IMPROVING QUALITY MANAGEMENT THROUGH CONTINUOUS PROCESS ANALYSIS

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Rezumat. *Asigurarea calitatii, in ceea ce priveste specificitatea, este privită ca un factor obligatoriu şi este cerută, în general, de către clienţi. Obiectivul principal al departamentului IRASM este îmbunatăţirea continuă a serviciilor oferite prin intermediul promptitudinii, performanţei şi complexităţii proceselor, prin urmare, obţinând o calitate maximă a produsului care este direct proportională cu satisfacţia clientului. Criteriile enumerate mai sus pot fi obţinute numai printr-o îmbunătăţire continuă a sistemului de management al calităţii. Scopul acestui articol este acela de a demonstra faptul că analiza continuă a proceselor este imperativă pentru o mai bună calitate a serviciilor obţinute chiar dacă firma deţine un sistem certificat al managementului calităţii, ISO 9001.Obiectivul constă în analiza sistemului de măsurare a erorilor apărute în timpul procesului de tratament, evaluarea acestuia şi găsirea unor mijloace de îmbunătăţire. Rezultatele obţinute arată adevăratul nivel al sistemului de măsurare, identifică defectele şi propune acţiuni de diminuare a acestora.*

Abstract. *Considering its specificity, quality assurance is regarded as mandatory and generally required by the customers. IRASM's department primary goal is the continuous improvement of services through readiness, performances and complexity thus achieving the highest product quality which is directly proportional with customer satisfaction. The entire above mention criterion can be accomplished only through the continuous improvement of the quality management system. The aim of this paper is to demonstrate that continuous process analysis is imperative for better quality services even if the company already owns a quality management certificate, ISO 9001. The goal is to analyse the error measurement system of the treatment process, evaluate it and find the means to improve it. The results show the real level of the error measurement system, identify the flaws and propose mitigation actions for excluding it.*

Keywords: error measurement system, efficiency, irradiation treatment, quality improvement, customer satisfaction.

1. Introduction

In today manufacturing and service providers market, there is a real and biting competitiveness aggravated by the financial crisis. Thus, customer satisfaction represents a stringent factor for business development because it represents a measure of how products and services supplied by a company meet or surpass customer expectation [1]. The ISO 9000 family of standards and in particular ISO 9001 provide an excellent management tool to measure a system's performances and success of an organisation. Due to the fact that ISO 9001 has an international application, operating on global economy assures that every product, regardless of its provenance, meets the same quality requirements. Owning a quality management certificate basically says that the company is determined to provide

products and services which are not only better than the competitors' but are more reliable and predictable [2]. The mission of quality management is to maintain a high level of customer satisfaction through continuous assurance and improvements in products and services by developing, documenting and maintaining a comprehensive quality management programme [3].

Therefore, the application area of this study refers to the domain of quality management system, ISO 9001:2008, with focus on error measurement which represents an important factor in assessing and complying with customer requirements, contributing to the continuous improvement and eventually leading to increased customer satisfaction. Nevertheless, for achieving improvement, it is necessary to apply a continuous process analysis of all activities in order to identify faults and also opportunities.

In this context, the error measurement system is a key factor for the quality management system, providing the means to identify, measure, assess, control and mitigate or exclude undesired and unpredictable results. A standard definition of an error measurement system is that of a set of operations used to determine the value of the errors' quantity [4].

The domain of this analysis is represented by industrial irradiation technology which is a well established process, reaching a commercial use since the 1960s. It is widely used in almost every domain, mainly for sterilization in the medical and pharmaceutical industry, preservation and decontamination of food, treatment of plastic materials and even in cultural heritage preservation. Due to its particularities and high demands in quality of the products, it is important to have an efficient and strong error measurement system which is capable to maintain the service provided to a high standard. This system is being analysed in order to assess its level of efficiency, identify its deficiencies and find the right measures to improve it both in using and in management. The methodology is useful to managers and quality responsible because it shows an approach on how to design and assess an error measurement system.

Because industrial irradiation is a rather particular and niche domain, papers and analyses are quite limited. Most of them describe the technology, its advantages, disadvantages, limitations, alternatives, etc. and rarely the analysis of the quality management system and its requirements in this domain. This error measurement system is unique and it is adapted to the type of the service which is provided, market and organization's particularities.

