In terms of identification and traceability of a sample, the objective is to be able, for any sample, easily find where it comes from, to whom it "belongs", to which protocol(s) or project(s) it relates, what it has undergone throughout its life-cycle, and vice versa be able to access all the samples and related data relating to a research and/or experimental protocol.

AQR The unit identifies the different types of samples that it uses for the different types of research projects that it undertakes.

AQR It identifies the life cycles of these different types of samples, the length use of the samples and the results that will result from them, and analyses the risks for the reliability of the results, for the personnel and for the environment, and according to the current regulations.

AQR For each of these types of samples, the unit defines the arrangements for:

- reception and/or production or sampling,

- **labelling and identification,**
- **storage,**
- **preparation,**
- **aliquoting,**
- **analysis,**
- **retention (means, duration etc.),**
- **distribution (internal or external), including**
  - **checks to perform before distribution,**
  - **the conditions for transferring materials outside the unit: Material Transfer Agreement (MTA) that the partners return before shipment,**
- **carriage,**
- **removal,**

and drafts the procedures and defines the related records.

Recommendations:

- *To find out about the conditions for the retention of samples and the checks to be carried out to ensure their quality, according to the nature of the sample, the Biological Resource Centres (CRB) are useful interlocutors.*
- *The retention period for a sample is calculated in terms of the regulations, contractual undertaking, specification in the implemented protocol and in terms of efficiency: under the defined storage conditions, is the sample still usable? Do people know where to find it? ...*

3.5 Control of Methods

3.5.1 Formalisation of Methods

AQR **Any sampling, measuring and analysis operation which has an impact on the reliability of the result undergoes formalisation, in a laboratory book if the method is being developed, and in an operating guide if it is stabilised and repetitive.**

AQR **The unit lists the operating methods to be formalised, plans their drafting, drafts them, distributes them on the media that it considers appropriate to ensure that they are used during the implementation of the operations.**

AQR **The unit defines and uses a standard format to draft its operating methods.**

Recommendations:

- *Integrate in these operating methods the prevention and protection of the environment aspects, to ensure that the operators only have to refer to a single document.*
- *Drafting can be performed in the form of texts, diagrams, pictures etc. and refer to suppliers' documents for the equipment, for example.*
- *Adapt the level of detail to the context: the number of different persons performing the operation, the criticality of the operation etc.*
- *Train / assist new personnel who perform the operations (see Human Resources Management 4.1).*

3.5.2 Validation of methods

Validating a method consists of providing proof that it is appropriate in relation to the subject-matter to be addressed, and therefore that it satisfies the conditions required to produce interpretable results with a known risk.

The methods concerned are: non-standardised methods, methods designed and developed internally, changes to standardised methods and standardised methods used outside their scope of application.


The unit identifies the critical methods in relation to the reliability of the results and non-standardised, on the basis of the needs defined by the scientists.


The unit defines the validation procedures for these methods (experiment plan, inter-laboratory comparison, accuracy profile etc.), schedules the validation and records the results of the validation.

Recommendations:

- *For the quantitative analysis methods, the INRA has contributed to the development of the "accuracy profile" method and advocates its use. This method is recognised by the V03-110 standard. For its implementation, refer to the special edition of the INRA Techniques Book published in 2010.*
- *A summary table of the results of the validation may be included in the operating guide for implementation of the method.*

3.5.3 Uncertainty Associated with Quantitative Results

The uncertainty associated with a measurement result allows a quantitative indication about the quality of this result to be provided. This indication is often essential for the interpretation of the result.


For the quantitative results, the estimate of uncertainty is given with the result itself.

3.6 Control of Data

To establish the continuity of traceability between project / protocol / experimentation / sample / analysis / result and enable the rapid and long-term use of research work, at each step and for each of the activities:


The unit identifies the different types of data that it produces and uses, for the different types of research projects that it undertakes.


For each of the data types, the unit defines

- **the retention period for data, their media and places of storage and archiving, according to the data's life cycle, traceability requirements, the regulations, purpose (in particular for intellectual property), the volume of the data etc.**
- **the metadata (information about the data: origin and intrinsic characteristics and/or related to the conditions of their production: devices, software etc.) to associate with the data as well as the storage and archiving methods for these metadata.**


The unit defines and implements appropriate methods for backing up its digital data and metadata.


