

Implementing an ISO 9001 management system in processes of additive manufacturing for medical use

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Abstract

Based on a case study, this paper presents a methodology to adopt ISO 9001 standards for organizations which make use of additive manufacturing to build products for medical use. Starting with a conceptual model, guidelines were identified to guide planning and operation of the management system, as well as its maintenance and improvement.

Keywords: ISO 9001; Quality Systems; Additive Manufacturing

Introduction

The last decade has witnessed several technological innovation breakthroughs, especially in shape of new products and services made available to the consumer, who has become increasingly demanding. Due to this context, organizations face the need to apply or even optimize quality management systems. Thus, technological modernization must be criterions, with the purpose to add value to the business processes that support each organization so as to achieve continuous improvement of its products / services.

Additive Manufacturing (AM) is a technology by which objects are created in three dimensions, making use of CAD (Computer-Aided Design) and 3D-printers. AM has revolutionized the world wide industries, enabling numerous benefits to companies and organizations that have introduced this technology into their production processes.

ISO 9001 series of quality management system aims to grant confidence to stakeholders, especially customers, and acknowledge the certification bodies that a certificated company manages the quality and fully meets the standard defined requirements (Carpinet et al., 2007).

According to Gartner expectations (2014), 2015 will be a milestone in labor relations between man and machine. More than 90% of durable goods industry will actively seek

external partnerships to support new business models focused on customized products and by 2017, approximately 20% of this industry will use 3D printing to meet the market demands.

In this context, the demand for fast delivery, low cost and individually customized products and services is pushing a deep change in the manufacturing market. The use of 3D printing is an option to make such new business model possible, reducing production costs. In few years all categories of durable goods manufacturers are expected to provide customized products because customers now have increasing and easy access to 3D printing, and due to 3D printing very production nature the industry will also need to bring customers closer to the design phase of new products.

This paper presents, based on a case study, a methodology to adapt the ISO 9001: 2008 for organizations that adopt the additive manufacturing as a production process for obtaining biomodels applied in healthcare.

Theoretical Foundation

NBR ISO 9001

The Quality Management Systems (QMS) are an interesting alternative to optimize business processes in organizations since they develop a pattern of improvement that spans from the staff motivation, passing through processes control, identification of requirements until meeting customers needs (Carlage; Lima, 2001).

It is recommended that the adoption of a quality management system should be launched by a decision made at the organization strategic level. This strategic alignment assumption is present in the ISO 9001: 2008 standard, which is an feasible guide to drive the development and implementation of a management system focused on reaching customers satisfaction by fulfilling their need throughout a set of effective and strategic aligned business processes (ABNT, 2008). When an organization goes through a management reengineering process in which its management system is built up from scratch or adapted to be compliant with the ISO 9001: 2008, the final product of such reengineering effort is the organization's quality policy, expressed in terms of a quality manual containing procedures, objectives, indicators and internal and external audit routines.

This pattern of adoption of ISO 9001 applies, at least in theory, to all organizations regardless industry in which it operates, size (facilities and number of employees) or type of product / service offered to the customers. The standard is considered a basic and introductory step to establish structured and organized management processes into a business, what makes ISO 9001 a common base to improve services and products quality and also to improve business management itself (Douglas; Coleman; Oddy, 2003).

According to Magd (2008) the most important and perceived benefits obtained by organizations which adopt ISO 9001 are: improvement of internal documentation, higher quality system efficiency; clear instructions to daily tasks and procedures, clear responsibilities assignment, support to select suppliers and improvement in product quality.

Certification is the instrument used to declare the quality of the production process. In Brazil, only institutions accredited by INMETRO (National Metrology, Quality and Technology Institute) can issue ISO 9001 certificates. The ISO certification was created to more precisely define quality for a company, in terms of the requirements imposed to

certificated companies to be granted with an ISO certificate. ISO quality requirements aim to avoid waste, increase productivity, efficiency and provide a higher level of internal organization of the company (Miranda, 2006).