In Romania, irradiation technology is centred at IFIN-HH (National Institute of Physics and Nuclear Engineering – "Horia Hulubei") which is the only owner of an industrial irradiator with radioactive sources (Co 60). It is placed at IRASM radiation processing centre which was established as a result of a technical

cooperation project between IAEA and the Romanian Government and functions since 2000. IRASM centre is first an R&D facility and secondly, client orientated, providing a full package of services like sterilization, decontamination, microbiological testing and analyses, training and research. IRASM's primary goal is the continuous improvement of services through readiness, performances and complexity thus achieving the highest product quality which is directly proportional with customer satisfaction. All these criteria can be accomplished only through the continuous improvement of the quality management system.

2. Analysis of error measurement system

The error measurement system was developed to comply with ISO 9001:2008 requirements and it uses three main tools in order to analyse and evaluate the performance of quality management system:

1. "Internal audit": it is a primary tool that continually assesses and up-dates the state of quality management system. Auditing is a way to ensure that an organization's systems match its processes and that new and improved techniques become normal practice. It defines and organises the process of planning and internal auditing. The internal audit process localises errors, describes them, applies corrective and preventive actions and assesses recurrences. Also, information from previous year is recorded in order to evaluate the efficiency of actions through the number of recurrences.

Table 1. Model of internal audit non-conformity form

Non-conformity	*Description*	*Corrective action*	*Preventive action*	*Recurrence*
SR EN ISO 9001:2008 4.2: Documentation requirements	the reference documents of procedures are outdated	yes/no	yes/no	yes/no

2. "Monitoring and measurement of errors in treatment processes and products": it represents an important part of the quality management system. Monitoring is used to observe, record and detect how processes perform and in what degree, products comply with customer requirements. Measurement determines the actual value of errors and how much it deviates according to objectives. The results are used in decision making.

Table 2. Model of registration of errors identified in treatment process

Criteria	*Zones*							*Total*
	Storage 1	Loading	Treatment	Unloading	Storage 2	Dosimetry	Expedition	

The process is divided into seven zones and the values are analysed and compiled against five criteria: 1) total no. of nonconformities; 2) errors occurred against

total no. of customer orders (percentage); 3) recurrent errors against present no. of errors (percentage); 4) non-conform products against the total no. of packages (percentage); 5) no. of customer complaints against total number of orders (percentage). The results are also compared with the objectives set at the beginning of the year. Regardless of the zones, the errors are summed. These values contribute to analysing the effectiveness of the quality management system in comparison with the previous year and with the objectives stated. Every error is documented and analysed according to Table 3.

Table 3. Model of registration of errors identified in treatment process

Number/date	*Zone*	*Error description*	*Causes of error*	*Correction*	*Actions*	*Decision*
1/1.10.2015	storage	broken package	handling	resealing	training	deliverable

The zone indicates the location of the event, error description is used to analyse if there is any recurrence of the problem, causes of error indicate if it is a human error and a training is needed or a machine failure so it must be checked/repaired, correction determines if the package can be repaired and then a decision can be made in the form of deliverable or non-deliverable.

3. "Evaluation of customer satisfaction": it analyses whether customers' expectations have been met, in what proportion, and it monitors the level of their satisfaction. The results represent the perception of customers regarding services and products delivered by the organisation. The zone indicates the location of the event, error description is used to analyse if there is any recurrence of the problem, causes of error indicate if it is a human error and a training is needed or a machine failure so it must be checked/repaired, correction determines if the package can be repaired and then a decision can be made in the form of deliverable or non-deliverable.

This assessment is conducted through a questionnaire in which customers grade the following: service quality, service readiness, professionalism and collaboration. Every answer is evaluated on a scale of four: very good, good, satisfactory and poor and the result is calculated as a percentage from the total number of replies. Total represents the sum of the grades, for example 25% equals to satisfactory and 75% means very good. As it can be seen, all the collected data are interpreted in a quantitative manner in order to be easily quantifiable.

Table 4. Model of customer satisfaction questionnaire

Criteria	*Very good*	*Good*	*Satisfactory*	*Poor*	*Total*

Another tool which supports the good management of the EMS is the corrective and preventive action working plan. Corrective means the appropriate action that must be taken and addresses the effects of the problem; it clearly defines what should be done to solve or rectify the problem. For example, if a package is broken, a corrective action is to seal it back into place. Preventive actions identify potential causes of errors that can lead to nonconformities. These actions are registered and documented in non-conformity forms, management analysis, internal audit etc. The tools used in EMS give quantitative results used to generate graphical reports.

