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# DEVELOPMENT OF SYSTEM FOR PRODUCT TRACKING AND DATA ACQUISITION OF DATA IRRADITION PROCESS IN LARGE GAMMA IRRADIATORS

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## ABSTRACT

The sterilization of medical care products using ionizing radiation is a consolidated technique. In Brazil there are in operation gamma irradiators with capacity between 0.37 PBq (10kCi) 185 PBq (5 MCi) using radioisotopes $^{60}Co$ as radiation source. The developed work provides an accurate control and data acquisition for the application of Good Manufacturing Practices during all phases of an irradiation process, required by the standards of ANVISA, technical ISO and IAEA recommendations for the treatment of foods and medical products. All the steps involved in the irradiation treatment are mapped into process flow (workflow), where each agent (participant) has its systematized tasks. The automatic data process acquisition using wireless ZigBee technology, monitoring and control, are based on a set of tools (free software licenses) integrated by a network of efficient communication, including the use of Web resources. Using the Gamma Irradiator Multipurpose IPEN/CNEN-SP all the development was performed to be applied in irradiators' facilities operating in industrial scale. The system enables a complete traceability of the process, in real time, for any participant and also the storage of the corresponding records to be audited.

Keywords: Irradiation, GMP, Workflow, Open Source, ZigBee.

## 1. INTRODUCTION

In Brazil, the use of irradiation processing technology was introduced in the 1970s, with the use of polyethylene irradiation in the production of insulation of wires and cables and sterilization of medical equipment. The current stage of application of irradiation processing industry shows that the use of technology is growing [5].

Currently in Brazil, there are irradiators in operation with a capacity range between 37 PBq (10 kCi) and 185 PBq (5 MCi) using sources of $^{60}Co$. One of the latest irradiators (2004) was designed and built in IPEN/CNEN-SP with national technology using the expertise of its researchers. Has a capacity of 74 PBq (2,000 kCi) [4].

The processing of food products, medical, in a gamma irradiator obeys with the most varied standards of quality, either national or international. They are known as Good Manufacturing Practices (GMP).

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The ANVISA published the Resolution RES 275/2002 [1] which introduces the practice of GMP and Standardized operational procedures; the RDC 21/2001 [2] establishes requirements for food irradiation; the RDC 59/2000 [3] determines GMP for medical products. ISO/FDIS-11137: 2006 [5] is specific for validation of process control and monitoring of routines on irradiation sterilization processes of products for health. This is applicable in continuous processing in batches on gamma irradiators using as source Cobalt-60 and for electron beams accelerator or x-ray generators. In document IAEA-TECDOC 539 [6], the irradiation plant is considered a part of the process of manufacture of the product, and whiles such, must be bound to Good Manufacturing Practices, and more comprehensively, to Good Radiation Practice (GRP).

Is required that, the irradiation certificate, presents the evidences of the accomplishment of the irradiation service and the phases that the product covered in the environment of processing of the irradiator, as requisite of certification of quality. Separate environments for non-irradiated and irradiated products. Dosimetry proving the absorbed doses is between the minimum and maximum allowed for the product.

The use of free software license in the construction of systems of most diverse purposes is an irreversible reality. This work describes a process management solution of irradiation of products in a large-scale gamma irradiator. The purpose is to make the follow-up (follow, track) the product from the initial budget request of irradiation service by the customer until the expedition and invoicing of the services.

The full description of this work can be found in [9]. Whose doctoral thesis project was the subject of article published in INAC 2007 [10].

### 1.1. Gamma Irradiation Facility

The Fig. 1 represents the gamma irradiator, the object of this application study. The boxes with the product for irradiation are placed on the carrier of steps. It introduced a box at a time in the radiator by the input door. In the same operation, is withdrawing a box by the output door. Inside the irradiator there are 17 positions, which the boxes occupy to complete all faces of the box for the internal irradiation of the product. Internally the carrier has an elevator to locate the boxes in the inferior part of the sources.

The process of sterilization by irradiation is a known and safe process. The low energy gamma ray emissions, an emission with energy of 1.17 MeV and another one with 1.33 MeV, do not leave the material to be radioactive and improper for consumption. The gamma irradiator of the Fig. 1 was inaugurated in 2004. There are two racks of pencil containing sources with $^{60}$Co. When dived in the swimming pool they are total safe. They are only exposed when the doors are closed and the whole system of interlock and control residing in a Programmable Logic Controller (PLC) are indicating operating conditions. The irradiation process is quite simple. The sources contend $^{60}$Co are emitting gamma radiation and an electron Beta. The $^{60}$Co is a radionuclide unstable.