The unit ensures the retention and integrity of the raw data and associated metadata, the retention period that it has defined (in compliance with the rules of confidentiality and in accordance with the agreements made with the owners of the data or decision-making bodies).


The unit ensures access to these data (media, software versions etc.) for the retention period it has defined (in compliance with the rules of confidentiality and in accordance with the agreements made with the owners of the data or decision-making bodies); it quotes or ensures the users quote the exact sources of the data used.


The unit defines and ensures the traceability of the processing and methods of data analysis used.

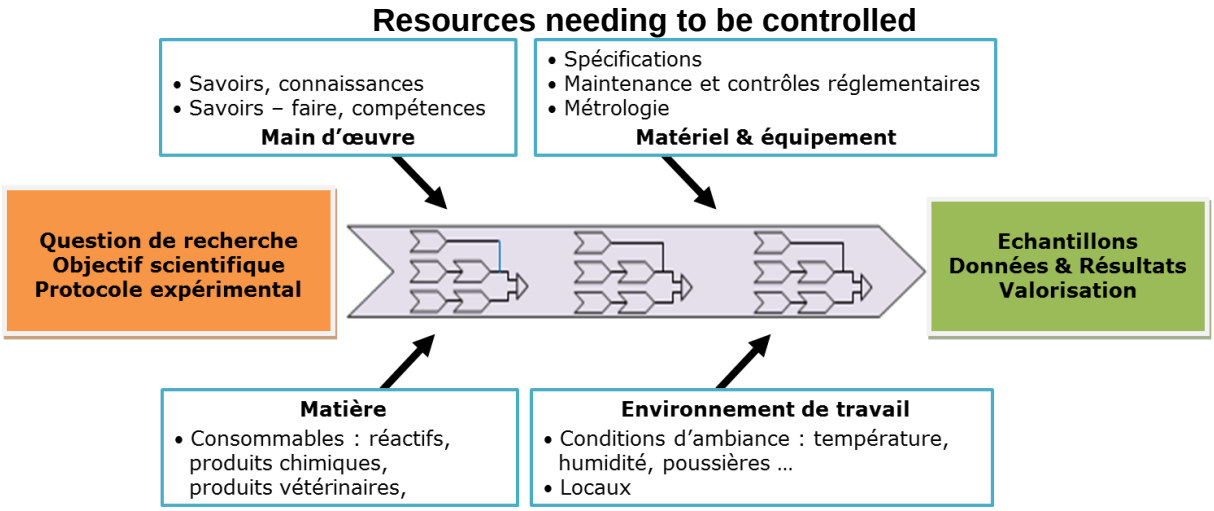
Improvement in the quality of the data is a continuous and iterative process. At the end of certain processing, the user of the data may have identified some errors that should be corrected for the benefit of all the users (feedback). The unit reports the identified errors and vice versa processes the errors which he fed back to it.

Recommendations:

- *Storage, backup and/or archiving may be undertaken by the unit or outside.*
- *Design common rules for naming and archiving, set up procedures for backup, storage and retention in identifiable places or spaces, accessible to other authorised users.*
- *The retention period is calculated in terms of regulations, contractual commitment, specifications in the protocol implemented, volume of data and in terms of efficiency: in the defined retention conditions, is the datum still usable? Do you know where to find and how to read it? ...*
- *The reliability of the data implies the possibility of monitoring their different states throughout their life-cycle, tracking them and keeping the operations performed on the data at each stage (verification, correction, improvement, enrichment etc.), before making them available to users, to preserve the files containing the scripts and procedures applied to the data sets and not to resort to manual operations not leaving any trace (such as copy/paste).*
- *The availability of the information about the data (metadata) is essential to enable the proper understanding of their content and their degree of elaboration (at what stage of the life cycle they are); this leads to the standardisation of this information through the use of metadata standards, ontologies and thesauri.*

4 Management of Resources

Control of the activities implies that the different kinds of resources are also controlled.