3. Results

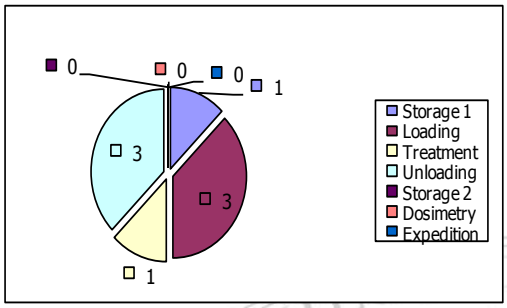
The EMS was evaluated based on the results gathered from the year 2015 and 2016 and also on how the targeted objectives were accomplished. All recurrences are established based on the previous year recordings. The results from the internal audit are represented in Table 5.

The total number errors increased more than double from 2015 to 2016. In 2015, 6 measures out of 7 require preventive actions while in 2015 6 measures out of 15 require preventive actions. The percentage of preventive actions increased from between 10% to 60%. Effectiveness has 3 scales, high, medium and low. It combines the total number of errors with recurrences and objectives. For internal audit there are no objectives defined.

The measurement of treatment process is based on information collected from the model of non-conformity documentation. According to criterion 1, Figure 1 shows the number of errors recorded in 2015 and Figure 2 shows the number of errors recorded in 2016. Comparing the results, the total number of nonconformities decreased by 3, whereas by zones, i.e. treatment process, it increased four times. Criterion 2 evaluates the number of errors related to the total number of customers' orders.

Table 5. Results of the internal audit

Year	*No. of nonconformities*	*Corrective action*	*Preventive action*	*Recurrence*	*Effectiveness*
2013	7	100%	6 – yes/ 1 – no	no	high
2014	15	100%	6 – yes/ 9 – no	no	medium



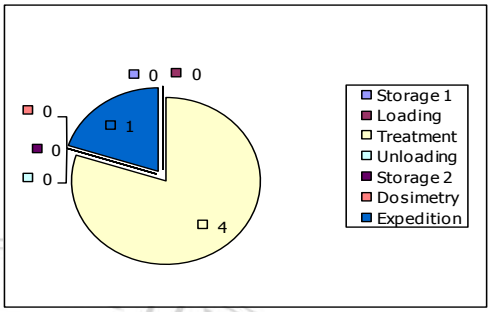


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Fig. 1: The structure of nonconformities in 2015 Fig. 2: The structure of nonconformities in 2016

The errors related to zones decreased for storage 1 and loading and appeared in expedition. For treatment process an increase of the number of errors by four times, equals a 60% increase in percentage. Nevertheless, in 2015, errors represented 1.72% of the total quantity of products (8/465 (%)) and in 2016, errors represented 1.03% of the total quantity of products (5/485 (%)) showing a 0.69% reduction in comparison with 2015. The recurrence of nonconformities divided by zones is indicated in criterion 3.

In 2015 it shows a recurrence of 5 errors out of 8 meaning 62.5% of the total number of errors. In 2016, were identified 3 errors out of 5 as recurrent meaning 60% of the total number of errors. Comparing the results, the recurrence decreased with a small value of 2.5%. Both in 2015 and 2016, according to criterion 4, there were not any non-conform products. In 2015, there were not any customers' complaints according to criterion 5. In 2016, only one complaint was received from the customers i.e. 0.21% so the objective was reached.

Table 6 shows the values of nonconformities from criteria 2 to criteria 5.

Table 6. Measurement of nonconformities for treatment process

Criteria (%)		*Place of error*							*Total*
		Storage 1	*Loading*	*Treatment*	*Unloading*	*Storage 2*	*Dosimetry*	*Expedition*	
2	2013	0.22	0.65	0.22	0.65	0	0	0	1.72
	2014	0	0	0.82	0	0	0	0.21	1.03
3	2013	0	12.5	12.5	37.5	0	0	0	62.5
	2014	0	0	40	0	0	0	20	60
4	2013	0	0	0	0	0	0	0	0
	2014	0	0	0	0	0	0	0	0
5	2013	0	0	0	0	0	0	0	0
	2014	0.21	0	0	0	0	0	0	0.21

Table 6 presents a report of the results of 2013 and 2014 and the established objectives. The objectives set for criterion 2 (4% nonconformities) were achieved. Both results of 2013 and 2014 were actually under 2%. For criterion 4, even if the

objective value is relatively small, the results are within the objective range with zero errors. Also, for criterion 5 the objectives were reached even if for the year 2014, one error was recorded meaning half of the objective.

