The contribution of the metrological management in the Moroccan center of blood donation

Khalid El Bekkaye[1,a,] Zaina Sidqi[2]

[1]Faculty of Science Mohammed First 60000 Oujda Morocco
[2]Regional Center of Blood Transfusion in Oujda Hospital al Farabi 60000 Oujda Morocco

Abstract. Metrological verification consists of proving by calibration measurements that specified requirements are met. The result of an audit is a compliance decision followed by re-commissioning or non-compliance followed by an adjustment, repair, decommissioning, or device reform. At the regional blood transfusion center of Oujda, from 2010 to 2018 the number of metrological qualification has increased from 88 to 152 acts with compliance going from 92% to 97%, thus the number of visit for preventive and curative maintenance of the share of external companies has also increased since 2010 to 2018 from 10 annual visits to 43 annual visits, which indicates a strong progressive metrological activity and an important place of the metrological process in the continuity of guaranteeing a safety of the result obtained from the operations carried out for the practitioners and for donor and recipient patients of the blood product. An action plan was implemented to correct the anomalies identified such as the acquisition of new metrology equipment, to predict the change of climatic chambers and non-adapted devices, the acquisition of more sophisticated machines and the establishment of a continuous recording system of the cold chain.

1. General

In Morocco, there are currently 18 blood transfusion centers distributed in 16 regions of Morocco according to the constitutional division of advanced regionalization endowed in 2015 which has established the region as a legal entity distinct from the State [1], with regulatory power to exercise their powers follows the commitment to a process of decentralization [2].

The Regional Blood Transfusion Center in Oujda is considered one of the largest centers where it receives 100% of unpaid voluntary donors since 1999. There were 25249 blood donors in 2018, with 36% of regular donors (22% national average) and whose women represent 46% blood donors, this is the highest rate in Morocco [3]. As for the population, it reaches 1.21% of the blood donors for the population of the eastern region and 2.4% for the city of Oujda (national average: 0.96%), this allows the center to cover all the demands of the eastern region of Morocco and enjoys local and regional self-sufficiency to and which fits into a goal of World Health Organization [4].

2. Metrological Process

2.1 Interest of metrological management

The management of the equipment is one of the essential points of the quality management system.

Indeed, a good management of the equipment in the laboratory and a follow-up of materiovigilance [5], are necessary to ensure the accuracy, of the equipment are numerous:

- ✓ helps maintain a high level of laboratory performance; reduces the variations between the results of the analyzes, and increases the accuracy of the results;
- ✓ reduces repair costs because less repairs will be needed on well-maintained equipment; increases the life of the instruments;
- ✓ reduces interruptions in operation due to breakdowns; increases security for employees; and allows a better customer satisfaction

[1] Corresponding author: elbekkaye2015@gmail.com

- ✓ Maintenance of the quality of operation of the device within the limits of its service life
- ✓ Made it possible to prevent breakdowns, and to eliminate non-compliances identified during their use.

Thus, the supervision of the equipment management program requires:

- ✓ Assign responsibility for all activities
- ✓ Ensure that all personnel are trained in the operation and maintenance of the devices;
- ✓ Monitor equipment management activity
- ✓ Update procedures when necessary and ensure that all procedures are followed.
- ✓ Update the material inventory notebook
- ✓ To draw up an activity report for the completed year and the action plan for the following year
- ✓ To foresee the necessary material needs for the various activities of the center since the collection, the production until the conservation, transport and delivery of blood products

2.2 The activities of the metrology manager

As a metrological quality manager it is necessary: [6]

- ✓ To draft, in a complete and thorough way, the basic rules of safety in its function when new activities or techniques are introduced in the laboratory;
- ✓ know the basics of safety management
- ✓ manipulation of chemical and infectious agents of moderate or low risk;
- ✓ Know how to implement a thorough risk
- ✓ To carry out safety audits in the laboratory.
- ✓ Participate in the various training courses on maintenance or installation and operation of the devices
- ✓ Monitoring the maintenance of the devices
- ✓ Broaden the scope of contracting in equipment, especially critical devices

3. Material and method

The metrology manager schedules a qualification of the equipment according to an annual plan, and identifies the visits of the preventive maintenance on behalf of the contractual companies, and which is well defined in a specification of load

The material used to qualify the equipment at the Oujda Regional Blood Transfusion Center is donated by the National Blood Transfusion and Hematology Center in Rabat. During the year 2018, about 152 devices and instruments are qualified. Activity is routinely performed for the various variable parameters such as: speed (centrifuges by tachometer), temperature (labile blood products storage enclosures and stable blood products by balanced temperature recorders, weight (scales by the standard masses), the volume (the accuracy of the micropipettes by graduated cones and the time (timer by the chronometer).

4. Result and discussion

The regional center for blood transfusion CRTSO has a metrology and materiovigilance service, well organized, traceability well archived, but managed with a very insufficient human resource and whose only motivation was the advantage of having up-to-date maintenance and continuous self-training, since 2010 through 2018 the number of metrological qualification has increased from 88 to 152 with compliance going from 92% to 97%, according to an annual quarterly control program to prevent any failure likely to occur, or after the appliance has been repaired to ensure compliance during use or during the installation of a new appliance in order to establish a life card in accordance with the required standards.

