Global BioImaging Project

D2.3 Common international recommendation for quality assurance and management in open access imaging infrastructures

Project N.	653493
Project Title	Global BioImaging
Project Acronym	GBI
Associated Work Package	WP2
Associated Task	Task 2.3
Lead Beneficiary (short name)	ABO
Nature	Report
Dissemination Level	Public
Estimated Delivery Date (Grant Agreement, Annex I)	30/11/2018
Actual Delivery Date	26/11/2018
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Funded by the Horizon 2020 Framework Program of the European Union

Abstract

A key aim of the Global BioImaging (GBI) project is to enable exchange of best practice on operation of imaging infrastructures between Euro-BioImaging and other European imaging facility staff with their counterparts from Australia and India as well as Canada, Japan, Mexico, Singapore, South Africa and the USA. To facilitate this important work and to support potential harmonization of quality assurance and management on the global scale, Work Package 2 (WP2) has a dedicated task to develop and publish an international recommendation for quality assurance and management in open access imaging infrastructures. Internationally harmonized quality guidelines will pave the way to future reciprocal use of imaging infrastructure services at the international level.

Exchanging expertise and knowledge with international Global BioImaging partners during the past three years at several meetings and workshops (i.a. *Exchange of Experience I*, Heidelberg, Germany 2016; *Exchange of Experience II* Bangalore, India 2017; and *Exchange of Experience III*, Sydney, Australia 2018) has facilitated international collaboration and sharing best practices among imaging communities. This collaboration is expected to result in international recommendations on exemplary practices for imaging infrastructures.

The present report constitutes the deliverable D2.3 of the Global BioImaging project. This work has been supported by the GBI QM Working Group who has provided their expertise in preparing the *Common Recommendation* item for *Exchange of Experience III* and this document. Composition of GBI Working Group can be found in Annex 2.

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Quality assurance and management in imaging infrastructures

Primary focus of quality assurance (QA) and quality management (QM) is often to meet customer requirements, to anticipate their needs and exceed their expectations. In science, a good quality system should also drive to ensure reproducibility of results, which is the core of high-quality science and good scientific practice. Quality management contributes to key features that lead to innovation and research impact and in past years, quality of data has become even more critical in overall scientific quality. This drives academic research and organizations to strong advocacy for the introduction of quality management principles. Common international standards for image data will be covered in a separate document as part of the work of Work Package 4 in Deliverable 4.3 *Common international recommendation for image data standards and open access repositories.*

Quality management systems

Quality management systems (QMS) in imaging core facilities aim at optimizing and standardizing the quality of the entire range of services of an access-providing facility. For facilities of different kinds and in different environments, this can only be achieved by formalized quality management procedures and defined quality standards.

Quality systems can provide a clear set of objectives for a way to i) decrease time wasted on inefficient processes, ii) ensure knowledge is not lost when personnel turn over, iii) focus on delivering outcomes to stakeholders, iv) capture the good things and build upon them and, v) structure for continuous improvement, which vi) can provide a competitive advantage for imaging core facilities. Standardized quality management ensures the capability of providing specialist services and expertise to the academic research community and to industry.

The decision on the degree of compliance with quality standards is one that every laboratory must make based on 1.) needs of users, 2.) resources available, 3.) alignment with laboratory mission and 4.) alignment with granting agency and institutional requirements.

Internationally recognized quality standards

Various different international standards on quality management and quality assurance have been established to promote common approaches to managing quality and environment. Common international standards are critical to international organizations to promote trade and cooperation and they contribute to dependability and a consistent use of data.

As it is later on shown by the results collected from global imaging community (Annex 1.), most imaging facilities do not have accreditation in any internationally recognised quality standard. Set up and maintenance of a quality management system to meet international standards takes time and resources.

Table 1. Internationally recognised standards and best practice examples relevant to imaging infrastructures.

ISO 9001/2015	Outlines guidelines for organization that are engaged in design, development, production, installation, and servicing of products or service. Importance of the involvement and communication of governance (leadership) and staff in the establishment and maintenance of a management system, "customer/users" Introducing to previous ISO 9001/2008 general requirements of a quality management system.
ISO 17025	Covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
ISO 15189	Requirements particular to medical laboratories (laboratories providing clinical reports)
ISO 13485	Requirements for groups wishing to supply services to users in the medical device industry.
ASTM WK59530	New Guide for Performing Quantitative Fluorescence Intensity Measurements in Cell-based Assays with Widefield Epifluorescence Microscopy

The most commonly applied quality standardization in imaging core facilities is ISO 9001, which covers general quality management practices. Another general but relevant international standard that is widely applied is ISO 17025, which covers quality management and technical practices for testing facilities. More relevant internationally recognized standards and best practices relevant to imaging infrastructures can be found in Table 1. Examples of specific imaging infrastructures applying the recognized standards will be introduced in the following section.