4.1 Management of Human Resources

To ensure control of the research work, the unit:

- **identifies the skills (knowledge, expertise, experience) needed to undertake the research and experimentation activities;**
- **identifies the training needs (internal or external) and defines the priorities, formalised in the annual training plan;**
- **monitors the implementation of this plan and verifies that these training courses meet the need;**
- **ensures reception of personnel (context of the unit including workplace safety and quality, missions etc.), the supervision and learning of new people (temporary personnel, newly hired personnel etc.); it drafts a**

procedure for personnel arriving at and leaving the unit: booklet, reception and departure information sheets etc.;

- **retains documentary evidence (diplomas, accreditation to direct research, training and/or tutoring certificates etc.) of initial and vocational training, expertise, experience and regulatory clearance and accreditation (animal testing, radiation protection, autoclaves etc.) or knows where to access it.**

Recommendations:

- ***The establishment of a matrix of knowledge and expertise allows the necessary / present skills to be identified and to identify fragile situations (key skills held by a single person etc.) in order to be able to consolidate them.***
- ***Include in the procedure/ the new personnel booklet, the aspects of quality, prevention, sustainable development, practical life etc. which are specific to the unit, and pool what is shared in the research centre's reception procedure.***
- ***Define a "charter" of the respective rights and duties of supervisors and non-permanent supervised personnel.***
- ***Recruitment by profile by a judges' panel constitutes sufficient evidence to attest that the recruited person has the skills required by the profile.***

The documents proof of personnel qualifications and training may be requested from the unit as part of scientific calls for proposals.

4.2 Control of Equipment and Materials

The unit manages equipment it has identified as having an impact on the quality of the result and equipment that is subject to regulations.

Recommendation: Special attention needs to be paid to organising the management of shared equipment and the sharing of information about this organisation.

4.2.1 Control of Equipment

AQR **The Unit maintains an inventory of its equipment (model, manufacturer's name, serial number, internal identification number and/or accounting number, commissioning date, location, person(s) responsible for it etc.).**

AQR **The unit determines what its critical equipment is: items which have an impact on the reliability of the results or are the subject to a regulation, in order to put in place appropriate arrangements in terms of purchasing, maintenance, monitoring, calibration and verification etc.**

AQR **For the acquisition of this critical equipment, it analyses the need, and formalises the specifications (technical features) and includes the metrological manager in making the choice.**

AQR **On receipt of new critical equipment and before it is commissioned, it performs checks or has them performed (including calibrations) that it considers necessary to ensure compliance with the need and the specifications of the technical specifications.**

AQR **The equipment is used in accordance with the manufacturer's instructions and those defined by the unit depending on the need, the diversity of the users, imperatives of safety in the workplace etc.**

AQR **Critical equipment is maintained, calibrated and checked and/or monitored (control cards for example) to meet the requirements of the reliability of the results, safety in the workplace, the lifetime of the appliance and the regulations.**

AQR **For critical equipment, these operations are written and available:**

- **procedure(s) for managing/controlling equipment (type of actions, frequency, the people involved etc.),**

- **instructions for use, maintenance, calibration/verification, monitoring.**

These operations are recorded (log books recording the dates and results of incidents and faults, adjustments, repairs, calibrations, checks etc.).

The unit ensures that devices that are decommissioned or taken out of service are not used by accident.

When a device is declared non-compliant, the validity of results previously obtained must be re-examined.

Recommendations:

- *Place the documents relating to a device close to it so that they are easily accessible and used.*
- *Define a standard format for specifications to facilitate drafting.*
- *With the aim of simplifying the management of equipment, generalise all or part of the provisions defined for critical equipment to other equipment.*

Note: the prevention of risks to personnel is taken into account as part of the risk control procedures, formalised in the action plan in the single document (OPPI at the INRA).

4.2.2 Metrological Connection

The unit identifies its needs for connecting to the international system.

Where the unit cannot or does not want make this connection, but has identified the need to ensure the proper functioning of an item of equipment, it defines other means such as inter-laboratory comparisons, the use of reference materials, etc.

The traceability of the metrological connection or other verification operations is recorded.

The unit drafts a procedure for managing its calibrations and reference materials/samples: reception methods, identification, storage, preparation, use, verification, retention and disposal.

4.3 Control of the working environment

The unit is responsible for monitoring, recording and, if possible, controlling ambient conditions when these have an impact on the quality of the research results.