Additive Manufacturing

Technologies strategically applied in healthcare have played key role in worldwide private and public health systems, imposing health and technology professionals to continuously updated with regard to different aspects of technological innovation (Castelo Branco, 2014). Three-dimensional printing (3D printing) is a concrete example of innovation in healthcare technologies.

Currently different raw materials are used in 3D printing processes, ranging from polymers to metals. The term “fast prototyping” was first coined by the industry referring to a process by which a representation of system or part of it is created before its final version or final marketing. The term emphasizes the rapid creation of an object, as the outcome of the object creation effort is a prototype or basic model, from which other improved models can be incrementally created (Nascimento, 2013).

The term “rapid prototyping” has been replaced with “additive manufacturing” (AM) since 2010, when a technical committee composed by members of the American Society for Testing and Materials (ASTM) agreed that a new and more technical term should be adopted. The purpose of this new nomenclature is to make clear that some machines embodied with this technology can build finished products from 3D CAD surfaces (Nascimento, 2013).

Additive Manufacturing process for medical use

The MA process involves high technology and complexity. This manufacturing process joins materials, (micron width) layer upon layer, with the purpose construct an object which in medical domain is referred to as biomodel (Gorni, 2007).

The acquisition of biomodels compatible with the human anatomy has been developed due a process that integrates CAD technology to technological advances in medical imaging. In short, this integration starts with Computed Tomography (CT), Magnetic Resonance Imaging (MRI), ultrasound (US) or 3D Scanner images properly saved in/converted into DICOM (Digital Imaging and Communication in Medicine) are processed in specific programs, to create a three-dimensional data set in the .STL format (Stereolithography). 3D data set in turn is sent to Rapid Prototyping (PR) stations, where, through CAM system (Computed Aided Manufacturing), human anatomy models (biomodels) are manufactured (Sugar, 2004).

Currently, many efforts in order to more and more reduce mistakes and / or secondary problems in medical surgeries, since the results obtained in these procedures are expected to be the highly accurate. Therefore, surgeons are now provided with an increasing set of additional information before performing surgery itself, despite ordinary clinical examination, laboratory tests and imaging lower the risk of complications or further damage to the patient. Making use of additive manufacturing technology, one can perform a complete surgical planning by studying three-dimensional model and also simulate surgical procedure with training or pre-validation purpose (Girod et al., 2001). Maxillofacial complex surgeries are an example of medical specialty that has broadly benefited from additive manufacturing.

Another context in which AM technology is currently applied is in manufacturing of molds for custom prosthesis used in reconstructive surgery of bony parts to repair congenital abnormalities or trauma of any part of the body.

Protocol to obtain a biomodel is to have a TM or MRI of the specific anatomical region in one-millimeter axial formatting, since slice thickness will determine biomodel quality and fidelity. This file must be stored in DICOM format. These 2D images are treated in specific CAD software, creating a three-dimensional dataset in the STL format, prompt to be sent to the 3D Printing station. Meurer et al. (2003) & Seitz et al. (2004) state that the steps of preparing prototypes must be followed with extreme caution and precision in order to obtain a model with high accuracy measurements in all its dimensions. An error in any of these stages may require changes, or even full repetition, at the end of the process.

Among all advantages cited in the use of Additive Manufacturing we can highlight the full independence of how complex is the geometry of the object to be reproduced in a model. For both elementary and complex shaped objects the very manufacturing step of the process described above takes place in a single step, making use of a single device (3-D printer), is virtually and automatically carried out for dedicated systems, is done in shorter time and at lower cost, and can also be done in large quantities (Volpato, 2007).

ISO 9001 implementation in Additive Manufacture for medical use

Introduction of quality management systems in environments that use additive Manufacturing process is still very restrict. One could put in a short list all AM practitioners operating under quality management systems. The cause for this limitation is that AM is a recent technology, still in initial boom phase. But, on the other hand, if observe medical services context, one can easily mention a large number of hospitals, clinics, laboratories and many other environments compliant with ISO 9001 certification, as the market required from them this standard of quality excellence.