Benchmarking international practices of quality assurance and management

In order to better understand a global status of quality management in imaging infrastructures, WP2 conducted an interactive survey questionnaire during the *Exchange of Experience III* held on 14-15th of September in Sydney, Australia. Results were collected using the *Kahoot!* online tool during the open discussion session by first benchmarking on current practices at different open imaging infrastructures. This was followed by an open discussion on what should constitute the guidelines for common harmonized standardization across infrastructures. Survey results include representatives from five different continents and 8 different imaging infrastructures: Australia, Canada, Europe, Japan, Mexico, Singapore, South Africa and the USA (total amount of responses 43). Summary and more details of the survey conducted can be found in Annex 1.

Quality management systems in place

The survey results confirmed expectations that the majority of imaging facilities do not have accreditation in any internationally recognised quality standard (Annex 1). From responses collected, 18% of the represented imaging infrastructures reported to have some internationally recognized quality management system in place, and only 7% implement an internationally recognized quality standard. Nevertheless, the majority of imaging facilities do implement some form of qualitative controls and almost half also implement quantitative controls.

One of the best practice examples, Monash University's (Australia) quality management system is certified to ISO 9001:2015 for all their Technology Research Programs. This quality system has been built gradually since 2012 and now has oversight of 27 technology research platforms worth millions of dollars. These platforms deliver more than 200,000 services per year to Australian and International researchers in academia and industry.

Another example of imaging infrastructure that implements internationally recognized quality standard comes from the France BioImaging national infrastructure, where several imaging core facilities have, a quality system compliant with ISO 9001 standards in place. In addition to implementing the ISO standard, France has its own quality certification system, NFX 50 900, which incorporates ISO 9001:2015. This national certification system specifically addresses and describes requirements for research technology platforms in life sciences, such as defining "scientific excellency" as a clear service mission. Some other imaging infrastructures, such as Singapore and Mexico are currently considering implementing ISO 9001 in their facilities.

Quality control practices in use

To benchmark general practices in different imaging core facilities, several quality assurance measures related to routine practice were addressed.

Maintenance and servicing of equipment. The survey looked at the usefulness of reports produced by commercial suppliers of routine maintenance of equipment. More than half the respondents were dissatisfied with service reports received from vendors. Most often reports were found not to be informative enough, and to be missing quantitative data that showed the state of the system before and after the service. Survey participants were then asked if they discussed their requirements for the content of reports as part of the service contract negotiation. Only 30% of respondents reported including a common agreement on the content of service reports into their contracts.

Collection and response to user feedback. Monitoring quality of service is an important part of a quality management system. Survey respondents were asked if they periodically collect user feedback. Almost 80% reported that they conduct feedback surveys and try to implement the improvements into operation of the imaging facility.

Data storage and transfer. The survey revealed that 37% of core facilities have periodic cleaning of a local system memory immediately at the end of experiment and do not store data in the local instrument. Almost half (44%) of the responses nevertheless show that clearing the system memory is done within 1-4 weeks and 19% inform that data is moved from the local storage less frequently than once a year or only when necessary. More than half (60%) of the survey respondents reported that transfer of data was through a local server while 10% use USB pen drives. The other 27% imaging facilities have established data transfer procedures in place that use different forms of centralized online data transfer and storage. Image data aspects were discussed in detail during a working group session on *Common international recommendation for image data standards and open access repositories* and are addressed in a separate GBI Deliverable 4.3.

Strategic impact and value created by harmonized quality in open imaging infrastructures

Implementing a quality management (QM) framework in an imaging core facility has direct and indirect positive financial impacts. Harmonized quality frameworks help to identify common quality risks across facilities and identifies actions needed to manage and address these risks. Leveraging the experience of the many helps decrease the "cost of risk discovery + cost of risk recovery" for a single facility. Facilities can avoid duplication of the costs of determining remedies and can save time and money. A good QM system may reduce down time of instruments and efforts needed on maintenance. This directly impacts the ability to decrease pricing of access and frees up facility staff for more high-level tasks enabling competitiveness of core facilities.

Implementation of a harmonized quality management system plays a crucial role in attracting external contributions to infrastructure investments and in access to research grants. It also facilitates capacity to host major research centres and programs as well as training of undergraduates and postgraduate students. QM systems strengthen the reputation of the infrastructure host, and attract new talent, collaborations and partnerships. Delivery of certified quality outputs have also a major impact on industry collaboration.

