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ASPECTS OF QMS IN RADIATION PROCESSING FACILITIES

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***Abstract*—**Industrial-scale radiation processing is a highly regulated industry due to the fact that most customers activate on the medical and pharmaceutical market. It is widely used mainly for sterilization and bioburden reduction in the medical and pharmaceutical industry, food industry, treatment of plastic materials and even in cultural heritage preservation. Considering its broad applicability insensitive and demanding domains, most clients require an accredited Quality Management System (QMS). The aim of this study is to present one approach of how some particular aspects of QMS impact the effectiveness of service realization. Due to the fact that there are numerous factors that influence the effectiveness of service process, the objective is to analyze few important criteria like traceability, maintenance and control of non-conform products and how it influence the desired results. The expected results show the necessity and utility of such an assessment in order to achieve improved results and implicitly, the increase in customer satisfaction.

***Keywords*—**quality management, effectiveness, customer satisfaction, radiation processing

I. INTRODUCTION

IN today manufacturing and service providers market, there is a real and aggressive competitiveness increased by the financial crisis. In the search for profit and sometimes for survival, companies change their market strategies and approaches, production, policies, objectives, diversify products etc. in order to maintain their market share at least, if not to increase it. Customer satisfaction represents a stringent factor for business development for it is a measure of how products and services supplied by a company meet or surpass customer expectation [1]. Paul W. Farris gives a broad definition of customer satisfaction, as being "the number of customers, or percentage of total customers, whose reported experience with a firm, its products, or its services (ratings) exceeds specified satisfaction goals" [2]. So, business success may simply be the extent to which an organization can produce a higher-quality product or service than competitors are able to do at a competitive price [3].

Having that in mind, a company can implement, use and maintain a general quality management system like ISO 9001. Based on its requirements, it offers the right approach and guidance in order to achieve the desired level of quality and continuous improvement of the processes on which an organization is managed. ISO 9001 has been revised with a significant change in its structure and requirements. The most important are: requirement for process approach, no mandatory quality manual, procedures, management representative, preventive actions and risk-based thinking approach. However, companies will have a 2 year period to re-design the quality management system for full compliance. ISO 9001, even if requires third party accreditation is not mandatory to conduct any kind of business activities. It depends on numerous factors like company size, product or service offered, market size and characteristics etc.

Nevertheless, there are several key reasons for which ISO 9001 is very popular among product and service providers: due to globalization of business and commerce it assures the customers that the same product, no matter of its provenience, meets the same quality characteristics, sometimes it is required by business partners, it provides confidence in a company's ability to deliver the required quality expectations products or services that fulfill customer needs and expectations, improve quality and organizational efficiency whether it is through cost reductions, eliminating defects or waste, improving processes and procedures, changing the organizational culture or adding quality control as a top priority [4].

Industrial scale radiation processing is a highly regulated industry due to the fact that most customers activate on the medical and pharmaceutical market. This type of processing, using gamma rays, reached commercial level since 1960. It is widely used in almost every domain, mainly for sterilization and bioburden reduction, preservation and bioburden reduction for the food industry, treatment of plastic materials and even in cultural heritage preservation.

Due to that, companies who offer radiation processing services are no exceptions in using the third party accredited certification like, ISO 13485, ISO 15378, ISO 9001 etc.

Companies also implement ISO 9001 for the same general criteria but, furthermore, it uses in order to gain acceptance by people, considering the reluctance toward radiation and its effects. When the public realizes that all industries follow a set of standard procedures, they become more confident in the process. Also, product acceptance increases when the process is transparent, acceptable by customers and the standards in use are visible.

Leading bodies that have developed quality standards

and guidelines include the International Organization for Standardization (ISO), the European Committee for Standardization (CEN), the Association for the Advancement of Medical Instrumentation (AAMI), the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO) and ASTM International [5]. These facts recognize the utility and need for quality management system and furthermore, applied to radiation facilities, increase product quality and safety (these requirements being the objectives of the process and strongly demanded by medical and pharmaceutical market) and also potential of business growth achieved through market share, cost reduction and on-time delivery.