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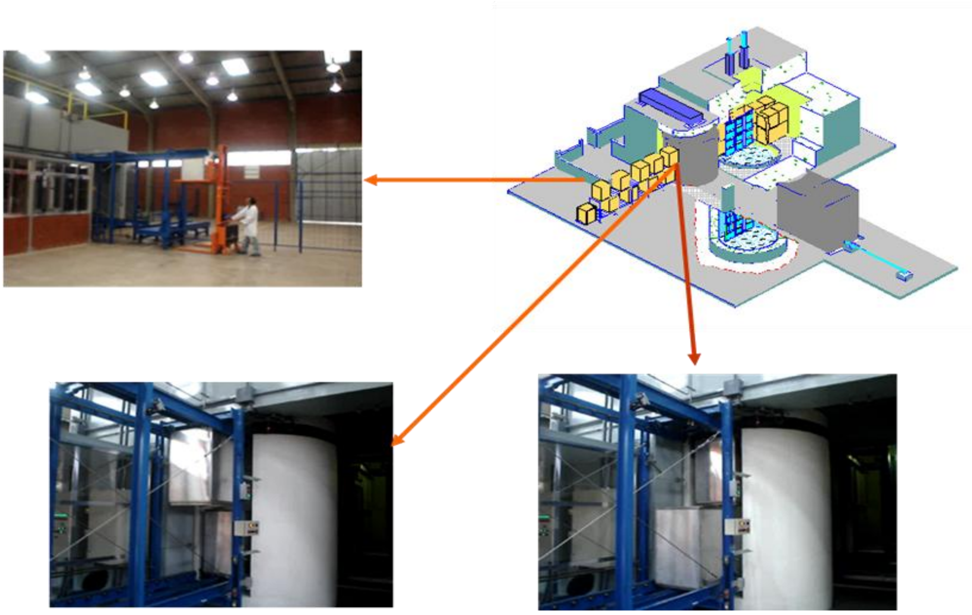

**Figure 1 -** Compact Irradiator Multipurpose of the IPEN **/CNEN-SP.** In the left superior photo, the operator introduces a box in the transporter. Photo of the right, a schematically drawing of the irradiator. Inferior photos, to the left: introduction of a box in the irradiator; to the right, the withdrawal of a box of the irradiator**. (Photos: Paulo Roberto Rela)**

Cobalt is gotten artificially with the bombing, per two years, of $^{59}Co$ inside a nuclear reactor (cobalt-59 is a steady atom). A neutron is implanted in the nucleus of $^{59}Co$ transforming it into $^{60}Co$, which is unstable. At some moment the spontaneous emission of an electron beta and the two emissions occurs gamma. The result is a radionuclide of nickel ($^{59}Ni$) steady. The compact irradiator multipurpose IPEN/CNEN-SP all projected and was constructed with national technology. Only the $^{60}Co$ pencils are imported. The configuration of the sources follows the called standard tote box and has a capacity of irradiation of 74 PBq (2.000 kCi) [4].

## 1.2 Good Manufacturing Practice (GMP)

Good Manufacturing Practice (GMP) is a quality system that assures that all process is safe and that the end item can be used for its intention. . It must be assured that the processed products follow international and national codes or practical guides of good in the production of medical or alimentary products. The necessary activities are listed to assure that the products processed with respect to the quality, security, performance are processed in accordance with the basic principles of GMP:

- An integrated system of manufacture and assured quality;
- Distinct responsibilities for the management of the production and the quality, appropriate places for processed and not-processed products;
- Trained staff, register of procedures in such a way for the production and for the assured quality;
- Appropriate register for lots, products, displacements and storage;

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- System of information recovery;
- System for auditorship of the GMP process.

Before the introduction in irradiation chamber and after leaving it, the product product will have to be manipulated by trained and experienced operators, in the places for irradiated or not-irradiated product, in accordance with the moment of the process. To make the following, each product will have its registered identification, your production batch, the number of units that will be reconciled with the data in the receiving documents. They are logged information: customer, product, service order, the quantity of product, batch, beginning and end of the process, absorbed dose, among others, for emission of Certificate of Irradiation and posterior auditorship of the services.

## 2 PROCESSING AND CONTROL SYSTEM

All products processed in the irradiator are identified by bar code. The acquisitions of data are made by equipment and systems of market. Are used in barcode readers in fixed input ports and output of the irradiator. A mobile reader for reading of the products in the storage areas, printer of bar code, reading of positioning of the sources gamma (“on” or “under”).. The communication between the diverse equipment and the server of application is made way wireless in accordance with the interface of the equipment. For safety reasons, at no moment, the control system of product processing will not have interfacing with the CLP system control and security of the irradiator.

### 2.1. TPI System

TPI-Tracking System of Irradiated Products was developed to be in accordance with Good Manufacturing Practices and Radiation belonged in the norms detailed throughout the text. The term tracking has the meaning of follow-up. For this system, tracking, accompaniment or monitoring of irradiated products has the intention to meet the requirements of GMP. For in such a way, the irradiation of products is made from the generation of Service Order for the accompaniment (tracking) of the product and its finishing with the emission of the Certificate of Irradiation the respective invoicing of the services of irradiation to the customer. The process ends with the sending of material through the bill of sale emission of remittance or a remittance letter when it will be the case.