Table 5. Results vs. objectives

Criteria (%)	*2*		*3*		*4*		*5*		*Effectiveness*	
	2015	2016	2015	2016	2015	2016	2015	2016	2015	2016
Total	1.72	1.03	62.5	60%	0	0	0	0.21	medium	medium
Objectives	4	4	no objective		0.05	0.05	0.05	0.05	high	high

The annual questionnaire records the grades provided by customers. Values collected from the customers' annual questionnaire are shown. In 2015 there were collected 7 questionnaires in which there were received only very good grades. In 2016 there were collected 15 questionnaires in which it were obtained very good but also good grade. Service readiness received one good grade and collaboration received three good grades.

Figures 3 to 6 show the evolution of customer satisfaction from 2015 to 2016.

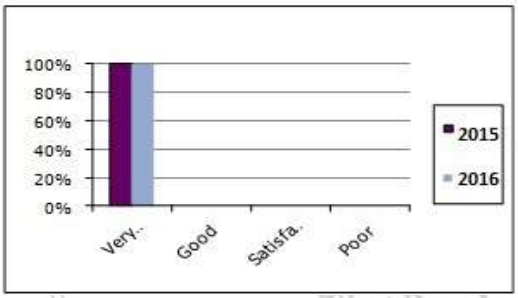

Fig. 3: Service quality results

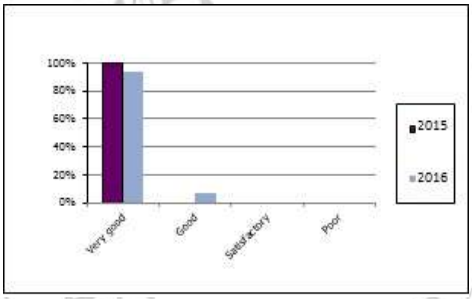

Fig. 4: Service readiness

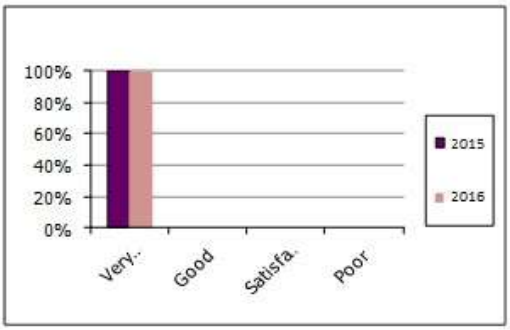

Fig. 5: Professionalism criteria

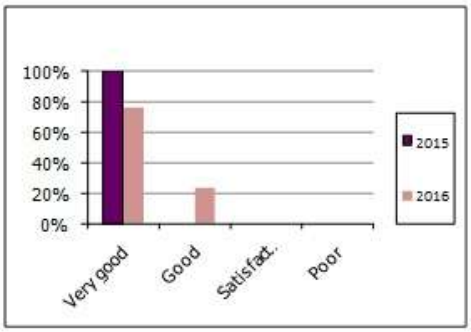

Fig. 6: Collaboration

4. DISCUSSION

The error measurement system is one of the most important elements of the quality management system. Its objectives are to identify errors using a series of tools like procedures, to measure it using non-conformity forms, assess it using management analysis i.e. policies and objectives for quality management, complaints, customer feed-back, effect of changes, etc., to analyse it by recurrence and objectives set at the beginning of the year, to improve it by adopting corrective and preventive actions and control it.

The analysis of the internal audit results shows an increase of nonconformities two times greater. Considering that there were minor changes in human resources and the reference standards did not change, it can be assumed that some errors were not properly identified because of the system's structure or because of the people. An objective explanation relies on the change of the responsible for the quality management in 2014. However, taking into consideration that out of 15 errors, a number of 9 did not require preventive actions, it can be concluded that the errors are minor and easy to handle. A very strong positive point is the lack of recurrence which states that the internal audit corrections were efficient. A drawback is revealed in the fact that there are no objectives set for the internal audit number of errors and number of recurrent errors. If objectives are not stated, people cannot relate to a specific value, thus their efforts are not focused on improvement. In this case, the continuous process analysis was very efficient and led to improvement.

