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An overview of Quality Management System implementation in a research laboratory

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Abstract. The aim of this paper is to show the advantages of implementing a Quality Management System (QMS) in a research laboratory in order to improve the management of risks specific to research programmes and to increase the reliability of results. This paper also presents experience gained from feedback following the implementation of the Quality process in a research laboratory at INRA, the French National Institute for Agronomic Research and details the various challenges encountered and solutions proposed to help achieve smoother adoption of a QMS process. The 7Ms (Management, Measurement, Manpower, Methods, Materials, Machinery, Mother-nature) methodology based on the Ishikawa 'Fishbone' diagram is used to show the effectiveness of the actions considered by a QMS, which involve both the organization and the activities of the laboratory. Practical examples illustrate the benefits and improvements observed in the laboratory.

Keywords: Quality / research / reliability / management / measurement / manpower / methods / materials / machinery / mother-nature

1 Introduction

Over recent years, a number of public sector research entities have been adopting a Quality process in order to improve their organization. In France, French standards association (AFNOR) formally recommends adoption of a Quality process by scientists [1,2]. However, implementation of a quality process in a public organization can come up against specific problems not encountered in a private organization [3]. Research requires both rigour and transparency in the production of knowledge, and involves specificities in terms of objectives, resources and organizational skills that can be very different from those of the industrial sector in which a Quality process has traditionally been found. In view of this, it is clear that the

implementation of a Quality Management System (QMS) within a public research organization cannot be carried out in the same way as in industry [4]. Clearly, the specific challenges that may be encountered in a research laboratory need to be addressed via specific solutions and actions to ensure the success of a QMS.

In the literature, few papers [5–7] deal with the implementation impact of QMS in a research laboratory. Spencer et al. [5] underline the advantages in Quality assessment of qualitative research for evaluations of research programmes. The quality of scientific research is often uneven and lacking in credibility, making it difficult to make a confident, concrete assertion or prediction regarding evidence for improving practice or consumer outcomes [6,7]. The debate is also due, in part, to the lack of consensus on the specific standards for assessing Quality research. Edmondson et al. [8] introduce a framework for assessing and promoting methodological fit as an

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overarching criterion for ensuring quality field research. Baker [9], Begley et al. [10], Giesen et al. [11,12], Bareille et al. [13] show the importance of a Quality process in sciences for improving research management and reliability.

In this paper, we identify the advantages of implementing a QMS in a laboratory of INRA, the French National Institute for Agronomic Research, whose mission is to produce and publish knowledge gained through reliable results, train researchers, offer expertise, create, and innovate.

After presentation of the quality policy of the laboratory, several Quality main actions are developed and discussed using a modified Ishikawa diagram [7Ms: Management, Measurement, Manpower, Methods, Materials, Machinery, Mother-nature (environment)] in order to show the effectiveness of implementing the QMS, which involve both the organization and the activities of the laboratory.

Practical examples are presented to demonstrate the benefits and improvements achieved by implementing a QMS in a research laboratory, as well as the challenges encountered and the solutions proposed to deal with these. The methodology uses the first author's own feedback drawn from three years' experience as Quality Manager in an INRA Laboratory.

2 Presentation of the laboratory and its Quality policy

2.1 Organization of the laboratory

The research laboratory (or to give it the INRA term, Unit) under observation was created in January, 2012 and is a relatively complex structure, operating under the auspices of three separate Institutions: INRA (French national institute for agronomic research), a School of Engineering (Agrocampus Ouest) specialized in agronomy and horticulture, and a University (University of Angers). As regards INRA, the laboratory is attached to three different scientific divisions, each covering several disciplinary fields where the research constantly explores new ground. The laboratory is the result of the merger of four MRUs (Mixed Research Unit), and currently numbers some 230 staff members organized into 16 teams (Fig. 1). From INRA's point of view, this is a Very large scale unit (VLSU), as the number of staff exceeds 100, whereas the average number of staff in an INRA Unit is 25. However, we have become increasingly accustomed over recent years to Units that merge with a view to pooling resources (i.e. sharing equipment and reducing the number of posts in Research Support Services while giving greater visibility to the Units). The laboratory is therefore of recent formation and has been subjected to extensive structural change.

The laboratory conducts research projects in seeds and horticulture. It is committed to an integrated approach of coordinated effort and expertise in the fields of genetics, epigenetics, genomics, pathology, physiology, ecophysiology, biochemistry, modelling, statistics, and bioinformatics.

Prior to the creation of the laboratory in 2012, the four former MRU (Mixed research unit) teams were located on different geographical sites. Figure 1 also shows the institutional membership of the laboratory staff. The INRA teams had already begun implementation of a Quality process in the year 2000.