### 2.2 Modeling process flow Service Order – overview

Fig. 2 shows a flow of service order process of irradiation of product, such as modeling illustration to meet system requirements. The description of the process follows the notation UML (Unified Modeling Language).

The workflow (flow) in which the client (solicitant of the irradiation service) initiates the budget order to irradiate a product. In a natural sequence of the process, the Commercial Sector prepares the form of the Budget, sends it (through the proceeding of the application) to the Management to analyze it. The Management decides if the product already was processed previously or if it is a new product. The Commercial Sector makes the fulfilling of the

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pertinent information and liberates the form so that the same it is sent to the Customer for the appreciation. The Customer has two options: to approve initiating it the process of the irradiation order, or to redispatch it the Commercial Sector to it for new negotiation.

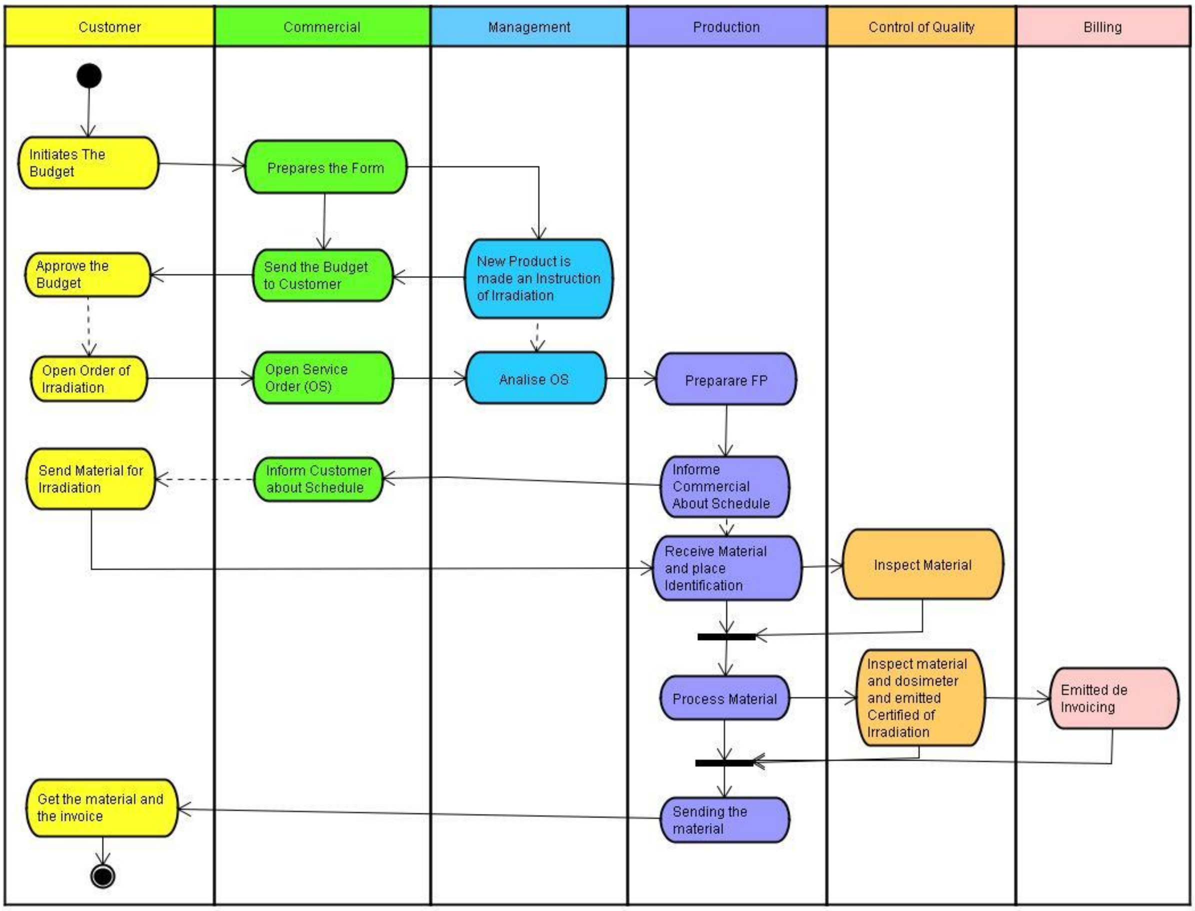


**Figure 2 – UML Modeling process flow of service request**

Still, in accordance with the Fig.2, if the Customer to approve the budget it opens an Order of Irradiation. The Commercial Sector opens a Service Order () and it directs it Manager to analyze it. If it will be new product is made an Instruction of Irradiation that will serve for next order. If the product has already known the flow follows to Production sector prepare the schedule of sending of the material and the irradiation. On the programming date for the flow follows Commercial to inform the Customer to send the material. As a result the material is received and inspected by the Quality. If the material will be in accordance with the order, this is identified with bar code, placed dosimeters and submitted to the irradiator. After the irradiation material is inspected verified dosimeter and, will be in agreement, is emitted the Certified of Irradiation and is authorized the invoicing and the sending of the material to the Customer.

