

DEVELOPMENT OF SYSTEM FOR PROCESS CONTROL AND DATA ACQUISITION IN LARGE GAMMA IRRADIATORS

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ABSTRACT

The radiation sterilization has technique well known and dominated. In Brazil there are in operation gamma irradiator with capacity between 0.37 PBq (10 kCi) to 185 PBq (5 MCi) in ^{60}Co . It must be assured that the manufacturers follow Guides of Good Practice of Manufacturing (GMP). The GMP principles are: an integrated system of manufacture and assured quality, distinct managements for production and assured quality, appropriate place, equipment and materials, trained staff, procedures registered for manufacture and assured quality, appropriate registers for lots and products, adjusted handle, transport and storage, recovery systems and system to audit the operation of GMP. The project aims at systematize the data acquisition process of the irradiator using an appropriate system. Interface WEB will make possible to the customer initiate the flow of the product to sterilization directly from its workstation or company, following the product until the return of the finish information of the process of irradiation without people physical displacement to verify or to follow the process. The system administrator can have remote access for any consultation or changing of data or parameters. The use of software free for use is available for this kind of system.

1. INTRODUCTION

Many efforts for using pacific nuclear technology have been made around of the world and in many areas, such as: medicine, foods, manufacture and electricity generation. In this direction, important nuclear science has been doing contributions in the supplement of basic necessities of humanity. Processes radiation has been used with success in some industrial segments promoting conservation of energy and ambient protection resulting in addition of value to the products¹.

In Brazil the beginning of the use of radiation technology was in the seventies decade with the cross linking of polyethylene used as insulator of cables and sterilization of medical care products. The current stage of radiation application shows that the technology is growing in accordance with the economic development and the necessity of manufactured products to be competitive in costs and quality in internally as in the external market¹.

1.1. Radiation Plant

The Fig. 1 represents an irradiator of continuous cycle of irradiation. It has a door for pallets access or boxes with products for irradiation and has another door for exit. The movement of the transporter occurs previously in programmed steps. The products pass around the source for a

complete irradiation of the all parts. In gamma irradiator there is a segregation of irradiated and non-irradiated products.

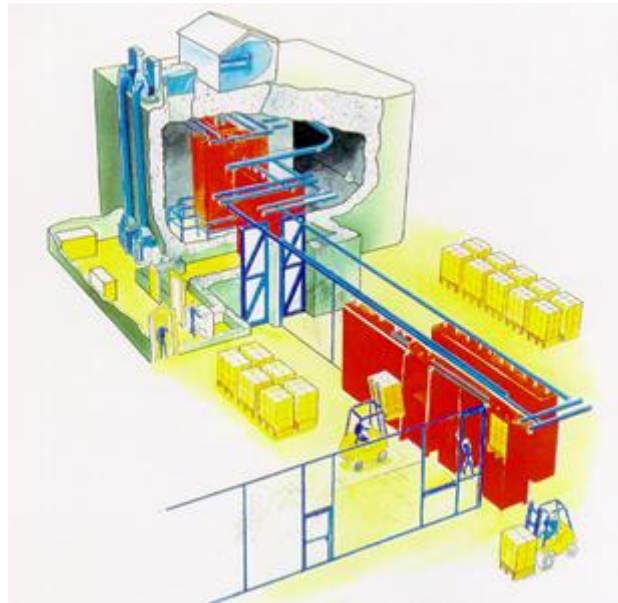


Figure 1. A representation of Gamma Irradiator with its source swimming, transporter, security equipments, operator console, input and output of products. The fences are to separate non irradiated product from irradiated products

The radiation sterilization is a technology well known and dominated. In Brazil it started has thirty years with the growth of demand for sterilization of products used in the medical area. Currently exist in operation in Brazil seven gamma irradiators with capacity between 0.37 PBq (10 kCi) to 185 PBq (5 MCi) in ^{60}Co . One of the most recent irradiators (2004) was designed and constructed in the IPEN with national technology using the knowledge of the local researchers. It is a tote box irradiator with capacity 74 PBq (2,000 kCi) ².

1.2. Good Manufacturing Practice (GMP)

Good Manufacturing Practice (GMP) is a quality system regulation for irradiation of medicinal products. It serves more than only to validate and to control the processes, it guarantee that all the process is safe and that the materials can be used for its purpose. It must be assured that the manufacturers follow Codes or Guides of Good Manufacturing Practice to be in conformity with established national standards for production of medical products. The necessary activities are listed to assure to the manufactured product concerning its quality, security and performance and generally, be elaborated according to the following GMP basic principles⁴.