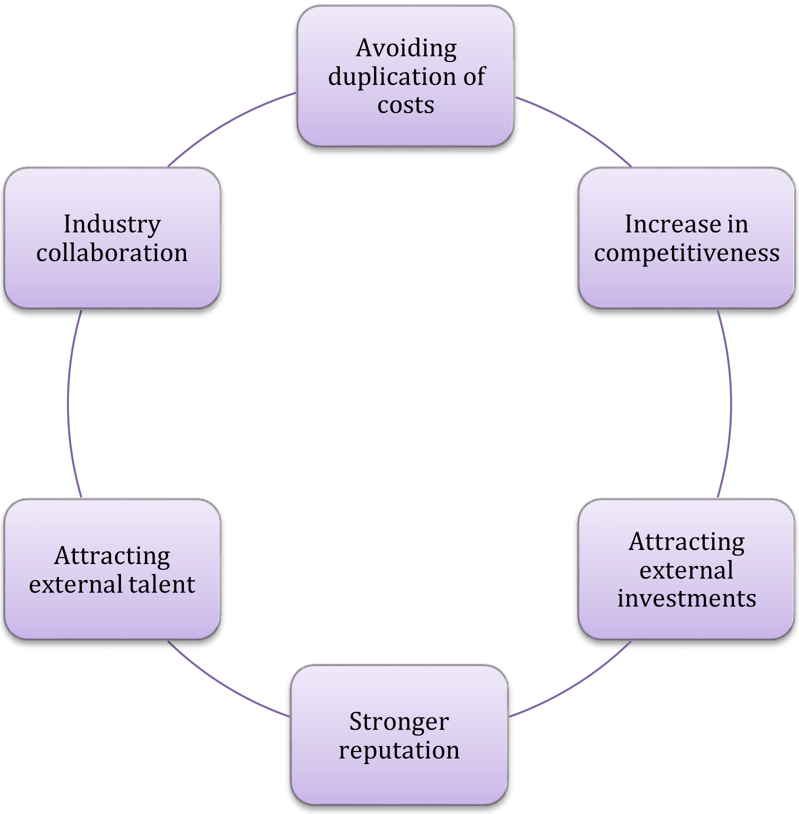


Figure 1. Impact and value created by harmonized quality assurance and management in open imaging infrastructures.

General principles of a quality framework

The general principles and evaluation criteria for implementing basic actions of quality management framework in imaging infrastructure are listed in Table 2. Principles have been adopted from OECD/DAC guiding principles and quality standards.

Table 2. Principles of quality framework in imaging infrastructure.

CLARITY OF REPORTING	QM framework should be structured according to a set of guidelines and all of the questions/sections required should be answered.
EASE OF USE	To encourage frequent quality measurements development of affordable tools and automated imaging and analysis software is ideal.
INDEPENDENCE OF EVALUATORS	Credibility of the evaluation relies on the independence of the evaluators. Evaluation should not be prone to internal or external pressures.
OBJECTIVITY	QM framework should be able to achieve a certain level of objectivity and impartiality.
PROTECTION OF INTERESTS	Security and the rights of the stakeholders involved in the evaluation process should be protected.
RELIABILITY	Results should be presented in a credible way and should be comprehensible.
REPRODUCIBILITY	Different evaluators using the same evaluation criteria and methodologies should arrive at the same conclusions.
STAKEHOLDER PARTICIPATION	All parties involved should participate in the evaluation process.
TRACEABILITY	Documented procedures and records should be in place to help to ensure traceability of measurements, processes and any relevant documentation needed for future evaluations.
TRANSPARENCY	Clear definition of the evaluation criteria, methodologies and priorities should be expressed and publicly open at all times.
UTILITY	Evaluation recommendations are used for improving performance and service. Feedback to political and operative decision makers must be guaranteed through a clear responsibility for the implementation of the evaluation results.

Different levels of quality management in the image core facility

LEVEL 1: PREVENTIVE MEASURES

- Full but gradual training of users: training workflow that includes application, technique selection and assessment of things learned.
- Development of core facility staff skills: training possibilities for staff both nationally and internationally.
- Clear establishment of operational rules.
- Periodic monitoring and assessment the need of service.
- Online facility management system.

LEVEL 2: ROUTINE MAINTENANCE

- Periodic basic cleaning following vendors recommendations.
- General cleaning of the area and platform.
- Routine follow-up of the system including e.g. testing of light sources, optical components and detectors.
- Possible software updates.

LEVEL 3: QUANTITATIVE QUALITY CONTROL OF THE SYSTEM

- Technology specific, periodic quality assurance measures that do not fall under level 2.
- Scheduled cleaning of local memory of the system.
- Moving data to storage or repository with clear policies.
- Monitoring procedures such as regularly collecting, responding to and documenting user feedback.
- Internal controls and audits.