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## 2.3 Project Process Flow

The Bonita software has one plugin that runs within the Eclipse development platform. The process flow (workflow) of Bonita follows the patterns of Workflow Management Coalition (WfMC).

### 2.3.1 Process flow of budget request

Fig. 3 shows the flow of the modeled process (Fig. 2) that it is initiated with the Request of Budget and goes until the opening of Order of Irradiation. The flow was drawn in Bonita software. They are possible manual and automatic activities. Calls of sub-processes, transitions for previous activities and others.

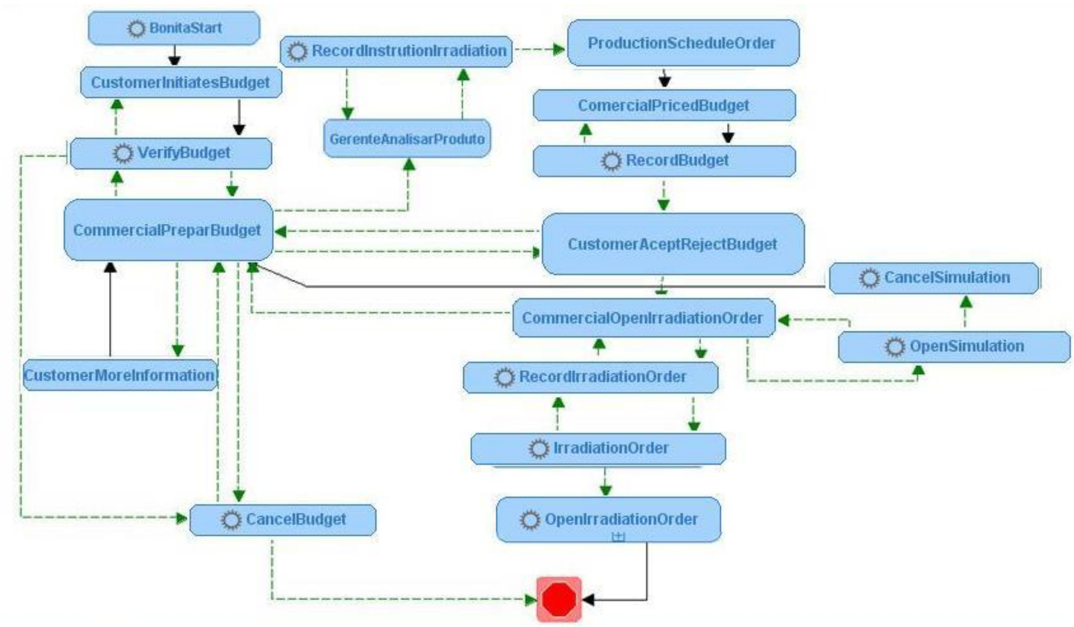


**Figure 3 – Flow Budget Resquest**

In this project the Customer requests a budget, this goes commercial to analyze it; following step the manager analyzes if is known product, if it will not be, is opened a budget of dosage study. Later the production it places execution stated period. The commercial place price. The customer can accept, reject or renegotiate the budget. If accepted is open request for the commercial and in the following a service order is opened.

The circular symbol in the activity indicates that the same one is executes for the system without interference of the user. Excessively they are directed for each user following the flow. On purpose the name of the activity initiates with the responsible user for the same one, example, ComercialOpenIrradiationOrder: this manual activity is executed by the Commercial Sector when the Customer accepts the Budget of the Service of Irradiation.

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### 2.3.2 Process flow for opening request for irradiation

The Fig.4 shows the flow of the process of Opening of Order of Irradiation that if it initiates with the approval of the Request of Budget. In this sequence of activities the number of them is substantial. It involves opening of lots of production, schedule a date, verification of amounts of material identified with bar code, the processing of the material in the irradiator. And, finally, the emission of the Certificate of Irradiation.