II. IRASM INDUSTRIAL IRRADIATOR

Radiation Processing Centre – IRASM is a part of "Horia Hulubei" – National Institute for R&D in Physics and Nuclear Engineering (IFIN-HH). Because it is a research and development department, IRASM main objective is the promotion of radiation processing to Romanian economy. IRASM is also client oriented, offering industrial radiation services, consulting, analyses, training and research in radiation processing to interested customers.

Clients are offered a complete set of services in the form of:

1) *gamma radiation treatment (sterilization and bioburden reduction);*
2) *microbiological tests for raw materials and products (pre-irradiation and post-irradiation tests);*
3) *validation of sterility obtained through radiation treatment;*
4) *detection of irradiated foodstuff;*
5) *physical and chemical tests (product qualification for radiation treatment);*
6) *research and development in radiation processing field.*

An industrial irradiator is a large facility where a product or material is processed with radiation at a large scale. In a radiation process, the product is intentionally irradiated by placing the product in the vicinity of a radiation source for a fixed period of time whereby the product is exposed to radiation.

IRASM holds the only industrial irradiator in Romania, operating since 2000, which is a result of a technical cooperation project between IAEA and Romanian Government, named "Multipurpose Irradiation Facility". Depending on the type of product and provided services not every standard accreditation is required or applied. Thus, in TABLE I it is represented the applicability of standard documents regarding the activities conducted at IRASM. The services, subject to quality management system at IRASM Radiation Processing Centre, are the following:

1) *radiation processing;*
2) *microbiological testing for raw materials and products;*
3) *validation of radiation sterilization.*

TABLE I
APPLICABILITY OF STANDARDS

Radiation processing	ISO 9001	ISO 13485	ISO 15378	ISO 11137	EU GMP
medical devices	yes	yes	no	yes	no
pharmaceutical packages	yes	no	yes	yes	yes
pharmaceuticals	yes	no	no	no	yes
microbiological tests	yes	yes	yes	yes	yes
sterility validation	yes	yes	yes	yes	yes

Radiation processing of goods is taking place inside the irradiation room when the radiation source is moved into working position. In order to keep the surrounding safe for people and personnel, the irradiation room has 2

meter thick concrete walls and a maze shape. The basic principle of radiation treatment is rather simple. The first step is to load the products into containers of 480x480x900 (mm) and send it inside the irradiation room with a system of automatic carriage on a 2 level/ 2 sided conveyor. The maximum capacity is around 10 cubic meters that fit into 52 containers fully loaded. The second step consists in raising the racks loaded with radioactive materials and start moving the containers around it using pneumatic pistons. Each movement has set a certain amount of time in order for each container to receive the same dose. After the total time has elapsed, the containers are moved out by the same carriage and on the same path but with respect not to mix the processed products with the unprocessed ones.

In fig. 1 it is represented a schematic of SVST Co-60/B IRASM's irradiator.

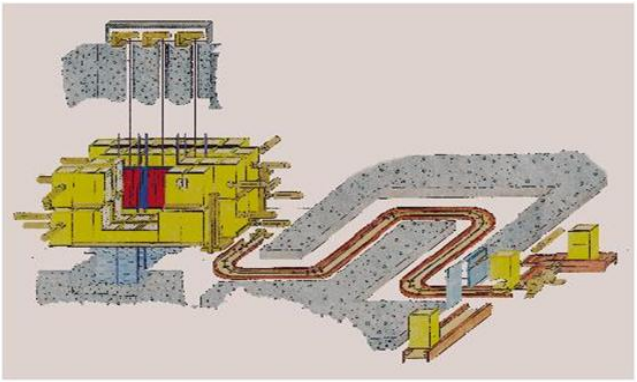

Fig. 1. SVST Co-60 industrial irradiator

III. QMS CRITERIA ANALYSIS

In order to provide services for sterilization of medical devices, IRASM uses an integrated quality management

system that requires correlated compliance with quality standards ISO 9001, ISO 15378 and ISO 13485. IRASM has documented procedures for the control of documents, control of records, internal audit, control of non-conforming products, corrective and preventive actions, purchasing, control of monitoring and measuring devices and data analysis. Its quality management shows compliance with general quality principles, continual improvement and focuses on customer satisfaction including a commitment to the safety of the product and the maintenance of the effectiveness of the QMS [5].