Recommendation: According to the case, particular attention should be paid to biological sterility, dust, electromagnetic interference, radiation, moisture, temperature, noise, vibration, the use of detergents for the cleaning of the premises, etc.

4.4 Control of supplies, products and reagents

For its activities, the unit uses chemicals, solvents, biological solutions, reagents, plant protection or pharmaceutical products etc., that it purchases or prepares itself, as well as that of small items (tubes, gloves etc.) which are often single-use ones: consumables.

The unit identifies the consumables and products or reagents which have an impact on the reliability of the results.

The unit is responsible for the traceability of the use of these consumables and products (chemicals, plant protection products, solvents, biological reagents, etc.). The traceability is organised for batches when the reliability of the results depends on this.

AQR **The level of control of the consumables and products is adapted: provisions are made to prevent the risks of breaks in availability, to avoid the unintentional use of consumables, products or reagents which are obsolete or from different batches for the same action if the batch has an impact on the result etc.**

AQR **The storage of these consumables, products and reagents must be in accordance with the regulations and the manufacturer's specifications. Safety instructions are accessible and observed.**

4.5 Control of sub-contracted activities

Where a unit does not have in-house expertise or equipment available to perform an experiment, a measurement, an analysis, a calibration or a metrological connection, it may need to sub-contract.

AQR **Where the unit sub-contracts an activity which is likely to have an impact on the reliability of the results, it defines its requirements and the information to be reported back to it in a technical specifications document, checks the competency of the provider and defines the controls to be performed as well as the elements to be logged: operating procedure(s) used, calibration certificate, etc.**

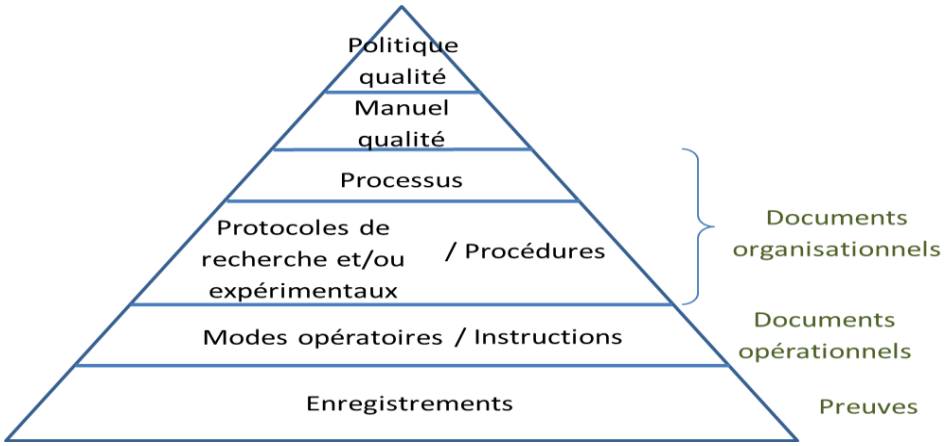
5 Control of the documentation

5.1. Documentary Pyramid - definitions

The unit's documentation in particular includes:

- **documents and records relating to the quality system;**
- **documents and records relating to other areas of the unit's activity;**
- **external documentation.**

Documentary Pyramid



Definitions:

- **Quality Policy (see 2.1): formalisation of the objectives and directions of the unit's quality procedures.**
- **Quality Manual: document presenting an overall view of the unit's quality system.**
- **Process (see 3.1): set of activities with input and output elements. Operating effectively requires identifying and managing many interrelated and interactive processes: often, the output element of a process is the input element of the following process. The identification and management of methodical processes, and more particularly the interactions of these processes, are called "the process approach" (source: ISO 9000). The "process" documents identify the processes and their interactions (input data, output 'products', actors, key points, indicators etc.).**

- **Research / Experimental Protocol (see 3.2): document summarising the objectives in relation to the research question and the activities, people in charge and resources which/who will be involved.**
- **Procedure: a document that describes what must be done, who should do it, when, where, how and with what (equipment, documents, what must be recorded, etc.).**
- **Operating guide and instruction: operational documents that describe in detail how an operation and/or a task are performed. These operational documents are called operating guides where they relate to laboratory and field activities. They can be called instructions where they relate to equipment or administrative operations.**
- **Record: a document containing results obtained or providing the evidence of the performance of an activity. The term record may also describe the recording medium.**