- An integrated system of manufacture and assured quality;
- Distinct responsibilities of management for production and assured quality, appropriate place, equipment and materials;

- Trained staff, procedures registered for manufacture and assured quality, appropriate registers for lots and products;
- Adjusted manuscript, transport and stock;
- Systems of recovery;
- System to verify the operation of GMP.

Before entering the product in the irradiation chamber and after the exit, the product will have to be manipulated by experienced and trained operator in proper areas according to the status of the product (no irradiated or irradiated). For the forwarding of the material the identification will have to be registered, lot of production (if used), and the number of units of the product will have to be reconciled with the contained original amount in received documents. In the specification of the process it will have to require that the following information are registered for revision for authorized individuals and enclosed in the processing registers.

1.3. Standards

Several standards had been emitted to guarantee the quality of manufacture and manipulation of medical products and food stuffy. International Standard ISO 11137-2000 establishes the requirement to assure that the activities associated with the processes of sterilization radiation is made property³.

The International Agency of Atomic Energy the IAEA edited document TECDOC-539 (1990) with guidelines for industrial radiation sterilization of medical disposable products (cobalt-60 gamma irradiation) that "The primary manufacturer must assure that all steps in the manufacture of the items to be sterilized are carried out in accordance with relevant Codes of, or Guides to, Good Manufacturing Practice." ⁴.

ANVISA (Agency of Sanitary Monitoring) from Brazil, published RDC 275-2002 Good Manufacturing Practice in Food Manufactures Establishments. The RDC 210-2003 determines Good Manufacturing Practice for Medical Products⁵.

2. CONTROL SYSTEM

All products within the irradiator's process are identified by bar code or RFID (Radio Frequency IDentification) tag. The system for data acquisitions are based in commercial or industrial systems. The equipments reader's interface for bar code or RFID tag uses communications such as RS232, RS485, Ethernet or wireless Wi-Fi/Bluetooth. This acquisition system is independent from irradiator control system, where the operation, interlocking and security are based on standalone Programmable Logical Control (PLC). The process information will be used to compose the report for certification of the products submitted to the irradiator.

2.1. Software and Workflow Systems

Currently the processes follow up are made by tools of computational systems called Business Project Management (BPM). Some are property of software companies and others are free for use. Example of free software available is ObjectWEB software (www.ow2.org). This institution is kept by companies and people that work on development and keeping software free for use. The license of free software allows without charging the use, the distribution, modification of the

original source code. However, it does not allow charging for the use of the software and does not allow registering as property of any part of it. The license of use of free software is defined in Lesser General Public License (LGPL).

2.1.1. Workflow tools

The software Bonita ⁶ is a tool of BPM. It allows to drawing the flow of process and sub-process, to describe the activities and the users. It is a design tool. The interface is published in the WEB. Where the participants of an activity can remotely access it, either the customer company has different involved sectors in the irradiation process.

The Fig. 2 shows Bonita's screen Console for Ipen irradiator's prototype (although this application serves to others irradiators). It can accept customization in order to show information about the application, in accordance with to show to the user profile login.

Orcamento	
Nome	<input type="text"/>
Responsavel	<input type="text"/>
ID_Cliente	<input type="text"/>
TipoPessoa	Juridica
Telefone	<input type="text"/>
Fax	<input type="text"/>
Email	<input type="text"/>
Produto	<input type="text"/>
Tipoproduto	ProdutoJaProcessado
CaracteristicaAplicacao	<input type="text"/>
Material	<input type="text"/>
UnidadeProduto	<input type="text"/>
VolumePeso	<input type="text"/>
QuantidadeEmbalados	<input type="text"/>
IDLotesFabricacaoCliente	<input type="text"/>
Observacao	<input type="text"/>
DoseMinimamGy	<input type="text"/>
DoseMaximamGy	<input type="text"/>
IDOrcamentoAnt	<input type="text"/>

Figure 2. Display from Bonita's Console⁶.

In the Bonita four different types of participants are defined: the Administrator that configures and has privileges to create users; the Designer that design the flow of the process, related the activities and the integration to diverse interfaces of the process; the Operator that has the function to manage the development of the diverse flows; and the User that has specific tasks to execute.

The Bonita allows that the User sees four lists of activities: Start: workflow that can be initiated by the user; Running: initiated tasks and that they are in execution; To Do: tasks that the user has that to execute; Done: tasks that already had finished. The Operator can verify details of the

models of processes, setup, the Logs of the applications, traces of the tasks and the History of the processes and activities.

2.1.2. Process Workflow Design

The software Bonita works with two types of process the Models and the Cooperatives, where the following entities of workflow are possible: transition or edges, conditions, subprojects, iterations, properties, users, decisions, loops and other sequences of activities. The Bonita supplies an interface drawing of these tasks.