Some important aspects regarding radiation processing involve product traceability, maintenance and control of non-conforming products. These processes affect first service realization and in general, the quality management effectiveness.

1) *Traceability of process represents the activity of tracking the product through all stages of production within the plant, starting with reception and ending with the expedition. Every stage uses specific documents required by quality standards.*

In fig. 2 it is represented the flowchart of radiation treatment and forms required by the quality management system.

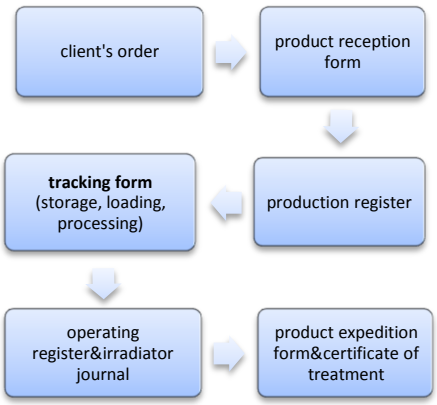

Fig. 2. Product traceability for radiation processing

For example, the tracking form contains data regarding the product (name, batch, number, manufacturer etc) and process (reception, storage, loading and dosimeters placing on the product, radiation processing, unloading, storage and expedition). Operators sign the tracking form according to the process that they accomplished. According to ISO 11137, the process is measured using dosimeters in a form of ampoules filled with a substance capable of given information about the radiation dose received by the product. Every ampoule has a unique number which is recorded on the tracking form. Based on dosimeters' reading, a certificate of treatment is released, which represent proof of complying with customers requirements regarding the treatment dose for their products.

IRASM has designed its specific system that identifies the product according to the stage of processing. Having a good traceability system allows for an efficient process of identifying, analyzing, reacting, control and improvement over the service treatment.

2) *Maintenance is required by the quality management system, in order to prevent irradiator systems to malfunction and damage the products.*

IRASM adopted a generic preventive and corrective maintenance program which is suitable for its activities as described in fig. 3.

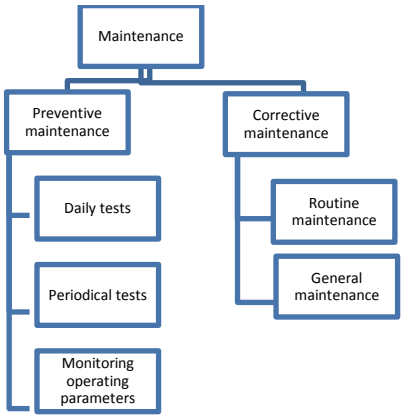

Fig. 3. Maintenance design for SVST Co-60/B

Taking into consideration the specificity of the radiation treatment, maintenance is a critical factor for the protection of the operating personnel. Thus, maintenance is required as a quality factor and as well as for personnel safe operation. The malfunctioning of the equipment does not necessarily lead to damaged products. In most cases, interruptions in treatment process increase the normal treatment process which can affect customer satisfaction by not delivering the goods in time. However, process restart allows for human errors which can lead to damaged products.

The most common errors in operation lead to damages to the products' external package. In addition, ISO 11137 requires to document how the preventive maintenance is conducted and to design a dedicated procedure. Thus, records of maintenance actions are filled in the maintenance register and are conducted according to „Maintenance procedure of SVST Co-60/B irradiator" and „Work instruction for periodical inspections and tests". Maintenance is scheduled considering weekly, monthly, semi-annual and annual frequency. Certain sub-systems are verified according to what type of inspection is conducted, including its components and devices. For example, in a weekly verification the following sub-systems and components are tested: the safety system (door locks, emergency buttons etc), water treatment system (water level, water pumps etc), radiation detector system etc.