5.2 Management of the documentation

5.2.1 General Information


The Unit prepares (a) procedure(s) for controlling the documentation to:

- **Uniquely identify and codify its documents (for easy reference);**
- **check (the substance) and approve (the format) of the documents before their distribution;**
- **review and update as necessary and check / approve the documents again;**
- **ensure that they include a means to identify the version (date, version No. etc.);**
- **ensure the availability on the places of use of up-to-date versions of the documents;**
- **ensure that documents remain legible and readily identifiable;**
- **prevent any unintentional use of obsolete documents and identify these appropriately.**


The unit lists the documents (procedures, operating guides, instructions, ...) that it considers necessary to write to ensure the traceability of the research work and the reliability of the measurable results, the durability of the expertise and compliance with the regulations applicable to its activities and it plans their preparation.


The Unit prepares and distributes these documents, and, as a minimum, those required by these guidelines:

- **The Unit's Quality Policy (2.1)**
- **Mission Statements (2.1)**
- **Action Plans (2.1, 2.2 and 6.4)**
- **Research and/or Experimental Protocols (3.3)**
- **Procedures for managing samples and in particular control procedures before distribution (3.4)**
- **Operating guides for the methods used (3.5)**
- **Training plans (4.1)**
- **Procedure(s) for personnel on arrival and departure from the unit (4.1)**
- **Procedure(s) for managing critical equipment, and operating guides (4.2.1)**
- **Procedure(s) for managing standards and reference materials (4.2.2)**
- **Procedure(s) for managing documentation and records (5.2)**
- **Quality Manual (5.2.3)**
- **Description of Processes (5.2.4)**
- **Procedure for managing traceability / laboratory log books (5.2.8)**
- **Self-assessment (6.2)**

Recommendations:

- *Establish document types, according to the management methods to which they are subject.*
- *Adapt the level of detail to the context: number of users and personnel turn-over, criticality of the activity etc.*
- *In research, certain practices are difficult to stabilise (permanent looping-back of the research). The related documents may then not be managed according to the strict provisions above, however their traceability is required.*
- *Identify changes to documents (e.g. bars in the margin, colour etc.) to facilitate their identification by their users.*

Note: confidential / restricted documents may only be referred to under a codified form, and their content may only be accessible with the manager's agreement.

5.2.2 Quality Policy

The quality policy is defined by the Unit Director (cf 2.1). Its support is managed as a record (see 5.2.8).

5.2.3 Quality Manual

The quality manual is a tool used for presenting the unit's procedures and system, both to the personnel of the unit and to its partners or customers.

AQR **The Unit prepares and keeps up-to-date a quality manual describing its quality system:**

- **The unit's quality policy and the objectives fixed or the reference to these;**
- **an overview of the unit and its processes;**
- **the reference to the organisational and operational documents of the quality system.**

Recommendations:

- *Obtain a translation of this quality manual in English.*
- *Write the quality manual after having begun to build the quality system.*

5.2.4 Process Management

Almost all of the topics covered in these guidelines can be analysed and managed using the process approach.

The description of the processes includes the main activities which compose it, the actors involved, the input elements and the output "products", the associated procedures and records, and the process indicators.

AQR **The Unit defines the standard format for the description of the processes, which makes preparing (check-list) and reading them easier.**

AQR **The unit drafts its process for conducting research and experiments and for all other processes for which it considers this formalisation to be useful.**

5.2.5 Management of research and/or experimental protocols

AQR **The Unit defines the standard format for its protocols, which makes preparing (check-list) and reading them easier.**

AQR **The unit ensures traceability of the research and/or experimental protocols and their archiving.**

5.2.6 Management of procedures

AQR **The Unit defines the standard format for its procedures, and manages their validation, their update, their distribution and their withdrawal.**

5.2.7 Management of operating guides and instructions

AQR **The Unit defines the standard format for its operating guides and instructions, and manages their validation, their update, their distribution their withdrawal and their archiving.**

Recommendation: It is not necessary to rewrite standardised methods or other recognised specifications if they are used in their original form. They should be managed as external documentation (5.3). However, any changes must be described and logged in any relevant recording medium.