LEVEL 4: ANNUAL QUANTITATIVE MAINTENANCE CONTRACTS

- Report from vendors /service company with quantitative data of the status of the instrument before and after service.
- All the technology specific quality assurance measures mentioned in Level 3 should be quantified and provided as result of the service it was performed.

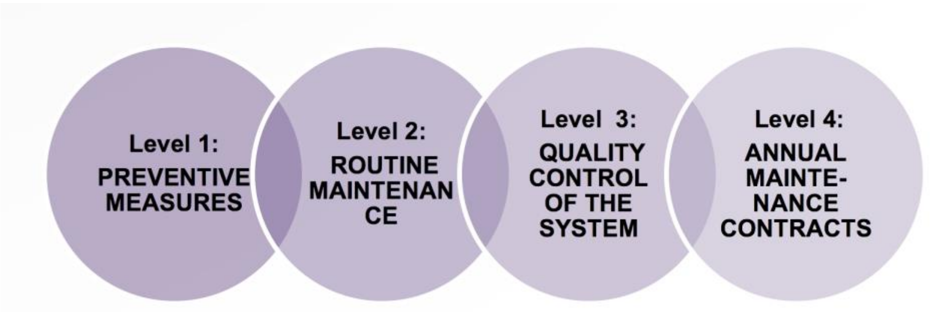


Figure 2. Four levels of quality management in imaging core facility.

International recommendations for quality assurance and management in open access imaging infrastructures

Based on all the information addressed above, general recommendations and guidelines can be set for how to establish and operate quality assurance and management in open access imaging facilities.

1. Establishment of operational rules

All imaging facilities should have established operational rules on general principles of operation, access and usage. These rules should define suitable levels of quality and identify relevant procedures of operation. In addition, rules should include:

a) Transparent user access policy and public administration. The access policy should include criteria for granting access, conditions of access (including any laws or regulations relevant to access), describe the access processes and possible support measures facilitating the access. Any restrictions should be clearly stated and communicated openly.
b) Possible agreement(s) between service provider and user (terms & conditions). This should include rights and obligations of the users and service provider.
c) System for identification and amelioration of any risks involved for users or facility staff in processes/samples.

2. Online facility management tool(s)

Use of robust, online facility management tool(s) is strongly recommended for larger imaging facilities. These e-management tools can include user access standard operating procedures (SOPs) and workflows, reservation system of instruments, integrated operational rules, payment conditions, reporting, possible digital signature, risk assessment, usage tracking and monitoring and document management. The management tool(s) should, when feasible, be compatible and not overlapping or contradictory with possible related tools of facility and access management used on a larger scale, e.g. those of an infrastructure or network the facility is a member of.

3. Image data management policy

Imaging infrastructure should be transparent to the user on how experimental data produced during the access is owned, stored, accessed and managed.

a) The imaging infrastructure and the user should commonly agree on ownership and intellectual property (IP) rights of the data obtained from the access.
b) Data should be FAIR (findable, accessible, interoperable, reusable) while held within the imaging facility storage system.
c) The imaging facility should supply a clear retention policy for user data that declares how long the facility will store user data, data security and backups during storage, and how/if users will be notified that storage periods are ending.

4. Training of users
On-site training and technical support for new users is essential to facilitate high-class research conducted at any imaging facility. Full but gradual training workflow should start from basic concepts and systems including system demonstrations. Training workflow should also measure progress and outcome of learning by post-training assessment. Assessment should demonstrate trainee has assimilated the concepts and is ready to independently operate instrument (where permissible) in trained environment (including workplace health and safety practices).

5. Training of core facility personnel
As imaging technologies and methodologies are rapidly evolving, it is very important to train the technology platform operators and technical staff of the facility. Skill metrics of core facility personnel should be annually evaluated, listing the skills obtained, mapping developmental points and setting next goals for the training progress. It is the responsibility of the imaging facility head to identify staff needs for training and carry out annual appraisals of staff. Core facility managers should also themselves provide national and international training possibilities to others when possible and encourage participation in job shadowing in other imaging infrastructures. These fact-finding visits can be important in avoiding common risks and issues by learning from the experiences of other infrastructures.

6. Periodic routine maintenance
To maintain the high quality of instruments, basic cleaning of systems should be conducted periodically. Maintenance measures should be defined as technology specific guidelines and instrument checks should be specified by daily, weekly, monthly and proper annual maintenance measures. Periodic cleaning should also include data clearance where image data should be periodically cleaned and transferred from local memory of the system.

7. Quality management system
Imaging infrastructure should define most suitable quality management system (QMS) to implement based on recourses available, needs of users targeted, overall mission of its research institution and any requirements set by fund granting agencies. The QMS should include collection of organisation’s processes and be aligned with organization's purpose and strategic direction.