The maintenance activities are conducted accordingly to ISO 9001 process approach of PDCA (plan-do-check-

act). In fig. 4 it is shown the management activities with respect to the quality management system.

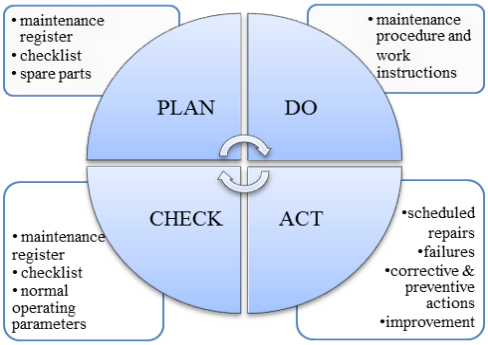

Fig. 4 Maintenance activities

In conclusion, good maintenance and operation of the irradiator influence positively the customer satisfaction and effectiveness of the treatment process.

3) *Control of non-conform products is required by ISO 11137, ISO 13458 and ISO 9001. IRASM has developed an adequate system for assuring that non-conform products are quickly identified, marked and isolated. In this way, the customer will not receive "out of specification" products and he will be quickly and officially informed about the status of his products. Once identified, the non-conform product is isolated from the batch, stored separately and labeled. It will be delivered separately and will not receive a certificate of treatment.*

All actions needed to identify the problems and responsible persons are described in a working procedure. Relevant data about the product, circumstances of occurrence, analysis and decisions are recorded within a document which contains relevant data and describes how the product was damaged.

The assessment identifies what corrective and/or preventive action should be considered in order to repair the product and prevent such events in occurring.

All non-conformities are centralized and divided into categories in order to assess accurately the location of error, the person responsible, the cause of the error, corrections applied, actions taken to prevent the error from occurring and decisions regarding the product (conform or non-conform). In fig. 5 it is represented the report of non-conformities from 2015.

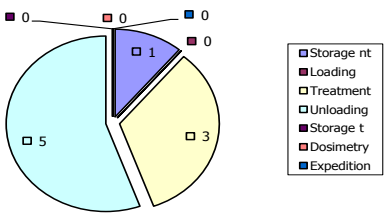

Fig. 5 Non-conformities arrangement

Failure to register and analyze data of non-conforming products lead to low-quality products, recurrences and impossibility to improve the process and implicitly, efficiency and effectiveness.

This process is monitored continuously in order to to observe, record and detect how processes perform and in what degree the products comply with customer requirements. In this way, the treatment process is improved every time an action to decrease the number of errors is taken and also lowers the probability of occurrence. Consequently, the effectiveness of service and as well of QMS are improved.

IV. Conclusions

QMS represents basically a framework for leading an organization and it is first orientated toward customer satisfaction and then of process owners. Providing services for medical and pharmaceutical markets that are rigorously regulated need mandatory compliance to dedicated standards along with a desired ISO 9001 accreditation. The reason is very simple: it assures the customer a clear and definite standard quality of the product.

Procedures for product traceability, maintenance and control of non-conforming products represent only a part of important aspects that concur to an effective QMS. Some other relevant criteria are: control of documents and records, internal audit, human resources, training, purchasing, dosimetry, calibration etc.

The existing QMS, first has proven very useful because it shaped and improved all the necessary operations used in service realization leading to efficiency and second because it increased customer satisfaction by continuous improvement and high effectiveness. Nevertheless, accreditation for ISO 9001 also increased the number of clients. In addition, the effectiveness of the QMS is recognized in not receiving non-conformities, minor or major, after external audit and also by maintaining the accreditation.

IRASM competencies are recognized through certifications, authorizations, accreditations and notifications. Starting from the accreditation with quality management certificates, IRASM adhered implicitly in using best practices thus increasing customer satisfaction.

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