When consider the restrict field of Additive Manufacturing notice that the production processes are still to be more formally stated, since there are several applications for this technology in the medical, industrial, construction, bioengineering fields, among others, and each community uses different methods, complementary technologies and business processes, what makes standardization an open challenge. However, there is in Brazil a well-known AM process ISO 9001 certificated, performed by the three dimensional Technologies Division (DT3D) of the Information Renato Archer Technology Center (CTI), which is the object of this study.

Methodology

This study is characterized as descriptive research, of case study modality, carried out through interviews, which application scooper was the three-dimensional Technologies Division (DT3D) of Information Technology Center Renato Archer (CTI), which has an ISO 9001 certified quality management system and searches continuously improve the efficiency of the management system and the quality of services provided.

According to Hart et al (2007) a descriptive researches observes, records and then analyzes and correlates collected facts to the reality. According to Barros and Lehfel'd (2000)

case studies must be focused on the collection and recording of information concerning one or more individualized cases, on the development and analysis of critical and organized and well organized reports, with the purpose to support decisions and interventions on the object studied in the research (a community, an organization, a business, etc.). Hart et al (2007) also reports that data collection entails several steps such as the preparation of the collection instrument, planning on the collection and also on the type of data to be collected.

Following the theoretical directives above, this case study was conducted through interviews and day-by-day monitoring of the organization's activities. And investigation script was compiled from ISO 9001: 2008 guidelines to operational processes. Most part of the questions contained in the script are directly related to ISO 9001: 2008 prescriptions, while some of them have been added by the authors in order to capture complementary information on the quality management system as well as the impacts, benefits and achievements that the organization selected for the study reached after introducing the standard into its business processes. This script can be seen in Table 1 below:

Table 1 – interview script to the case study

Interview script	
Organization Profile	Name
	Start up date
	Location
	Industry/playing field
	No of employees
Certification Scope	Standard adopted
	Product line(s) certified
	Certification date
	Assessment entity
	N° of certificate renewal
Implementation Process	Motivation to certificate
	Decision maker
	Implementation start
	Implementation finish
	Implementation leader
	Number of components of implementation team
	Profile of implementation team
	Supported by external consultant?
Implementation Methodology	Main difficulties faced during the implementation.
	Documents created (procedures, instructions, records) - Quantity?
Benefits and Outcomes	Documents created (procedures, instructions, records) – Which?
	Direct benefits
	Indirect benefits
	Qualitative outcomes
	Quantitative outcomes

Case Study

Organization History

The organization selected for this case study is the three-dimensional Technologies Division (DT3D), one of units of competency of the Information Technology Renato Archer Center (CTI). The Center is a research institute affiliated to Brazilian Ministry of Science, Technology and Innovation (MCTI) and is engaged in research and development in information technology.

The DT3D Division started to operate in 1997, and since then has been dedicated to research, development and technological applications in various areas of knowledge, supporting the Brazilian industry and medical service providers by means of either internal endeavors or projects in partnership with several universities. Currently, special attention and great effort is put in the medical field by DT3 division, by mean of support to hundreds of hospitals, and services and technology provision to support Brazilian industrial development, as well as pure and industry applied research. These activities are housed in three major programs: the ProMed - focused on research, development and medical applications; the ProInd – dedicated to support the industrial development; and the ProExp - a program focused on the development and broadcast of 3D technologies unconventional applications in industry and scientific experiments. These programs work together as a strategy to seek partnerships in the industry, universities and other R& D centers with the purpose to empower the raise of innovation, scientific publications technological diffusion and relevant services to society (Silva 2013).

QMS Implementation Process

The Quality Management System Implementation in the organization was made by ISO 9001: 2008 in order to gain reliable and demonstrate that their processes and, consequently, its projects and services were performed in order to meet the requirements and customer satisfaction;

The implementation process spent 32 months, from mid-April 2009 to November 2011, when the DT3D was granted with certification after audit process conducted by BUREAU VERITAS certification body. The certificate was first valid until November 2014 and is now through its renewal path. To make data collection possible and data analysis feasible to our research team resources, that limited the case study scope to DT3D Research Project and Development (R&D) and services based on three-dimensional technology to the industrial areas, medical service providers and experimental research, including the activities of prototyping, 3D printing, technical evaluation and image reconstruction.