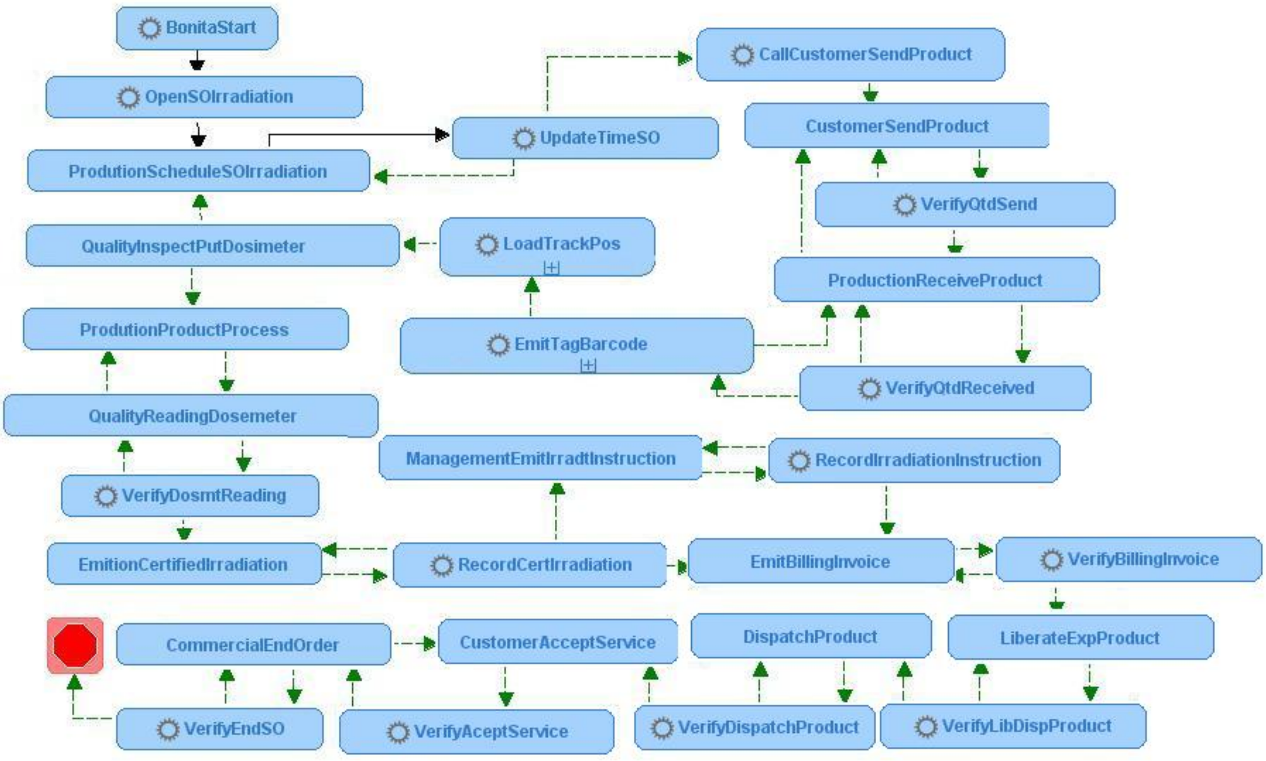


**Figure 4 – Service Order Flow Irradiation**

In the final part of the flow of the Fig.4 are the activities of emission of the invoicing, the release of the material for expedition and the finishing of the service orders.

### 2.4. Software and Workflow Systems

Currently many businesses have their processes accompanied for computational tools called Business Process Management (BPM). Some are of property of software companies and others are of free use. Examples of free software are available in the Object Web (www.ow2.org). Institutions of this sort are kept by companies and people who work around of the world to keep and to distribute software free of license payment. All using it will have to agree to the terms of license of the Lesser General Public License (LGPL) which forbids that a software is patented and assures that the modifications are shared by all.

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### 2.4.1. Workflow tool

Bonita software [7] is a BPM tool. Ability to design the flow of processes and sub-processes to describe the activities and their users. Its interface is published in the WEB. Therefore, each participant will be able to interact exactly with the activities of the process remotely, either the customer or different the involved ones in the irradiation process.

The Fig. 5 shows the screen of the Bonita's Console and the screen in which the user chooses which task it will go to initiate. Although some processes to be available, the processes "CustomerActivities" and "1- RequestsBudget" are only apt to be initiated for the Customer "palmer" (in the shown example).