MRU 1 had been internally audited by the INRA Quality task force in 2008 in accordance with INRA Guidelines Version 1 [14]. The result of this audit concerning management responsibility, documentation and resources management was highly complimentary reflecting the considerable efforts the MRU had made to meet the requirements of the INRA Guidelines version 1.

MRU 2, a Biology Resource Centre (BRC) has had ISO 9001 certification [15] since 2008. This BRC has achieved international renown and has a very dedicated Quality manager.

In MRU 3, a Quality process had been introduced. Quality, equipment and metrology managers were appointed in this research unit.

MRU 4 was operating under the auspices of a University that had not adopted a Quality process for its research departments. The same was true for the teams working for the School of Engineering, which had ISO 9001 certification for academic activities only but not for the research activities. Nevertheless, all university and engineering school teams were using laboratory notebooks, had drawn up operating procedures, conducted equipment inventories, implemented life cycle files or equipment monitoring logs, and observed the minimum requirements concerning external checking of pipettes and weighing scales.

The merging of these four MRUs however created a number of challenges for which several actions were used:

- The first one was due to administrative dissimilarities between the three institutions (INRA, the School of engineering and the university). This obstacle has been solved by delegating management of the new VLSU to INRA via a contractual agreement;
- The second one concerned the multidisciplinary nature of the scientific community and the need to get individuals with different backgrounds and habits working efficiently together as well as to create synergy around Quality within the laboratory. This necessity had already been identified when the four MRUs were created, and became even more apparent when the VLSU came into being. The laboratory defined an objective of constructing a common QMS for all its research activities. One of the actions decided upon was the recruiting in September 2013 of a Quality manager to work full-time on Quality, health, safety and environment;
- The Quality manager's first task was to establish an inventory of the existing situation, before moving the laboratory towards harmonization of all practices, bringing them in line with INRA guidelines version 2 [16]. However, teams that had made significant progress as regards quality felt that they were being made to regress following the merger and there has been a need to involve and remotivate them via the Quality actions undertaken;

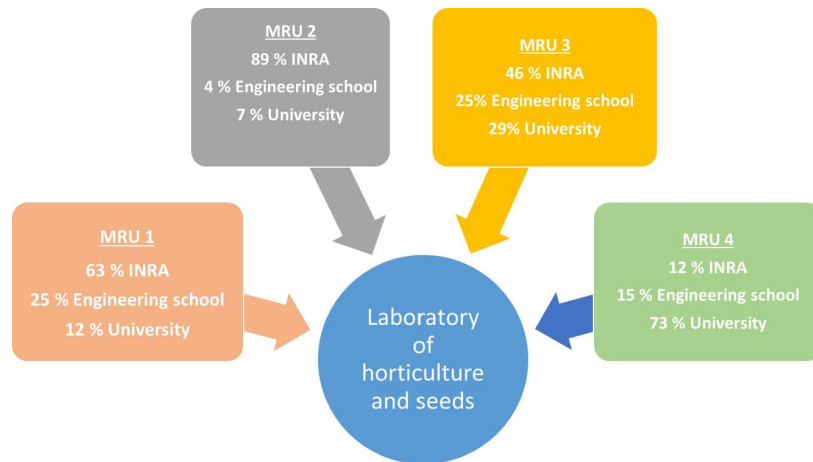


Fig. 1. Institutional membership of laboratory staff.

– The third one was the geographical spread of the teams. In 2012, all teams were still dispersed over four distant sites. Communication and common working were facilitated when the Institutions that benefit from county council funding received a brand new building, which enabled teams to be relocated to a single site during the summer months of 2015.

2.2 The key to success: a committed Management Board

The success of a QMS depends on the commitment of staff, and most particularly that of top management. This commitment was formally expressed in a Quality policy statement (an obligatory step for any organization with ISO 9001 certification [15] or EN ISO/IEC 17025 accreditation [17]). The Quality policy outlines the objectives of the organization and the planned operational rollout of the associated action plan.

For INRA, the aim of the Quality process is to further the pursuit of scientific excellence, while enhancing the attractiveness and creativity of its Research and Experimental Units. This aim is stressed in the letter explaining the Quality policy written by the Laboratory manager. In parallel with the INRA management board, the biology laboratory sent out a letter outlining its main focuses and annual priorities. The actions set up as part of the implementation of the QMS within the laboratory are based on the INRA global Quality policy and the INRA Quality guidelines Version 2, itself based on the ISO 9001 Standard. The laboratory's Quality process actions seek to:

- Guarantee reliability of measurable results via controlled methods and equipment;
- Ensure traceability of research work;
- Contribute to long-term conservation of data;
- Guarantee quality of biological materials;
- Guarantee quality of services provided by Biology Resource Centres (BRC);
- Manage samples;
- Contribute to human and environmental as well as collaborator risk management;

- Ensure appropriate planning and organization of projects;
- Harmonize practices, methods and operating procedures common to various teams;
- Instigate appropriate and effective improvements.