During the construction of this case study the DT3D was prompt to be re-certified, adding to the certification renewal the Project Development process as a new candidate process to be granted with ISO 9001: 2008 certification.

Dr. Jorge Vicente Lopes da Silva, current head of DT3D, made the initial decision to introduce a QMS in the unit. The implementation team assembled to implement the quality management system was composed by the unit director and four other members, including three internal staff, an external consultant.

Implementation Methodology

We used the turtle diagram to identify each service delivery process, including the activities of the support processes that composes the quality management system and its application. Barnes (1982) states that turtle diagram is a good technique to express process dynamics in a compact view in order to make it easier to understand and further improvement.

One turtle diagram was made for each DT3D processes required to the development of the Quality Management System, such as: Management, Quality Management, Administration, Production, PROIND, PROMED, PROCEXP, Projects, according to the format shown in figure 2 below.

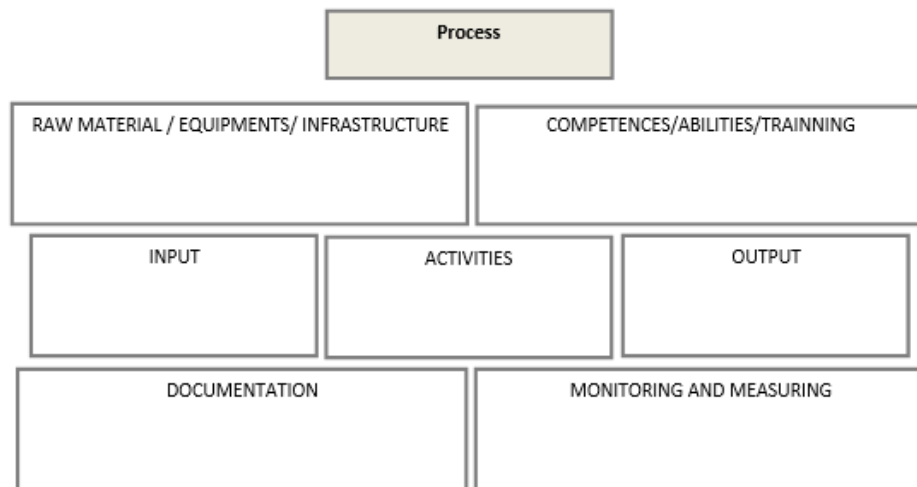


Figure 2 – Diagram displaying the DT3D processes

In each item of the diagram it is described what each process needs to be executed. Special attention is required to items Documentation and Monitoring and Measurement, because in these processes entail the quality procedures (PQ), work instructions (WI) and the quality control documents (QD) that each process needs to be performed as well as the quality registers (QR) that must be made at the end of each procedure.

According to item 4.1 which deals with ISO 9001:2008 general requirements, the organization must: determine the processes that compose the quality management system and its application throughout the organization; determine the execution sequence and interactions of these processes; determine criteria and methods needed to ensure effectiveness in operation and control of these processes; ensure the necessary information and resource provision to support the operation and monitoring of these processes; monitor, measure where applicable and analyze these processes; implement actions that these processes require to achieve planned results and keep in continual improvement.

With this organization the Quality Manual (QM) was described in levels, how would be the structure of the documentation DT3D. Level 1 document is the QM itself, which describes all QMS in its policies, objectives and the Division responsibilities. Level 2 documents were prepared in terms of quality procedures, in each process step is described in detailed

instructions. Level 3 documents were prepared in form of work instructions and quality control documents in which are as well described in detail and sequentially every activity that must be done to get the result of a particular procedure. In the DT3D case it was determined that IT only would be done when the activity performed was considered critical in the QMS. In level 4 documents the procedures are registered in the form of quality records, which are issued to objectively show that the activities have been actually executed.