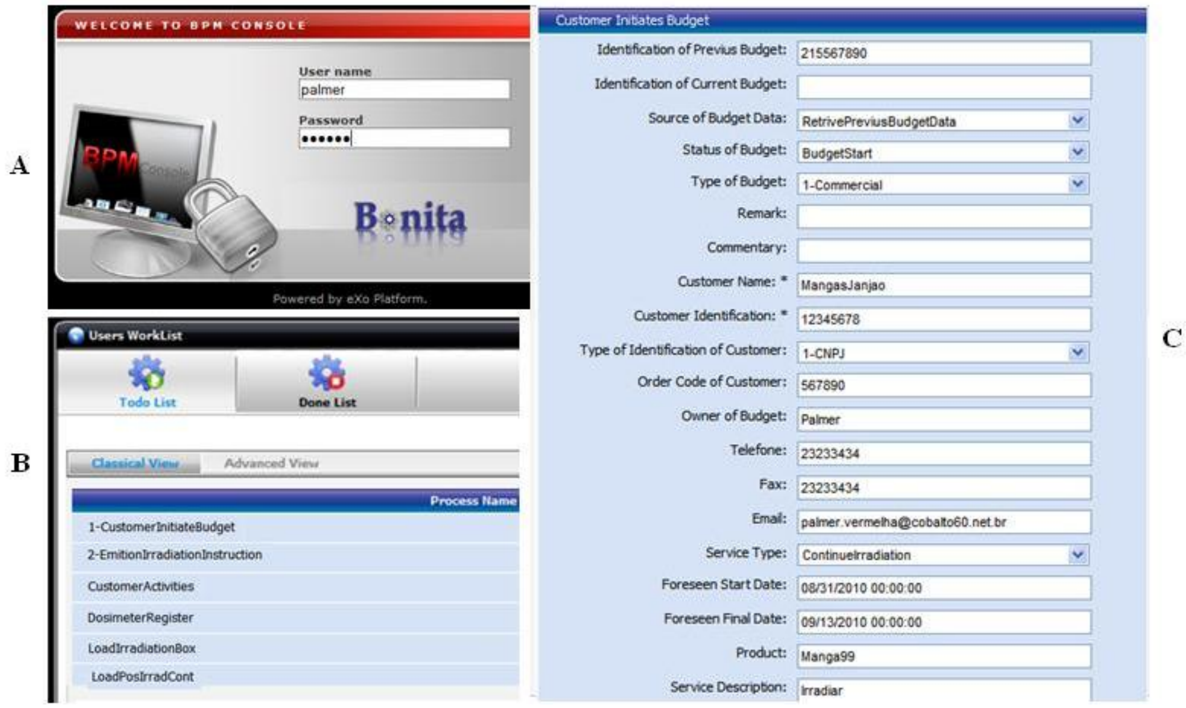


**Figure 5. Display of Bonita Console.**
**A: Login,**
**B: Screen of available process,**
**C: Data entry form of user activity.**

In the Fig.5, it has broken, part C (Form of data entry of the activity), is shown the manual activity that the Customer initiates to request the Budget of Service of Irradiation (to see first activity of the Fig.3). All the activities of users present some type of form for data entry in the system.

The system is available in a server of application WEB and can be had access by any user connected to the Internet. To operate the system the user must have login and password that can be of user, operator or manager of the system

### 2.4.2. Software used in the system

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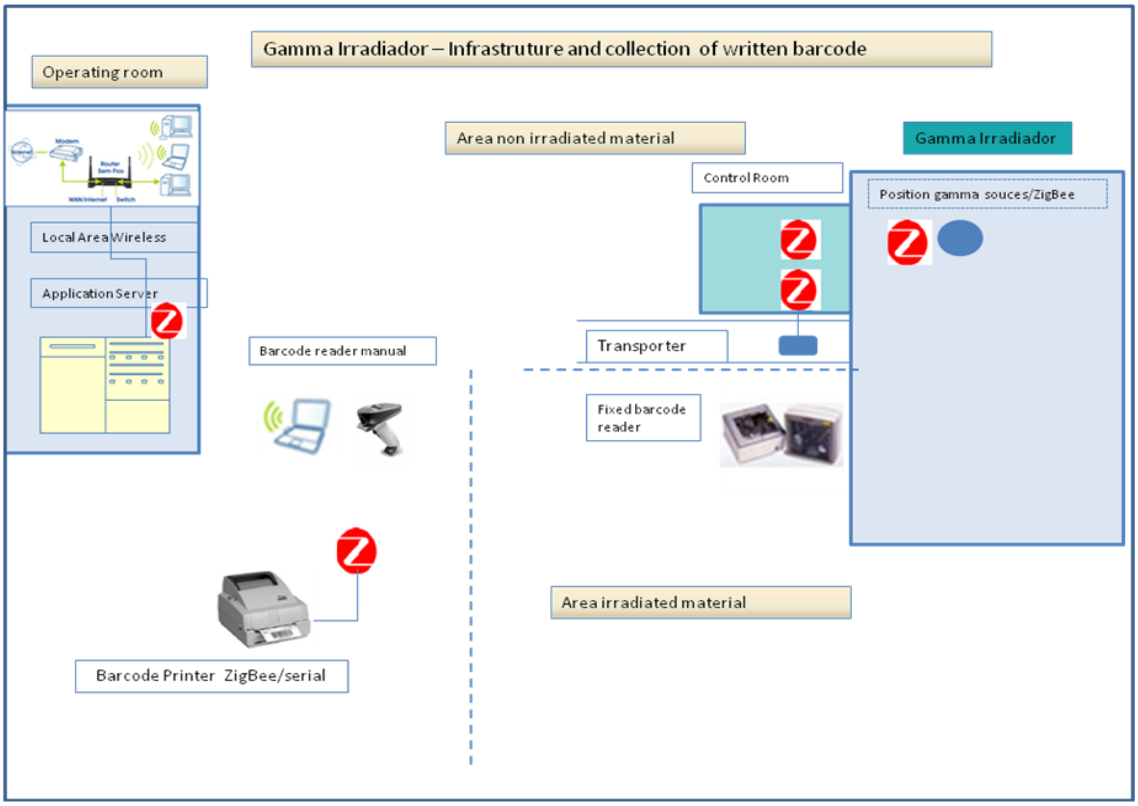
The TPI system was all designed and developed using free software license. For modeling UML Jude/Community was used. The development platform was the Eclipse with plugging of Bonita and the language of development JAVA. The data base was the H2 and the server of application JONAS. Operational system Windows XP in the development and for the server the Linux.