2.3 Choosing Quality guidelines appropriate to a research organization

Convinced of the absolute necessity of the Quality process in the scientific environment, INRA officially embarked upon the Quality process in the year 2000. The INRA management coordination committee sent out its first Quality policy statement in March of that same year and instigated the INRA Quality task force. In 2005, INRA published its first Guidelines (Version 1) as well as introducing a self-assessment tool for the Units. These first Guidelines comprised five chapters: Quality Management and management responsibility; Documentation; Management of resources; Core activities; and Measurements, Analysis and improvement. In 2006, the first steps towards implementing the Quality process came into effect in INRA support services. A review of actions undertaken between 2000 and 2009 reveals the support given to the Quality process by the INRA Board of Management, the commitment of the research departments (12 out of 14), the commitment of the Units (25% in 2000 rising to 95% in 2004), and the application of international references such as ISO 9001 and EN ISO/IEC 17025 (15) for strategic platforms certified by the National commission for collective Tools (CNOC), as well as ISO 14001 [18] for Experimental Units, and ISO 9001 [15] or NF S 96-900 [19] for certified Biological resource centres.

INRA's next ambition was to extend the Quality process to research activities, thus bringing Quality to the very heart of INRA's activity. In 2012, the INRA Management coordination committee's new 2012–2016 Quality policy emerged. Version 2 [16] of the INRA Quality guidelines comprises five chapters: Quality management and responsibilities; Conducting research; Management of resources; Control of the documentation; and Measure-

ments, analysis and improvement. This new version of the INRA Guidelines was presented to quality or metrology managers in laboratories.

This new guide is intended to be easy to read, using everyday language to ensure accessibility for the scientific community, since Quality terminology is rather specific and becoming familiar with it can take time. The INRA Quality task force also contributed to the drawing up of the NF X50-553 Standard (management of research activities) [2] and made sure the INRA Guidelines were consistent with this Standard. The INRA Guidelines deliberately make no reference to customers in order to avoid resistance from the scientific community to a concept commonly associated with the commercialization of knowledge. Version 2 of the INRA Guidelines is about accrual of experience and reinforcing continual improvement. It puts emphasis on conducting research as a process (design, implementation and publication/practical usefulness) with a view to managing and controlling the risks inherent during a research project. At the outset of the project, the person heading the research states the hypotheses involved, defines the experimental protocols, coordinates sampling/analyses/simulations, and interprets data and designates its uses.

The laboratory is required to draw up an inventory of all its research projects and establish research and/or experimental protocols. These protocols cover the objectives defined for the research project as well as the resources necessary to achieve them (methods, materials, resources, installations; persons and entities involved, provisional schedule, critical aspects requiring special attention and procedures for communication, retention period of samples and data, as well as any other specific criteria). The INRA version 2 Guidelines also put emphasis on management of methods: their formalization and validation, and the uncertainties associated with quantitative results. The version 2 INRA Guidelines come with a new dedicated self-assessment tool for the research units and specific tools for the implementation of the Quality process at national level: the INRA Quality task force is coordinated by a network of Quality managers located in centres across 17 different sites in France and the 13 scientific divisions. However, the ideal is not so easy to achieve in reality and many of the scientific divisions that were involved with the first version of the guidelines have since lost interest in the Quality process, and some centres are still without a Quality manager. The effect of this is to isolate the Quality managers in the units, just as these units undergo the process of merging and have growing staff levels.

When it comes to the VLSU, structural complexity complicates smooth coordination, as is evident in the case of the biology laboratory under observation: acceptance of the INRA guidelines needs to be achieved across 16 Laboratory teams (irrespective of the institute individuals belong to), in the centre of INRA Angers-Nantes, and in the three INRA scientific divisions (only one of which has a Quality manager).

At the same time, in the face of such extensive restructuring, the implementation of a QMS could actually be seen as an opportunity, offering the possibility on the one hand of managing risks specific to research

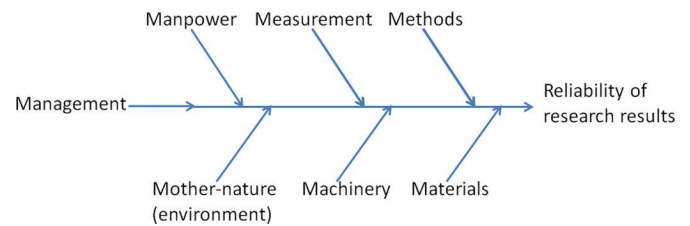


Fig. 2. Ishikawa 'Fishbone' diagram (principle of 7 Ms).

activities, and on the other of enhancing cohesion between teams and ensuring that knowledge acquired is put to good purpose.