8. Technology specific quantitative quality controls
In addition to preventive measures and daily maintenance, good quality management systems include periodic quantitative quality controls of the system. These are technology specific quality assurance measures that are designed to highlight any changes in performance over time and the identification of possible problems. Quality controls include instrument specific performance tests (for example testing of light sources, optical components and detectors) defined separately according to the technology (for example ConfocalCheck or SIMCheck).

9. Monitoring: Feedback mechanisms

For constant evaluation, development and improvement of infrastructure services, imaging facilities are encouraged to create formal mechanisms to collect user feedback. This information will help facilities to measure many aspects of user satisfaction/dis-satisfaction and service provision and by utilizing this information, increase the quality of service and science conducted. Feedback can, for example, provide information on courses and training organized, help to identify new technology needs and to collect information on publications, patents and additional funding that has come about through the services provided. Collected feedback also provides valuable data for underpinning future funding for new acquisitions.

10. Agreement on content of service reports

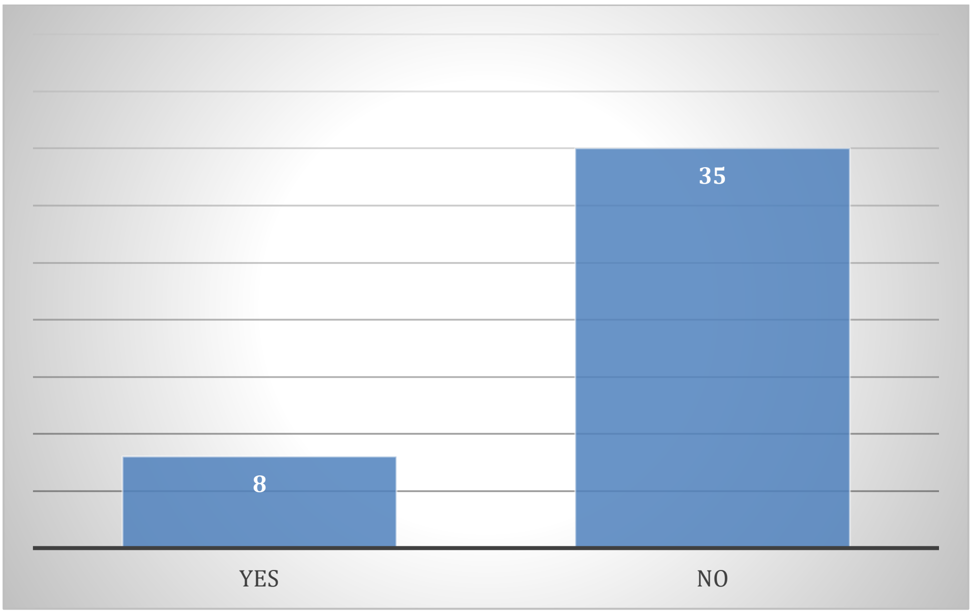
Content of annual maintenance service reports should be discussed and agreed together with the maintenance-providing entity and implemented in the service contracts. The service reports should include suitable quantitative data of status of the instrument before and after the service and describe the testing and service processes undertaken. Reports should also contain a "Pass/Fail" comment by the service supplier.

Annex 1: Benchmarking international practices of quality assurance and management in imaging infrastructures

Summary of WP2 interactive survey questionnaire conducted during the *Exchange of Experience III* held on 14-15th of September in Sydney, Australia. Results were collected using the *Kahoot!* online tool during the open discussion session. Survey results include representatives from five different continents and 8 different imaging infrastructures: Australia, Canada, Europe, Japan, Mexico, Singapore, South Africa and the USA (total amount of responses 43).

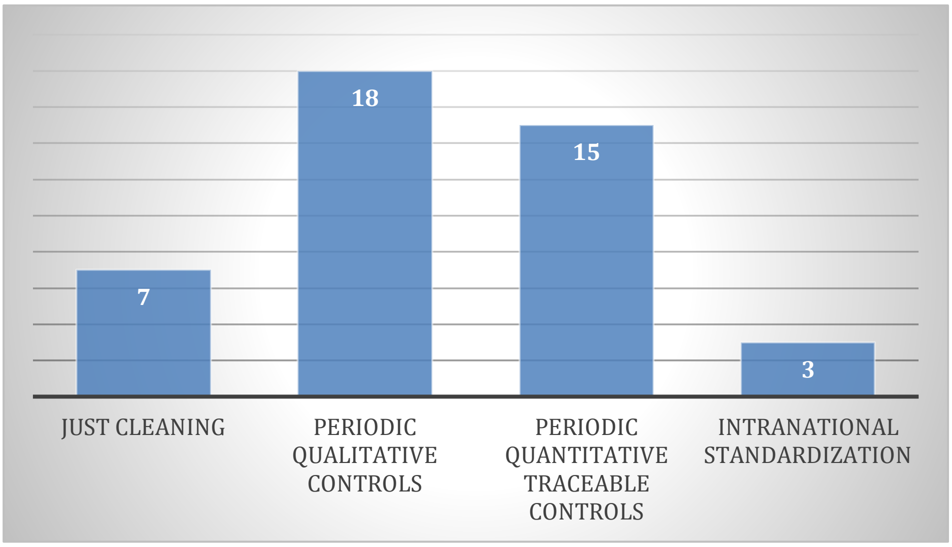
1. Do you have any internationally recognised QM system in place at your core facility?