The second analysis is made on the treatment process which is the core process of IRASM irradiation centre and it has a crucial impact on customer satisfaction. According to criteria 1, the evolution of the total non-conform products shows an improvement, meaning that identification, measurement and actions taken for storage, loading and un-loading processes were efficient. However, for the treatment process, the number increased four times concluding that evaluation and preventive actions were insufficient or wrong. In conclusion, a continuous process analysis is required because it is not sufficient to consider only the total number of errors but also the total number of errors on a process. Combining the results from the customer questionnaire where a decrease in satisfaction was recorded in 2014 at service readiness and collaboration, it can be stated that nonconformities registered on treatment processes are certainly one of the reasons. A risk analysis of cause and effect is necessary to evaluate the impact of errors from every zone on customer satisfaction. Thus, adequate actions can be made in order to, at least, preserve the quality of products if not improve it. A deficiency was identified when assessing the zones, namely that reception of products, which contains a process of filling and receiving products' documents, checking the goods, etc. is not subject to analysis. Receiving non-conform products or incomplete documents leads to a high amount of time consumed to identify where the error was

produced. The customer will have to be involved in these actions, resulting also in time consuming.

Even if the objectives were achieved for criterion 2, maintaining the same value, 4%, was not correct. Given the fact that in 2013 the error percentage was around 2% and the number of orders was considered to be relatively the same, the objective value should be up-dated accordingly. Keeping the same value objective even with a decrease in error numbers does not contribute to continuous improvement. Another deficiency was found in the correlation between the total number of nonconformities and the total number of orders i.e. these two characteristics have no directly proportional relationship. According to the results, for 465 orders 8 errors were recorded as for 485, 5 errors, interpreted as inefficient actions. Linking the results with the increase of errors in the treatment process, it results a medium efficient error system. Means of obtaining proportional relationship and according to an up-dated and reasonable objective value will concur to high efficient error system, preventing unknown fluctuations in the treatment process.

The recurrence of errors in criterion 3 indicates deficiencies in any actions, meaning the system is in general partially efficient. In 2013, the system was not efficient because there were registered 62.5% recurrence of errors. The error system did not work when trying to change the inputs (errors) into outputs (correct actions). Nevertheless, the decreasing recurrence from 5 to 3 indicates an improvement. Still, when reporting to the number of customers orders, which slightly increased by 20, the improvement is equal to 2.5%, a very small value. There is also a need to define objectives for this criteria in order to act and control decisions. For criteria 4 and 5 the error system is efficient because the objectives were reached. Also the difference between objectives and results is high.

The third analysis, customer satisfaction shows a relatively efficient system. It is normal to have a decrease in positive answers along with an increase in number of responses. There is also a need to state objectives for every question and identify the causes for answers lower than “very good”. A very helpful approach is to directly ask the client at least half-yearly about its requirements, preferences and any other means in order to increase its satisfaction. Also, these actions must be documented and analysed.

Continuous improvement was identified in areas where the number of nonconformities and recurrences decreased and the objectives where reached. Because of that, the conclusions are stated only for these periods and cannot be generalized. The degree in which an error measurement system is efficient should be analysed taking into consideration more data. Another limitation is given by

the particularities of the business so, the results can be used partially or need modifications or different approaches in order to be applied for other applications.

Conclusions

The error measurement system was evaluated based on the results it generated. The assessment comprised two approaches: a comparison of the results between two years, 2013 and 2014, and another comparison between results and objectives. Effective actions were found at: internal audit – no recurrence and decrease number of nonconformities; treatment process: decrease number of errors, recurrences and objectives accomplished for criteria 2, 4 and 5; customer satisfaction: adequate and linear system. Ineffective actions were identified at: the internal audit – high numbers of nonconformities and no declared objectives; treatment process: increasing errors per zones, missing analysis or wrong assessment of critical zones were nonconformities occur, no up-dated objectives for criteria 2, not defined objectives for criteria 3, non-linear evolution for the total number of errors; customer satisfaction: no declared objectives.

Mitigation actions must be undertaken either as adequate preventive actions, or defining and up-dating regularly the objectives.
In general, the error measurement system analysis provides efficiency above medium and its effectiveness is proved by constant certification for ISO 9001 since 2002.
The aim of the paper was reached, showing that the continuous analysis made through a system of tracking, collecting and analysis of data is imperative for a better quality management system in general and an error measurement system in particular.

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