3 Implementation of a Quality Management System: actions undertaken

3.1 Managing the 7 Ms in a laboratory

The research community is agreed on the principle that scientific publications must be founded on reliable scientific data obtained in an environment where all factors capable of influencing the quality of a result (see Fig. 2) are tightly controlled [20–24]. These factors can be displayed in the manner of the Ishikawa Fishbone diagram with 7 principal categories (see Fig. 2): Machinery, Methods, Materials, Mother-nature (environment), Manpower, Management and Measurement.

Assessing the reliability of research results consists in attributing a confidence level relative to both the obtainment and the use of the results. In the case of research activities, it can be difficult to assess reliability with an appropriate confidence level but the minimum that can be expected is to be in control of all the factors mentioned in Figure 2. The implementation of a QMS which integrates the principle of the 7 Ms constitutes an opportunity to ensure quality of research results, and to improve and obtain recognition of the work carried out in a research laboratory.

The main actions implemented in the laboratory under observation are described in the following sections, for each of the influence factors illustrated in Figure 2. All actions that were put into effect came about as a result of the continual improvement dynamic brought to the laboratory by the existence of the QMS.

3.2 Management and Manpower

The QMS constitutes a tool with which to control and steer the activities of the unit.

The laboratory has chosen to adopt an integrated approach to Quality management that includes aspects linked to prevention and sustainable development. A participative management style was chosen by the Management Board for implementation of the QMS [23] with the intention of encouraging inter-team and inter-discipline exchange. In September 2013, the Quality manager was appointed with a brief to implement and steer a Quality system common to all laboratory research

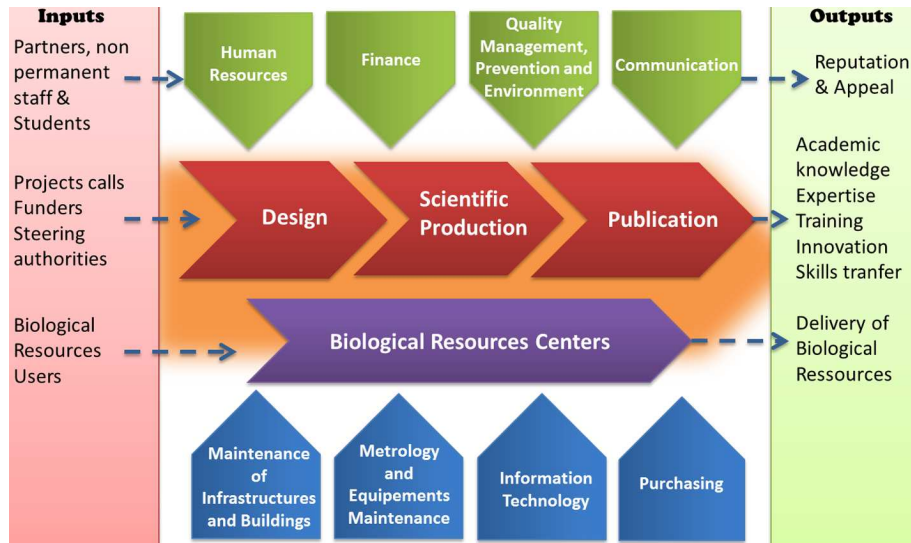


Fig. 3. Laboratory process mapping proposed.

teams. He has extensive independent powers to enable him to fulfil this brief, as well as an operating budget. He attends monthly steering committee meetings for the laboratory, at which any matters relating to Quality and prevention can be raised if necessary.

The danger was of the Quality manager finding himself shouldering this huge task single-handed. With the support of the laboratory manager, a Quality network was created with more than 60 researchers of the laboratory: the laboratory manager, the 16 research team leaders, the 16 Quality representatives (one per team), and 35 Equipment and Metrology representatives. The Quality representatives meet every two months. A mission letter was sent to the Quality manager, the Quality representatives and the Equipment and metrology representatives.

In order to help the laboratory's Quality manager and Quality representatives to deploy the Quality process among research teams, the Quality manager made good use of the commitment of students on work experience in the laboratory. The advice of their mentor, a specialist in Quality management and metrology, went a long way in ensuring implementation of the QMS was possible with the cooperation of all concerned. This tight collaboration had a number of positive offshoots and several actions have been dealt with, such as process mapping (see Fig. 3), a Quality manual, and procedures for document and equipment control, all of which advances formalization of process and operating procedures [15].

To ensure reliability of research results, it is essential from the outset to pay due regard to Human Resource management [23,25]. This consists in identifying the functions and skills required (in terms of knowledge, know-how and experience) and hence training needs, welcoming new recruits and retaining records of initial and ongoing training.