The Fig. 3 shows a typical workflow example for initiate a process where the customer asks for an order to irradiate a product. The commercial stuff prepares the pre-sale document, send to the manager to analyze it. The manager decides if the product is already process in the past or if it is a new product. The commercial stuff completes the information and sends to the customer for approval, disapproval or resend to commercial for new negotiation. If the customer approves the pre-sale, a sub-process is initiates for a formal order of new product or product already processed.

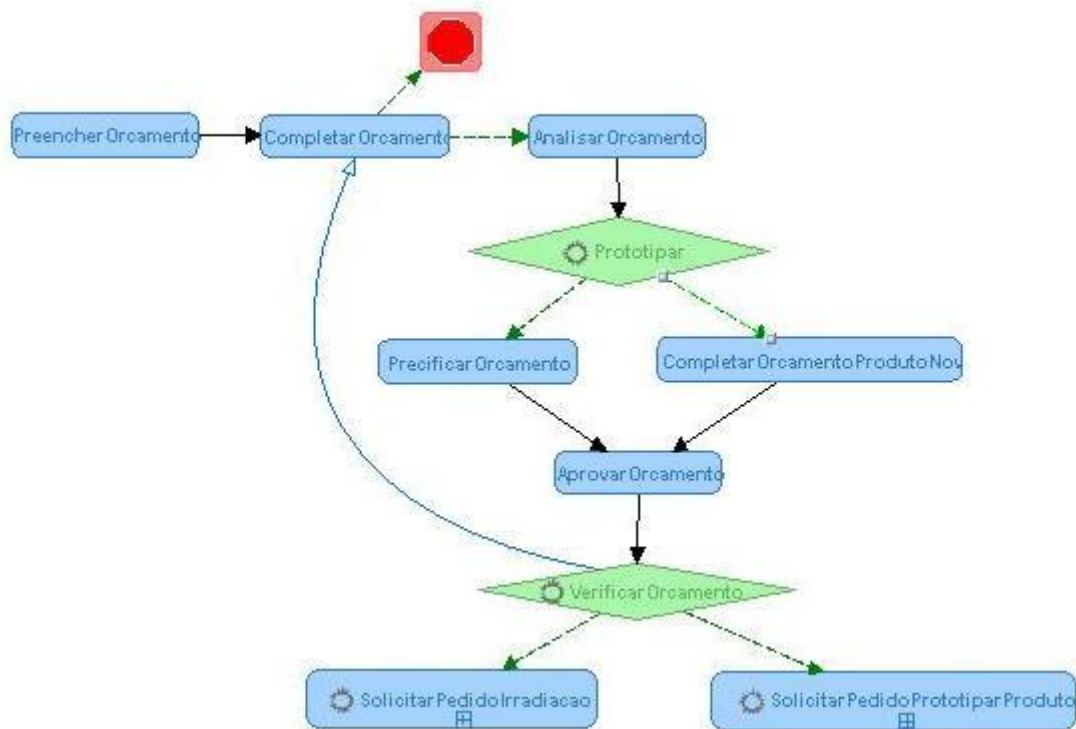


Figure 3. Bonita workflow design example.

The complete workflow initiates when the customer creates a service order and sends the product for irradiation. In the warehouse it is received and identified with bar code or RFID tag. Then in an appropriated production schedule time, it is done the accompaniment of the product before, during and after the irradiation. After that, the product is sent to the customer. All the time the participants can see the real status of order using Bonita's Console.

2.1.3. Bonita Architecture

The Bonita uses technology XPDL (Process Definition Language) to represent the flow of the process. This way of application allows that the flow is developed as imported application from JAVA and as a flow inside of Bonita

The Bonita ⁶ beyond the JONAS ⁷ can be installed in other servers of applications, Jboss for example. All are written in JAVA. Therefore they execute in platform JVM (Java Virtual Machine), this means that they can be installed in any equipment that is supported technology JVM, Linux for example. It supports interface with data base such as PostgreSQL, MySQL, Oracle, DB2, among others. It makes interactions with other applications through WEB Services.

3. CONCLUSIONS

The use of workflow software to follow all steps of products irradiation in a large gamma irradiator, allows the guarantee and the rastreability of the process. The use of free software for this work is a guarantee of continuity in the evolution in such a way of software as in the evolution of the accompaniment system. It only depends on personal involved in this task. It does not need great amount of financial resources for the acquisition license. The product follows up process is a powerful tool concerning to the information access. It can go to highest precision levels of automation.

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