The majority of imaging facilities do not have any internationally recognised quality management system in place (> 80%). Facilities that report to implement certified quality management system, comply either to international standard ISO 9001 or updated standard ISO 9001:2015 or other internationally recognised QM system. These facilities come from Australia (Monash University), European Molecular Biology Laboratory (EMBL) and France (several imaging facilities part of France BioImaging network). In addition to implementing the ISO standard, France has its own quality certification system, NFX 50 900, which incorporates ISO 9001:2015.



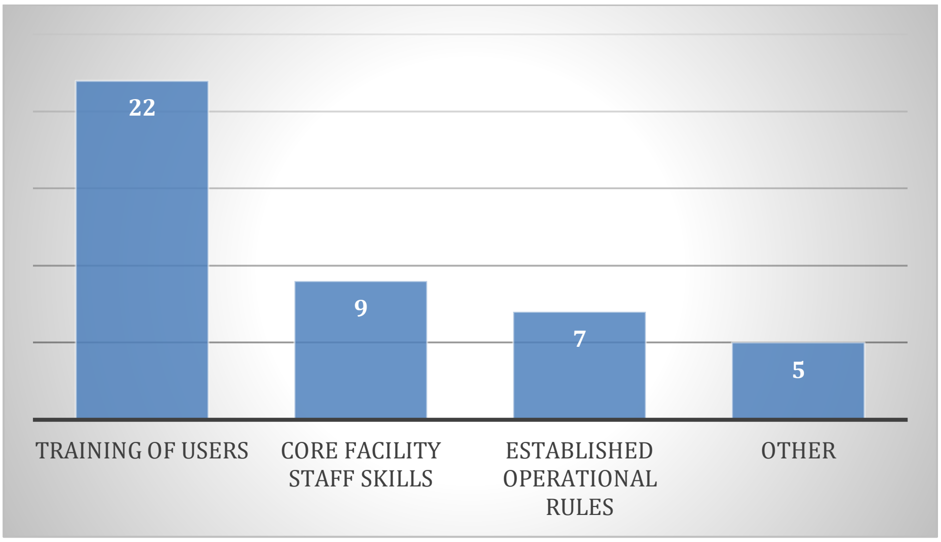
2. What kind of QM system do you have in place?

From responses collected, 18% of the represented imaging infrastructures reported to have some internationally recognized quality management system in place and only 7% implement internationally recognized quality standard. Nevertheless, majority of imaging facilities do implement qualitative and almost half also quantitative controls.



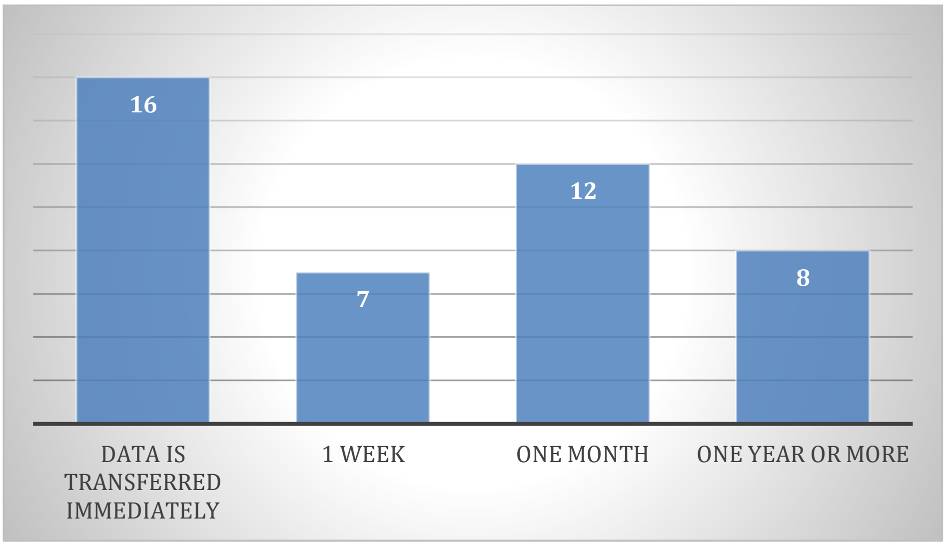
3. What is the most important preventive measure in your opinion?