Every two years, at the activity meetings held between the members of staff managed by INRA and their line managers, a review is made of the different activities, of prospects, of skills acquired and needing to be developed, and of training needs. A training programme is thus

established for the laboratory, and priorities are set in line with the laboratory's Guidelines. It has been noted that staff training in Quality and metrology needs to be developed [25,26] as the lack of this is slowing down the progress of the laboratory.

3.3 Methods

When analysing test results, researchers need to have at their disposal all the information that could have an influence on results [20]. Therefore the formalization of methods is essential. This consists in noting down all sample collection, measurements, analysis of apparatus used, kit lot numbers, the samples themselves, their identification numbers, storage temperatures, etc. In accordance with INRA Guidelines, these operations are written down in a laboratory notebook when the method is being set up; the operating procedure is in place once the method has been fully defined and is workable. INRA is in the process of developing electronic notebooks to further encourage their use by scientists and facilitate the traceability of information. The use of laboratory notebooks by scientists in INRA laboratories is a long-standing practice. Once a method is deemed reliable, it is transcribed in the operating procedure (using the model defined by the laboratory).

In the laboratory, research teams formalize the validation steps of their methods in accordance with the instructions in INRA guidelines version 2. In other words, the evidence is created to confirm that the method utilized is appropriate to the question being treated; any question of the conditions required to produce interpretable results with a known level of uncertainty can be answered.

Data management is also a crucial matter, one which the bioinformatics team at the laboratory would like to improve. The development of a Laboratory information management system (LIMS) is underway and will improve the management of samples (identification, localisation) tested and the traceability of their associated data. The

objective is to be able to find easily where a sample comes from, whose it is, to which methods it relates, everything that has been done throughout its life cycle and how to use dispose of it [16,17].

The LIMS will also be used for the management of equipment (which will facilitate the work of the Equipment and Metrology Representatives), and also consumables so as to avoid the use of different product or reagent lots where this would impact upon results.

Document management is another essential factor that has to be properly handled by the laboratory. The laboratory lists the operating procedures that need to be formalized, schedules their realization, has them written up, and disseminates them via any means considered appropriate to enable them to be used in operational conditions. The laboratory defines and utilizes template documents for the writing of operating procedures. An initial list of documents has been created. It is updated by the Quality representatives in such a way that every scientist can be aware of all operating procedures in existence as well as of modifications to them. Documents created and validated as part of the QMS are made available for use by means of a document management tool. This tool is encountering a certain amount of resistance as some scientists object to this general availability of what they consider to be their own documents.

All researchers know that it is essential to describe precisely their methods and to validate and to improve their scientific works. It is also important to record correctly the validation methods used and the associated results and data. For the continuous improvement of the research laboratory, the useful QMS tools allow the laboratory to also share knowledge and better capitalize on a know-how.

3.4 Machinery and Measurement

The laboratory has responsibility for managing equipment that is subject to regulations or is identified as having an impact on the quality of research results. This empowers it to ensure that the purchasing, maintenance, calibration, and verification of equipment are conducted appropriately [27–29].

When it was created in 2012, the laboratory had eight different types of inventory for the listing of equipment. Critical equipment was not always identified as such and several different service-providers could be involved in the regulatory control of a single apparatus type depending on which teams used it. It was a matter of high priority to standardize the inventory and equipment management systems (pertaining to information such as model, make, serial number, commissioning date, person responsible, etc.). It took almost two years to develop an internal network with a referent for each team (a matter of 35 Equipment and metrology representatives) and collectively define their brief: to ensure regulatory verifications with a view to prevention (autoclaves, fume hoods, centrifuges, oxygen meters, etc.) and/or metrological verification and calibration (weighing-scales, pipettes, thermometers, incubators, water baths, etc.).

Each critical device identified has its own service-life file enabling the tracing of incidents and the monitoring of maintenance, verification, and/or calibration. When a piece of equipment fails a conformity check, the validity of all preceding results must be re-established. All operations pertaining to equipment are covered in the common equipment management and control procedures, and in equipment user, maintenance, calibration, verification and monitoring instructions. An annual schedule for both internal and external verification of critical equipment has been set up [27]. For example: weighing-scales identified as critical are periodically checked in-house with calibration weights and control charts [28–33]. The weighing-scales are also verified annually by an external service-provider. Weighing-scales that are identified as non-critical undergo in-house verification only. In molecular biology, pipetting of reagents is a critical activity which can have a significant impact on a result, especially where small volumes are concerned. Due to the number of pipettes in use, these make up a significant proportion of the equipment to be checked. A joint decision has therefore been made to perform verification in-house for pipettes with a volume above 10 μL and to use an external service provider for pipettes with a volume below 10 μL as well as for multichannel pipettes [33,34]. For temperature, the laboratory has acquired a reference thermometer, calibrated annually, with which to verify operational laboratory thermometers. For verification of more complex equipment such as thermal cyclers, a workgroup has been set up with the aim of developing a procedure to be used for in-house verification.