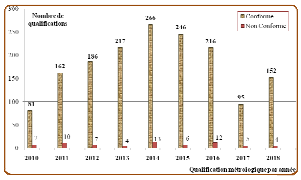

Fig 1 : Number of qualifications completed (2010 to 2018)

Thus, the number of visits for preventive and curative maintenance by external companies has also increased from 10 visits to 43 visits per year from 2010 to 2018, which indicates a strong progressive metrological activity and an important place of the metrological process in the continuity of guaranteeing a safety of the result obtained from the operations carried out for the practitioners and a confidence for the patients donors and recipients of the blood product.

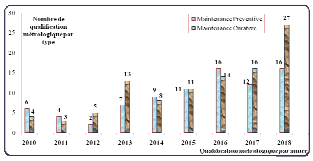

Fig 2 : Number of maintenance visits performed by the subcontractor companies in CRTSO (2010 to 2018)

Recently the acquisition of new automata has reduced the use to minimize errors and reduce the number of human resources, reduce the reaction time and increase the sensitivity of the reaction, as well as the economy in the consumption of reagents, especially with the gradual increase of the samples received and therefore a high productivity which must be maintained throughout the year in order to reach the planned objective and estimated according to the indication of the management review established at the beginning of each year by the management of the center according to existing and available resources (budget, human and material)

In fact the new automata are of high rate and high sensitivity (in serology and immunology-hematology) more endowment of the center by new sampling equipment (bag shakers, welders) and conservation of blood products have facilitated acts performed by practitioners and to obtain a reliable result

and a safety against any anticipated contamination. Together, it is important to use all the recommendations for the resolution of the problems which are: the degradation of the reagents or kits, the degradation of the control equipment, an error of manipulation of the operator, a defect in the follow-up of the instructions from manufacturer, outdated, obsolete procedure manual, equipment defect or calibration error [7].

The generalization of maintenance contracts for critical devices and their maintenance of qualification and cleaning, became a primordial necessity, which motivated the central management to expand contracting with maintenance companies, in addition to system installation monitoring of the cold chain, and the analysis of monitoring indicators regularly, the integration of a generalized and online computer system following the successful implementation of the ePROGESA software solution which provides support for management activities blood [8], participate and prepare for audits, and update metrology procedures according to acceptability criteria for ISO 9001 / v2008 accreditation. [9]

Conclusion

The maintenance of medical devices does not only concern the material itself, but also its performance during its use. Therefore, the integration of the practitioner concerned by the use of the equipment must imperatively be involved either during the market for the purchase of the devices and devices or during the ratification of the maintenance contract and the specifications in order to 'identify all the circumstances that may arise or react in handling, in addition to the requirements must be respected to correct the non-conformities noted during the last audit carried out by the French laboratory of biological fractionation [10, 11] among these steps:

- ✓ Layout of duplicate critical devices
- ✓ Motivation of metrology staff (documented and approved training by certification, attendance at conferences and seminars)
- ✓ Calibration of metrological qualification material by certified reference laboratories and Standardize metrology procedures
- ✓ Anticipate material needs during 5 years and by imposing a high warranty period (greater than 1 year)
- ✓ To generalize and systematize the preventive and curative maintenance for each type of device.

Finally, good management of human capital requires planning skills, keeping track of achievements and harmonizing transversal relationships between service staff and creating a sense of belonging. Despite the existence of some dysfunctions opposing the good approach of certain activities such as the insufficiency in human resources, periodically qualified metrology equipment and the non-availability of sensors temperature sensors, not to mention the building whose small premises of laboratories do not allow a good installation of the material or to the staff of the personnel, but with a will, and the belonging of citizenship allow the challenge and to create the difference in the good sense of approach and to innovate, and of highlighting a collective work environment and achieving the targeted objectives.

References

1. Rapport du Conseil Economique, Social et Environnemental, Exigences de la régionalisation avancée et défis de l'intégration des politiques sectorielles (n° 22/2016)
2. Djelloule MARKRIA; Indimaj Oriental, Initiative pour un développement inclusif à l'attention des migrants dans la région de l'Oriental (2018)
3. M. Benajiba *Moroccan Health Journal* **9-10** série N° 22 (Nov 2018)
4. OMS, L'autosuffisance dans l'approvisionnement en sang grâce aux volontaires non rémunérés: un objectif atteignable, *dossier d'actualité* (2013)
5. Réflexions sur la Vision et Stratégie de développement de la Transfusion Marocaine 2017-2021 'Métrologie et matériovigilance' (2017)
6. Instrumentation CIRA « Métrologie » (2006-2007)
7. Système de Gestion de la Qualité au Laboratoire, **21-36**, Manuel, OMS (2013)
8. L'implantation réussie du progiciel ePROGESA porte à un nouveau niveau les activités de collecte de sang MAK-SYSTEM Montréal, (2015)
9. Christian Virmaux, iSpé2m, conseil en management Qualité, Formation SMQ (2014)
10. Cahier de charge « Plasma Marocain pour Fractionnement » **20** CDC LFB – CNTSH (n° 2015-0065)
11. Rapport d'Audit Qualité (TAF) LFB-CRTSO (2015)