### 2.4.3. Network collection/write Wireless ZigBee/WiFi

The infrastructure of collection of data and writing of labels of bar code of the system is made automatically. They are two fixed collectors of bar code: one to read the code of the box of irradiation in the entrance of the irradiator and another one in the exit. A device to read if the sources gamma are "in low" (inside of the swimming pool) or "on" (irradiating). All the data are transmitted for the local server through communication wireless with ZigBee protocol.

**Figure 1 - Writing infrastructure and collect bar code and placement of irradiation sources**




All the used equipment has interface of communication RS 232. These are connected to the communication devices that compose the ZigBee net based on the standard IEEE 802.15.4. The reason of this communication is the risk of if to have linked equipment for cabling with the server and to occur some outbreak that may intervene with the operation of the irradiator. The data that pass through in the net wireless are criptografados and the net is configured not to accept interference external.

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### 2.4.4. Data transmission to the application server

The data collected for the ZigBee network is sent to the server of application (remote) for intermediary of Web Services. Also the writing of labels of bar code follows the same technology. The use of WEB Services as technology of transmission between the local server, connected the ZigBee network, and the application server (remote) is made using the Internet protocol (HTTP).

## 2.5. Certificate of Irradiation

One of the objectives of system TPI is the emission of the Certificate of Irradiation in the end of the process of irradiation of products. In it the main references of the Customer and the order of irradiation are contained, the Service Order/Lot that was processed and the main evidences of the processing as well as of the received dosages. The Fig. 7 shows an example of a Certificate of Irradiation. The data contained in the document are extracted of the database of the TPI that is independent of the database of process of the Bonita system. The data are stored to be audited in accordance with the GMP rules.

The Fig.7 shows the image of a Certificate of Irradiation. The Certificate of Irradiation is the document that officializes the processing of the product in irradiator gamma. This certificate is elaborated according to necessity of each customer, having been able to have more or less information. In it the information of the Customer are present, of the Order of the Customer, the maximum and minimum doses that the products had received. In the end the responsible one for the irradiator signs the same.

Are showing the main information on:

- Are showing the main information on:
- Service Order and the Lot of processing;
- Amount of item of the lot;
- The serial number of the batch in the order of service;
- The total time of irradiation of the products. This time is counted only for the time of the displayed sources (“on”);
- Doses minimum and maximum in kGy that the products of the lot had received.
- Used dosimeter (type and lot)

As evidence of the measures of doses absorbed by the products are listed the items that directly received lots or dosimeters, also were in boxes that received dosimeters for measuring absorbed dose.

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CERTIFIED OF IRRADIATION OF PRODUCTS Number: 1

The INSTITUTE OF ENERGY AND NUCLEAR RESEARCH (IPEN/CNEN-SP) with headquarters in the campus of the University of São Paulo (São Paulo /SP-Brazil), certifies that the products below related in its respective amounts and pertaining lots of manufacture to the MangasJanjao had been treated in 22/08/2010 for radiation gamma (Cobalto 60) with 33.53 kGy of minimum doses and maximum of 44.0 kGy.