For machines that carry a degree of safety risk to the user, such as centrifuges, autoclaves, etc., regulatory checks are compulsory at the intervals defined in the relevant regulations. For autoclaves, an authorization given by an external body is required.

3.5 Mother-nature and Materials

The INRA guidelines require units to ensure proper monitoring, recording, and if possible control of ambient conditions when these have an impact on the quality of research results.

Discussions are currently underway with Equipment Managers in charge of freezers and cold rooms on the subject of identifying critical aspects requiring special attention where samples need to be stored at -80°C . The laboratory stores pathogenic agents (bacteria and fungi), seeds, leaves, twig fragments, pieces of fruit, and also DNA, RNA, and proteins. In order to control the risks associated with poor cold storage conditions (at temperatures of -80°C , -20°C and $+4^\circ\text{C}$), several requirements have been pinpointed: the requirement for an on-site power generator, the installation of -80°C freezers in an air-conditioned room, of a monitoring system for each freezer and cool room to ensure reliability (for a backup -80°C freezer, for maintenance of freezers and cool rooms by an external company with a rapid response time in the event of failure) and, finally, for an in-house team capable of dealing with failures at weekends.

The INRA version 2 guidelines require laboratories to ensure correct cold storage of samples (cryopreservation, -80°C , -20°C and 4°C). To satisfy this requirement the laboratory is in the course of defining a clear policy concerning management of freezers and refrigerators, as well as standardized numbering for all samples within the laboratory in order to ensure their traceability. The Quality representatives are also discussing protocols for the collection and acquisition of samples, types of packaging (e.g. tubes, plates, bottle, boxes, etc.), and methods of identifying the samples. A disposal policy for samples (post publication, at end of project.) and the scheduling of cleaning days are also under discussion.

The laboratory is responsible for the traceability of consumable and other products (chemical and phytosanitary products, solvents, biological reagents, etc.). The question of traceability is not handled in exactly the same way by every team. Nevertheless, all teams adhere to use-by dates and required storage conditions. The storage of consumables, other products and reagents must conform to regulations and manufacturer specifications. After the merging of the research units, which saw more than half the research teams move to a new building and the construction of new greenhouses, a massive sorting of chemical products was undertaken, with comprehensive inventories being drawn up and appropriate storage made available: clearly defined product bins ensure that acids, bases, inflammables and toxic and carcinogenic, mutagenic, toxic to reproduction (CMR) substances are kept separately from each other. Ventilated cabinets have been purchased for all the laboratory buildings. A special room dedicated to the preparation of phytosanitary products has been built near the new greenhouses. Chemical safety information has been centralized in a computerized folder to which everyone has access.

4 Discussion, analysis and improvements

4.1 Measuring effectiveness of the system

The effectiveness of the system is measured via internal audits and the annual self-assessment tool implemented by the INRA Quality Task Force. An internal audit is organized by the INRA Quality task force every five years, a year before the HCERES (French High Council for Evaluation of Research and Higher Education) assessment of the laboratory. To the overall laboratory assessment are adjoined the Quality audit report, the ensuing action plan, the results of the action plan and the quality indicators selected. Nevertheless, it would be a positive step if the bodies assessing the laboratory were to pay closer attention to the efforts made by the laboratory towards enhancing reliability of results. In order to foster a more self-critical view and further the objectives of continual improvement, it is intended that the laboratory will, for the first time, conduct a Quality review at the end of the year to evaluate the Quality actions undertaken, assess their effectiveness, and define new objectives for the coming year based on the indicators defined by the laboratory for each of its processes. It is hoped by this means to give individuals a real opportunity to enhance their relationship with the

Quality system and to instil dynamism in the pursuance of improvement. The Quality process is progressing well and awareness of the benefits attached to a QMS is growing within the laboratory.

4.2 Effect of QMS on organization of the laboratory

The INRA Management coordination committee recommends laboratories to undergo a Quality audit a year ahead of the *HCERES* assessment which takes place every five years. In response to the wish of management, therefore, an INRA internal audit was held in the VLSU in March, 2015 organized by the INRA Quality task force. The auditors took the time to audit every team (on every site) in accordance with the different requirements of the INRA version 2 guidelines. This very pedagogical action allowed scientists to measure in real terms the improvements made or needed to be made by their teams. This internal audit made it possible to draw up individual team-oriented action plans based on specific needs, followed-up with an action plan for the laboratory as a whole. The actions decided upon were prioritized according to three objectives: improvement of documentation management, of equipment management, and of cold-stored samples management (cryopreservation, -80°C , -20°C , 4°C and lyophilisation). These objectives were then confirmed in the management mission statement, which was updated in 2016. The audit was therefore a very effective means of continuing to involve teams in the Quality process and of facilitating interaction between the teams and the Quality manager, and was also a means through which the collective objectives of the laboratory could be developed. This is in keeping with the concept of participative management put into effect by the laboratory management board.