Most important preventive measure in maintaining the good quality in the imaging facility (> 50%) was reported to be training of infrastructure users. Other measures raised were regular routine maintenance and periodic quantitative quality controls of the system and robust online quality management tools.



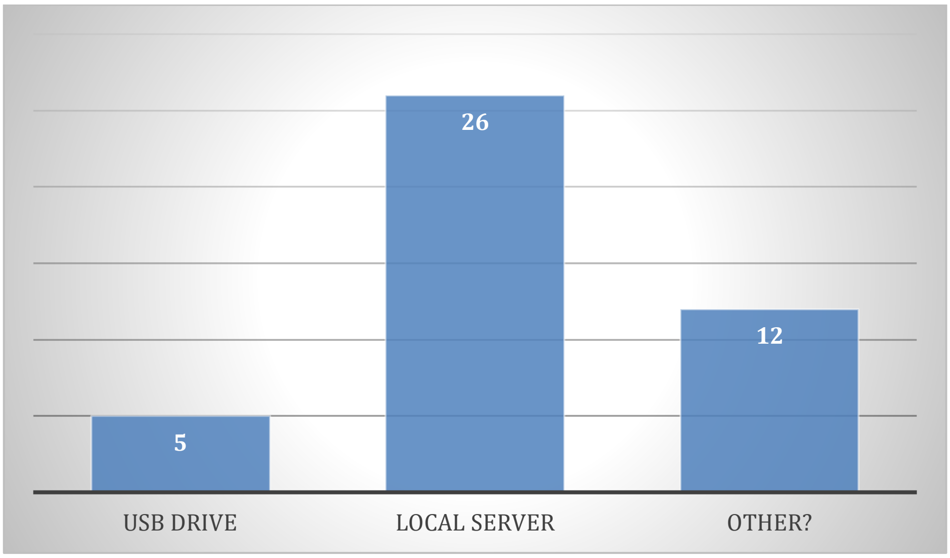
4. How long can users store the data in the local instrument?

One third of core facilities (37%) have periodic cleaning of a local memory of the systems immediately at the end of experiment and do not store data in the local instrument. Almost half (44%) of the responses nevertheless show that it is done within 1-4 weeks and 19% inform that data is moved from the local storage less frequently than once a year.



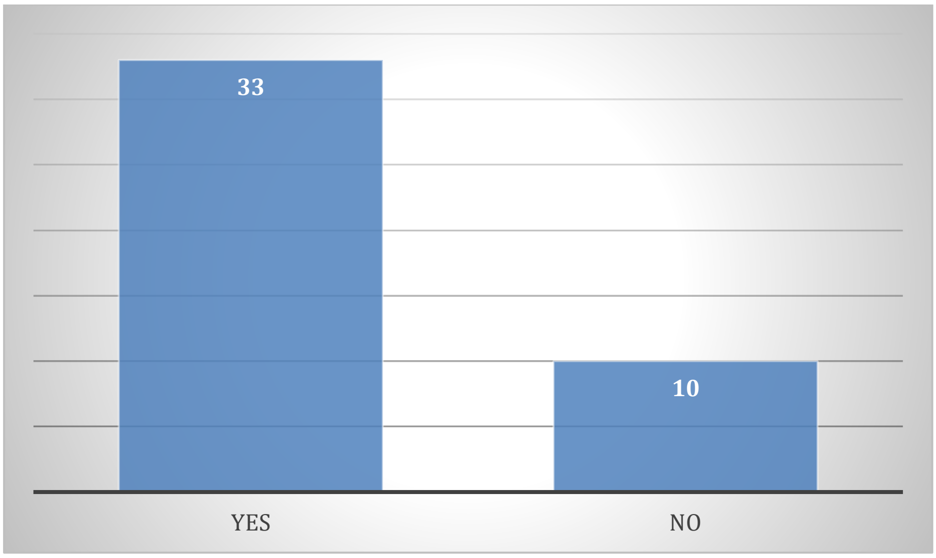
5. What kind of data transfer system do you have in place?