5.2.8 Control of records

The specific records relating to the quality system provide evidence of the implementation of the quality system.

e.g.: quality policy, protocol and operating guide standard formats, process sheet, audit report, quality review /outcome report, self-assessment report, log book, calibration certificate and verification certificate, control card, etc.

AQR **The records relating to the quality system are classified and archived so that they can be retrieved easily.**

AQR **A procedure for controlling specific records of the quality system is drafted to ensure their identification, their accessibility, their classification, their archiving and their elimination.**

Recommendations:

- *Each recording medium (form, file etc.) contains data areas identifying the record (metadata): title, date of update, pagination, path and version of the software for digital files ...*
- *Define forms for the records, so that all the information is contained on each record.*

The unit has many other records relating to its activities, for example flowcharts, research and/or experimental protocols, requests for analysis or experimentation, observations, calculations, job schedules, parcel maps, data files, images, photographs, log books ... and of course the publications: scientific journals, periodicals, books, communications at conferences, theses, dissertations, reports and minutes, etc.

The standard formats of these various documents, when they exist, are managed as specific records within the quality system.

AQR **The unit establishes the list of records that it considers necessary to write to ensure the traceability of the research work.**

AQR **These records are sorted and archived so that they can be retrieved easily. They must be able to be connected to the operation or to the project from which they originate. The requirements of records contained in the research contracts are taken into account.**

AQR **When the content of a document has been modified or could not be applied as planned, describe, on any relevant recording medium, the changes and/or the reasons for their non-application, in order to preserve traceability and facilitate feedback.**

Recommendations:

- *Define the retention times for records, in particular when signing contracts.*
- *In the case of electronic records, take all the necessary measures to avoid their unintended modification or the loss of the original data.*
- *To name the files:*
  - *choose a short and meaningful name;*
  - *use only numbers, non-accented letters and the following characters '_' or '-' or '.'. All other , so-called 'special' characters should not be used;*

- *avoid including spaces in the file name*
- *for dates, the year month day format (e.g. 2012_01_16 or 120116 or 12-01-16) may facilitate sorting and filing.*

- *Use the experimental protocol or project No. as an element of the identification marking (coding) of all the documents and samples that are related to it, in order to make traceability easier.*
- *Using the ProdInra application is sufficient in principle for managing publications and other written "products" of the research.*

Managing log books

The term, traceability log book, includes laboratory notebooks, experiment log books, input/output records, incident log books, care log books, livestock records, etc.

AQR **The Unit drafts the rules for managing and using traceability log books: identification, allocation, use, storage and archiving.**

Recommendation: for laboratory notebooks, particular attention is paid to the application by non-permanent personnel of the provisions that the unit has defined.

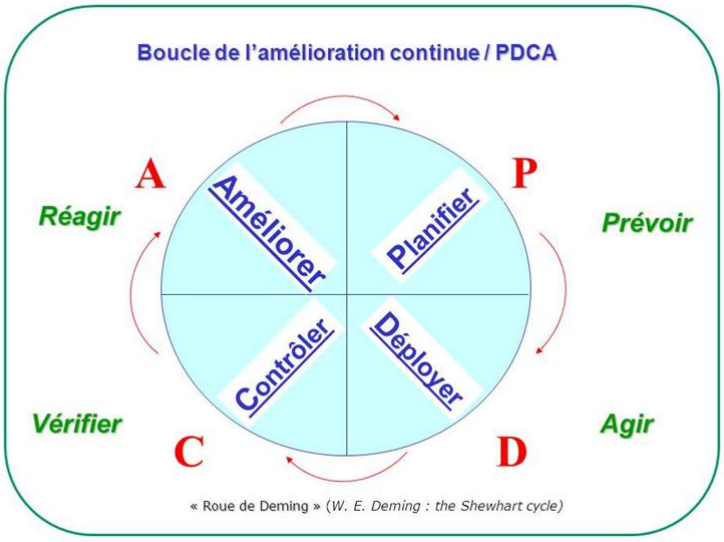
5.3 External Documentation

Documentation of external origin includes as a minimum scientific and technical documentation (bibliography, user manuals, etc.), standards, and the regulations applicable to the unit's activities.