4.3 Effect upon commitment and motivation of laboratory staff

The fact that the laboratory is under no obligation to pursue the certification objective means the scientific community may suffer a lack of motivation. However, this is actually a very positive situation: it allows staff the time it takes to become fully conversant with the new managerial process, one which actively encourages the participation of individuals, promotes a shared outlook, and fosters an ongoing critical regard of the organization of the laboratory. The process management constitutes a tool with which to steer laboratory activities with regard to key performance indicators. It involves every member of laboratory staff, favouring continual improvement of the operation, organization, and practices of the research laboratory via the Quality policy, Quality objectives, and results of self-assessment and audits.

In order to deepen the commitment of its scientists to the Quality process the laboratory is developing, in conjunction with its closest partners, a network of Quality managers, which it is intended will be broadened in order to benefit from the experience of other Organizations, such as INSERM (French National Institute of Health and Medical Research) and CIRAD (French Agricultural Research

Centre for International Development). As the Quality process is not inscribed in the official duties of staff, implementation is not easy. Fortunately, the laboratory is able to count upon the commitment of its willing staff.

Recognition for individuals who participate in collective tasks needs to be increased. While the contribution of individuals to collective tasks such as prevention and risk management does come up at activity meetings and in competition for promotion, staff generally feel that only their scientific contribution (in the form of scientific communication and publication) is taken seriously. Only this, it seems, has any real effect on career development. In the light of this it is easy to understand why a number of laboratory staff takes little or no part in this type of collective activity.

5 Conclusion

This paper presents the different actions involved in setting up a QMS in a very large French research laboratory (very large scale unit) through a voluntary approach.

This paper clearly illustrates the effectiveness of the actions considered by looking at the 7M method and giving practical examples which involve both the organization and the activities of the laboratory.

Many improvements were made at the time of setting up the QMS in the laboratory. These have had a positive impact on the functioning and the activities of the laboratory.

Putting a QMS into place certainly improves the functioning of the laboratory since it provides information on where people are, what they are doing, how they are doing it, how what they do is being checked and how things can be anticipated. Quality tools allow laboratory staff to be accompanied in a spirit of continual improvement in order to maintain effectiveness and robust activities of research of the laboratory.

The management of quality also aims at opening up discussion so researchers can put meaning into their work and improve their research activities. The participative management aspect of the Quality process encourages a shift, initially on an individual basis but consequently at organization level, from wanting change to enjoying it. This participative style of management brings together different perspectives that enable anticipation, cooperation and innovation.

The QMS is still young and more needs to be achieved for it to be completely operational and cover all the processes linked to the activities of the laboratory. All the laboratory staff needs to acknowledge the QMS and become involved for it to function correctly. Efforts to increase researchers' awareness are continuing in the laboratory and in field work by showing, step by step, that the QMS exists to enable the laboratory and its quality staff to continue to progress from an organisational as well as scientific point of view.

Although it enjoys the support of the laboratory management, the implementation and development of a QMS is encountering resistance both from scientists and from the Institutions, notably in the latter case, for financial reasons: the IT tools, for example, that improve

the management of documentation, equipment, consumables, and chemical products take time to develop satisfactorily and necessitate a training budget. And yet these tools help underpin the management of collective intelligence. Currently, the financial support of the Institutions contributes to the cost of fluids and research projects but provides nothing for the development of structural tools. Despite the economic pressures, scientists within the laboratory do willingly support the QMS. The laboratory could also take its work on the validation of the methods further, increasing emphasis on the estimation of uncertainties associated with results. Among other aspects that need to be improved are the control of outsourced activities and the evaluation of supplies and suppliers. It is perhaps useful at this point to refer to the experience of other laboratories: despite the difficulties encountered during the implementation phase of a QMS, of all those questioned who had been in a position to observe the changes to the organization of their laboratories, none expressed a wish to backtrack. This seems to reinforce the claim that a QMS, while admittedly demanding a certain effort from everybody in the laboratory during the implementation phase, does serve to enhance reliability and improve the functioning of a laboratory.