According to the item 4.2.1, which refers to generalities of ISO Documentation Requirements 9001: 2008, the quality management system documentation shall include: documented statements of a quality policy and quality objectives; a quality manual; documented procedures and records required by this Standard; documents including records, determined by the organization as necessary to ensure the planning, operation and the effective control of its processes.

In compliance with the 9001: 2008 standard DT3D has ten documented procedures, which are one DT3D Quality manual, eight quality procedures as required by the standard, and one work instruction for rapid prototyping. There are also six Quality Documents related to the quality objectives and indicators, the responsibility and authority matrix, the personal protective equipment (PPE) , the division professional profile, the specification of critical items such as materials, supplies and services and the failure report processes.

Also according to the standard several quality records have been made, among them master list of QMS documents, minutes of meetings, action and training plans and assessments of their effectiveness, critical analysis of products requests and offers, records of proceedings and check-list of all 3D printers division, record control of production, maintenance reports of 3D printer, control and application of corrective and preventive actions, consolidated indicators and internal audit plan, customer satisfaction survey.

All procedures, records and work instructions are performed by key stakeholders, in digital format, but with manual movement within the division, thus making up a risk, since it can happen any human error in the proceedings. Even with this documentation format, there are no reports of errors, and have been developed over three million cases of success in PRE MED program for surgery and cost reduction.

The DT3D also executes support processes, since this organization is a unit of CTI. They are: DSC - Computer Support Division, the division responsible for support and maintenance of IT infrastructure; DINF - Division responsible for take care of DT3D facilities; DSUP - Division of Supplies and Services division responsible for carrying supplies purchases and services when purchased with direct funds from the Federal Budget (Brazilian Federal Government), in these cases it is up to DT3D the technical specification of the purchase of items and after receipt, verify that they are in accordance with specified requirements; HRD - Human Resources Division, the division responsible for the safekeeping documentation related to DT3D employees CTI work contracts; and finally FACTI - a legal entity private, non-profit, Information Technology Foundation with full administrative autonomy dedicated to CTI operations, providing complementary human resources and materials in order to speed up CTI interaction with the market (Silva, 2013).

Within DT3D the QMS FACTI takes intermediation between the division and its customers, in what concerns to sale, service and goods acceptance and administration of the resources earned by the division, through the provision of services. FACTI is responsible for purchasing supplies and services, provide skilled labor to complement the team DT3D and keep documentation of these employees (Silva 2013)

Note that the printed prototypes in PROMED program are mostly free, because prototyping services requests come from physicians and / or hospitals in the Brazilian public health system. When request comes from private sources prototypes are made at the request of the physician, for patients who afford prototype. Requests processed in DT3D come from all over the country and even from other countries.

Benefits and Results achieved with implementation

The DT3D directive board claim that the ISO 9001:2008 - based QMS introduced in the division came to standardize and systematize activities already practiced in their service and products providing routine, since they had been already trying to adopt a systematic management model while they did not have certification yet. With the QMS implementation DT3D has achieving an standardized the entire system according to ISO 9001: 2008, made indicators collection and demonstration to Brazilian Ministry of Health straightforward, being able to express more clearly express in numbers and processes every advance that the organization reached. In addition a complete activity map was built, which enabled clear communication and comprehension to all levels staff, thus harmonizing the work environment. Standardization of procedures enable also more security to perform DT3D processes activities.

Conclusions

In the course of this study, was described the whole methodology of implementation of the Quality Management System in the 3D Technologies Division of Renato Archer Information Technology Center. As products of the implementation process we had the Quality Manual, a document that defines the scope of the QMS, the Quality Procedures according to the standard, the work instructions for the correct development of activities, quality documents that include the information in the procedures and documents define a standardization of reports and records used by the organization through quality records.

Throughout this study, we can see that the implementation of the QMS was conducted smoothly without causing any harm to the organization. Was efficient, since before the implementation of the standard already intuitively followed a pattern for the proper functioning of the system. We conclude the implementation of ISO 9001: 2008 a concrete advance to the DT3D, consolidating and standardizing processes by means of its the Quality Management System.

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