AQR **The external documentation relating to the unit's activities with an impact on the reliability of the results or the traceability of the research work is filed so as to be easily retrievable.**

6 Measurements, analysis and improvement

The unit continuously improves its way of operating and its quality management system by using the quality policy, quality objectives, the results of self-assessments and audits, improvement actions and Quality reviews.



6.1 Indicators

An indicator is a decision-making tool which allows the effectiveness of a system to be measured which is observable, measurable and/or determined through calculation and which identifies in a quantifiable manner (thresholds, trends, acceptable levels, etc.) an improvement or deterioration of the subject-matter examined.

 **The Unit defines the indicators it considers relevant to its research and experimentation activities and in relation to its quality policy, ensures their monitoring and promotes their use internally and in relation to its supervisory bodies.**

Recommendations:

- *A good indicator is "SMART": Simple/Specific, Measurable, Acceptable, Realistic and Temporal.*
- *Indicators may measure progress, effectiveness or results. These must not be overdone!*
- *Re-evaluate one's indicators periodically in light of changes to objectives and the results obtained.*

6.2 Self-assessment

Self-assessment is a simple and factual method which has a dual objective:

- **It is a tool for planning the implementation of the quality approach in the unit,**
- **it measures the progress of the implementation and life of the quality system and is one of the unit's quality indicators.**

The self-assessment tool is built as part of a logic of continuous improvement: action identified - planned / defined - formalised / implementation - used / evaluated - revised.

 **The unit performs this self-assessment annually, and forwards it to the supervising department(s) and centre correspondents and to the quality delegation.**

6.3 Internal quality audits

Quality audits are performed by auditors who are independent from the unit, to assess:

- **the compliance of the unit's quality management system with the requirements of the present guidelines;**
- **the effective and permanent implementation of the quality system and the effectiveness of the quality measures performed by the unit.**

Two types of quality audits are practised:

- **consulting audit, in which the definition of the breadth and scope of the audit is on the unit's initiative in consultation with the auditors, and with a large consulting part,**
- **compliance audit, using the model of the third party audits (certification ISO 9001 for example), and at the end of which the auditors assess the unit's compliance in relation to the present guidelines. This compliance audit may concern only a part of the Inra's and/or of the unit's quality guidelines. Where compliance is recognised, this recognition is given for two years, and a new compliance audit may lead to a renewal for two years.**

 **The Unit Director organises, at least as often as the unit's scientific assessments, an internal quality audit; he chooses the type of audit (consulting audit or compliance audit) and, for a compliance audit, its scope.**

The INRA's quality delegation organises audits according to the present INRA guidelines.

6.4 Improvement actions

The feedback and contribution of all the actors are the main sources of progress. In particular following audits, self-assessments or incidents, ideas for improvement are envisaged.

 **The unit puts in place arrangements for logging anomalies or suggestions for improvement.**

 **The unit performs actions to eliminate the causes of malfunctions so they do not recur: analysis and study, including the analysis of the causes, research and choice of solutions, planning, implementation and verification of their effectiveness.**

Recommendations:

- *The unit may put in place a procedure for processing all the anomalies and suggestions according to the above principle: classification (type, consequences etc.), attribution (who is going to deal with it), stages of the investigation including the analysis of causes, research and the choice of solutions, planning of the implementation of the solutions, implementation and finally the verification of the effectiveness of the solutions.*
- *All anomalies or suggestions should not be dealt with one by one since the classification may result in a decision to do nothing in the immediate future. However, a periodic review of all the anomalies and suggestions may generate a decision to act (repeated "minor" problems etc.).*

These actions may be described as

- **curative when they are intended to correct a failing (e.g. repeat the analysis etc.),**
- **corrective when they seek to correct the causes of a problem so that it does not recur,**
- **preventive when they are designed to avoid the occurrence of a potential risk.**

6.5 Quality Review


As already indicated in paragraph 2.1, the unit examines, at a set frequency, the outcome and results of the actions undertaken and assesses their effectiveness, on the basis of self-assessments, audits and indicators.


It defines accordingly what new objectives and actions to engage.


As indicated in 2.1, the Unit Director and the Quality Coordinator communicate to the whole of the unit the decisions thus taken.