References

1. A. Jaime, M. Gardoni, D. Vinck, *Quality Management, Framework of Knowledge Capitalization at Research Organizations IAMOT 2004* (International Association for Management of Technology, USA, 2004)
2. NF X50-553, Management des activités de recherche (AFNOR, Paris, 2014)
3. A. Matei, C. Antoni, The new public management within the complexity model, *Procedia Soc. Behav. Sci.* **109**, 1125–1129 (2014)
4. G. Gruening, Origin and theoretical basis of new public management, *Int. Public Manag. J.* **4**, 1–25 (2001)
5. L. Spencer, J. Ritchie, J. Lewis, L. Dillon, *Quality in Qualitative Evaluation: A Framework for Assessing Research Evidence* (National Centre for Social Research, London, 2003)
6. What Are the Standards for Quality Research? Technical Brief Number 9, National Center for the Dissemination of Disability Research, 2005
7. R.J. Shavelson, L. Towne, *Quality Research in Education* (National Research Council, National Academy Press, Washington, 2002)
8. A.C. Edmondson, S.E. Mcmanus, Methodological fit in management field research, *Acad. Manage. Rev.* **32**, 1246–1264 (2007)
9. M. Baker, Quality time. It may not be sexy, but the quality process is becoming a crucial part of lab life, *Nature*. **529**, 456–458 (2016)
10. C.G. Begley, A.M. Buchan, U. Dirnagl, Robust research: Institutions must do their part for reproducibility, *Nature* **525**, 25–27 (2015)
11. E. Giesen, Quality management for robust and reliable research, *Int. J. Metrol. Qual. Eng.* **6**, 407 (2015)
12. E. Giesen, Ethical and efficient research management: a new challenge for an old problem, *Int. J. Metrol. Qual. Eng.* **6**, 406 (2015)

13. R. Bareille, B. Baudouin-Massot, M.P. Carreno, S. Fournier, N. Lebret, I. Remy-Jouet, E. Giesen, Preventive actions to avoid questionable research practices. Use of EERM (Ethical and Efficient Research Management) during arrival and departure of a co-worker, *Int. J. Metrol. Qual. Eng.* **8**, 10 (2017)
14. INRA Quality Mission, INRA Quality Guidelines, Version 1. 2003-2005. INRA, contact: qualite[at]inra.fr.
15. ISO 9001, Quality Management Systems – Requirements (2015)
16. INRA Quality Mission, INRA Quality Guidelines for Research and Experimental Units (2013), Version 2. INRA Sciences and impact, contact: qualite[at]inra.fr.
17. EN ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories(2005)
18. ISO 14001:2015, Environmental Management Systems – Requirements with Guidance for Use (2015)
19. NF S96-900, *Qualité des centres de ressources biologiques (CRB)-Système de management d'un CRB et qualité des ressources biologiques* (AFNOR, Paris, 2011)
20. S. Belouafa, F. Habti, S. Benhar, B. Belafkih, S. Tayane, S. Hamdouch, A. Bennamara, A. Abourriche, Statistical tools and approaches to validate analytical methods: methodology and practical examples, *Int. J. Metrol. Qual. Eng.* **8**, 9 (2017)
21. L. Martin, Ch. Baudassé, N. Leménager, M.-F. Thévenon, The metrological approach: a major key factor for the accreditation and continuous improvement of the wood preservation laboratory of Cirad, *Int. J. Metrol. Qual. Eng.* **4**, 117–120 (2013)
22. F.M. Beyer, Language and strategies at work studied through the implementation of quality procedure standards, *Sociol. Trav.* **41**, 235–54 (1999)
23. ISO 10018, Quality Management–Guidelines on People Involvement and Competence(2012)
24. ISO 10012, Measurement Management Systems–Requirements for Measurement Processes and Measuring Equipment (2003)
25. Guide on equipment qualification: <http://www.edqm.eu/en/quality-management-guidelines-86.html>. 2015
26. L. Martin, M.-F. Thévenon, Evaporation as an ageing procedure prior to wood preservative biological testing: when standardization needs metrology, *Int. J. Metrol. Qual. Eng.* **5**, 405 (2014)
27. G. Gomah, A traceable time interval measurement with a reduced uncertainty, *Int. J. Metrol. Qual. Eng.* **6**, 301 (2015)
28. S.B. Amara, J. Dhahri, N.B. Fredj, Control chart limits based on true process capability with consideration of measurement system error, *Int. J. Metrol. Qual. Eng.* **7**, 401 (2016)
29. S.F. Beckert, W.S. Paim, Critical analysis of the acceptance criteria used in measurement systems evaluation, *Int. J. Metrol. Qual. Eng.* **8**, 23 (2017)
30. J.-M. Pou, L. Leblond, Control of customer and supplier risks by the guardband method, *Int. J. Metrol. Qual. Eng.* **6**, 205 (2015)
31. M. Wiederhold, J. Greipel, R. Ottone, R. Schmitt, Clustering of similar processes for the application of statistical process control in small batch and job production, *Int. J. Metrol. Qual. Eng.* **7**, 404 (2016)
32. ISO 8655-1, Piston-operated Volumetric Apparatus-Part 1: Terminology, General Requirements and User Recommendations (2002)
33. ISO 8655-2, Piston-Operated Volumetric Apparatus-Part 2: Piston Pipettes (2002)
34. ISO Guide 30, Reference Materials-Selected Terms and Definitions (2015)

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