The treatment was effected in accordance with the order: 5434567 of the customer above.

| ServiceOrder/ Lot | Amount ItensInLote | Order Lot | LeadTime Hours | Doses in kGy Minimum | Maximum |
|---|---|---|---|---|---|
| 000095/000153 | 17 | 1/2 | 20.5333 | 33.53 | 44.00 |

Evidence measurement of dosage is demonstrated in the following item:

ItemLote=8000095000153010 Ordem:10 Pass:2 CodBarCustomer:7891035539701

| Dosimeter | TotRead | TotDose | InstalationDate | PositionDosimeter |
|---|---|---|---|---|
| 900010001010 | 3 | 34.34 | 2010-07-16 17:14:26.046 | Top |
| 1234567801 | 1 | 40.0 | 2010-07-18 17:12:39.169 | Top |
| 1234567804 | 1 | 34.0 | 2010-07-18 17:31:12.247 | Box:FrontralSuperior |
| 1234567805 | 1 | 44.0 | 2010-07-18 17:31:50.684 | Box:LateralRightMedium |

ItemLote=8000095000153011 Ordem:11 Pass:1 CodBarCustomer:7891035539701

| Dosimeter | TotRead | TotDose | InstalationDate | PositionDosimeter |
|---|---|---|---|---|
| 900010001005 | 0 | 0.0 | 2010-07-15 18:59:41.796 | FrontalInferior |
| 1234567802 | 1 | 42.0 | 2010-07-18 17:12:53.825 | Topo |
| 1234567804 | 1 | 34.0 | 2010-07-18 17:31:12.247 | Box:FrontralSuperior |
| 1234567805 | 1 | 44.0 | 2010-07-18 17:31:50.684 | Box: LateralRightMedium |

ItemLote=8000095000153012 Ordem:12 Pass:1 CodBarCustomer:7891035539701

| Dosimeter | TotRead | TotDose | InstalationDate | PositionDosimeter |
|---|---|---|---|---|
| 900010001006 | 0 | 0.0 | 2010-07-15 18:59:41.875 | BackMedium |
| 1234567803 | 1 | 43.0 | 2010-07-18 17:24:35.606 | Top |
| 1234567804 | 1 | 34.0 | 2010-07-18 17:31:12.247 | Box:FrontralSuperior |
| 1234567805 | 1 | 44.0 | 2010-07-18 17:31:50.684 | Box: LateralRightMedium |

ItemLote=8000095000153013 Ordem:13 Pass:1 CodBarCustomer:7891035539701

| Dosimeter | TotRead | TotDose | InstalationDate | PositionDosimeter |
|---|---|---|---|---|
| 900010001009 | 3 | 33.53 | 2010-07-16 17:11:21.093 | LateralRightSuperior |
| 1234567804 | 1 | 34.0 | 2010-07-18 17:31:12.247 | Box:FrontralSuperior |
| 1234567805 | 1 | 44.0 | 2010-07-18 17:31:50.684 | Box: LateralRightMedium |

ItemLote=8000095000153014 Ordem:14 Pass:1 CodBarCustomer:7891035539701

| Dosimeter | TotRead | TotDose | InstalationDate | PositionDosimeter |
|---|---|---|---|---|
| 900010001003 | 0 | 0.0 | 2010-07-15 18:47:17.437 | FrontalSuperior |
| 1234567804 | 1 | 34.0 | 2010-07-18 17:31:12.247 | Box:FrontralSuperior |
| 1234567805 | 1 | 44.0 | 2010-07-18 17:31:50.684 | Box: LateralRightMedium |

Paulo Roberto Rela
Physicist/Engineer

**Figure 7 – Image of Certified of Irradiation of Products**

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### 2.6. Final Considerations about the TPI

The system TPI was object of doctoral thesis. Throughout the prescribed stated period of the doctorate two projects in parallel had run: one of the thesis properly said with lessons, qualification, seminary and defense of the thesis. The other one, of the project of the TPI that followed all the phases of a project of commercial software adopted by any company of consulting of software. A methodology of project development was written involving diverse documents, data-collecting of processes; feasibility study; interview with manager and operators.

The development of the TPI all was based in the use of free software of license. Nor therefore its development was less complex. It consumed about 5.000 working hours involving the phases of requirements of the system; documentation of process and technique; development of the process flows; development of entrance forms and exit of data; development of the Java classrooms that interface with the processes in real time; development of the interface of ZigBee communication; development of servers WEB Services (master and slave). Beyond the effort in the learning of diverse software used and the study of as to adapt them it the processes of the TPI.

## 3. CONCLUSIONS

This work is result of doctoral thesis [9]. Its main features were announced in previous work [10]. The goals of developing a system of monitoring and control of products into a large irradiator according to good manufacturing practices were achieved.
This work is result of doctoral thesis [9]. Its main features had been announced in previous work [10]. The goals of developing a system of monitoring and control of products into a large irradiator according to good manufacturing practices had been reached.

The participants of the processes, at any time, can have access the information of each service order to verify the course of the same one. The emission of the Certificate of Irradiation is the objective biggest of all process. This certification guarantees the quality of the process and that the product was irradiated according to necessity of the Customer. The data are stored in relational data base being able to any time to be audited.

The project still meets in implantation phase. As future work can be thought of in making the TPI multi company and multi irradiator. The characteristic of communication of the data remotely using Web Services technology opens this possibility.

## ACKNOWLEDGMENTS

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