More than half (60%) of imaging facilities reported to transfer data through local server and a bit more than 10% using USB pen drives. Rest of imaging facilities (27%) have established data transfer procedures in place, using different forms of centralized online data transfer and storage



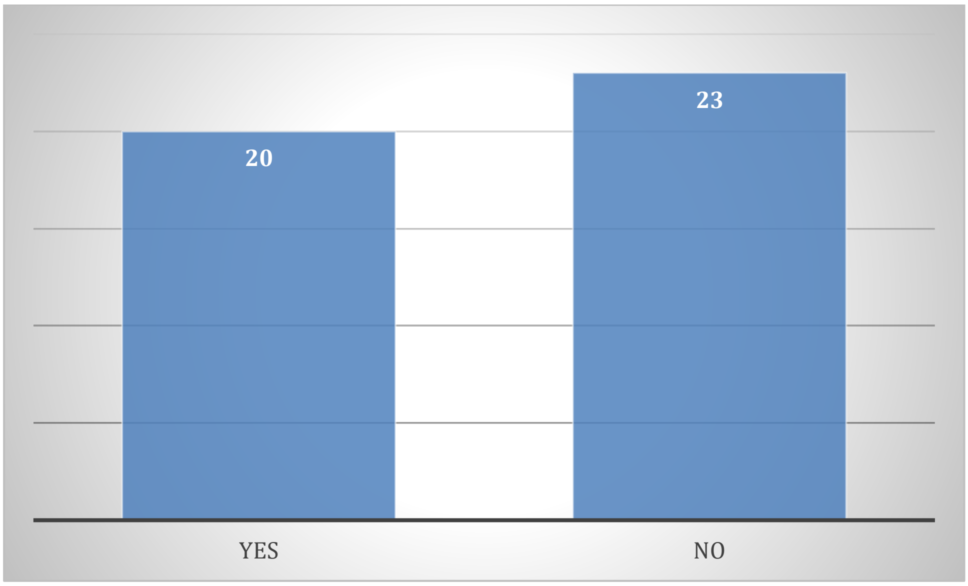
6. Does your core facility periodically collect user feedback?

Responses show that majority (almost 80%) conduct user feedback surveys and try to implement the improvements into operation of the imaging facility.



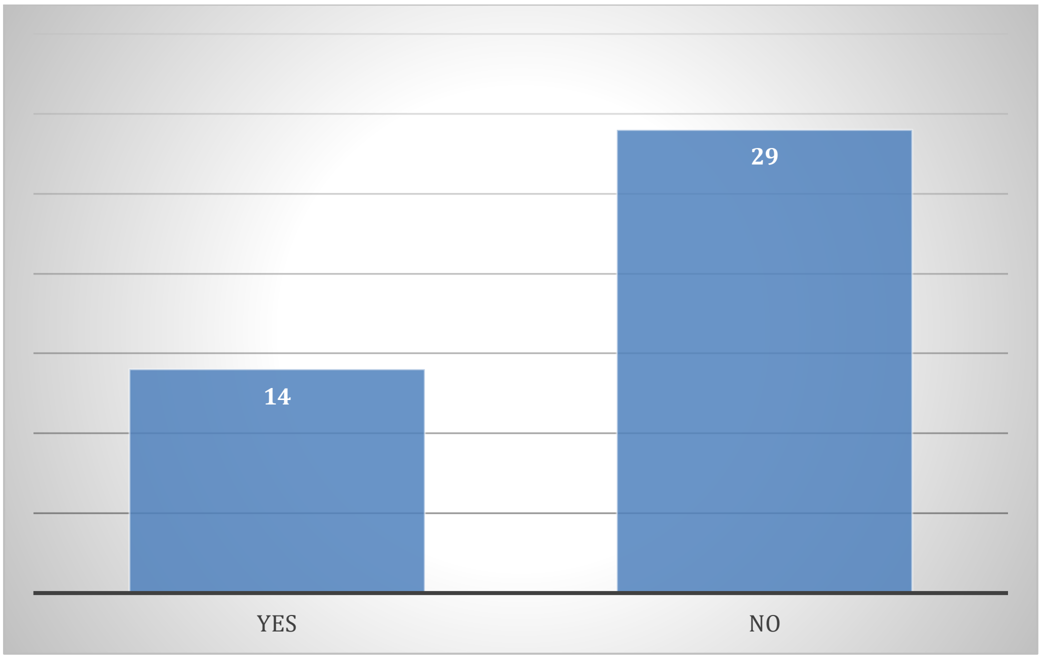
7. Are you happy with the reports you receive from vendors?

More than half of imaging facility representatives (53%) replied to be unhappy with service reports received from vendors. Most often reports were found not informative enough, missing the quantitative data of the system before and after the service.


20
23
YES
NO

8. Is the content of service reports discussed in the service contracts?

To better understand difference of service received by the core facilities, it was asked if the content of service reports is already discussed in the service contracts with the vendors. Only 30% of responses reported to include common agreement on the content of service reports into their contracts, which does explain difference in satisfaction.



Annex 2

Composition of Global BioImaging Quality Assurance and Management Working Group

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Dr. Caroline Fuery	Microscopy Australia (MA)
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