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SCUOLA DI INGEGNERIA INDUSTRIALE
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Executive Summary of the Thesis

Agile Production in Software Projects for *Mission Critical* Systems: Wizard Based Product Line Lifecycle Management carried out at *National Center for Oncological Hadrontherapy*

Laurea Magistrale in Space Engineering - Ingegneria Spaziale

Author: Marco Papa

Advisor: Prof. Giovanni Consolati

Company Thesis Manager: Dr. Casalegno Luigi

Academic year: 2020-2021

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1. Introduction

This essay describes the work carried out in the thesis "*Agile* Production in Software Projects for *Mission Critical* Systems: Wizard Based Product Line Lifecycle Management carried out at *National Center for Oncological Hadrontherapy*". This thesis contains particular research on the certification of the medical devices in the CNAO Center.
The author focuses on analyzing the *Agile* development methods of software in *Mission Critical* environments, identifying the toolkit under development and describing the shorthand specification file for producing a technical file for the software. Research is put into practice by the author, creating new applications using a State Machine wizard. The applications are coherent with the work of the thesis, in order to simplify the steps for creating the validation documentation of a software in the CNAO Center.

2. What is CNAO?

CNAO short for *Centro Nazionale Adroterapia Oncologica*, located in Pavia, is a clinical institution that works exclusively in the Oncology field using the Hadrontherapy, using a particle accelerator, named synchrotron. The continuous technological improvements of the particle accelerator of the Center are the result of the development of research accelerators used in nuclear and high-energy physics.
The construction phase of the CNAO Center was started in 2001. The design of the control system began in 2003, analyzing the accelerator specification and elaborating a set of requirement documents for the control system. From these requirements, the control system and its sub-systems were designed and developed until 2013.[2]

2.1. The Control System

The Hadrontherapy is a specific type of oncological Radiotherapy, which makes use of protons and carbon ions. Every patient, that is subjected to the medical treatment, receives an energy beam accelerated by the synchrotron. The dose of energy provided by the accelerator eliminates the tumor, reducing the dose delivered to surrounding healthy tissue.
Before the patient treatment, there are many processes which need to be analyzed and vali-

dated. Some processes are steered by the Control System of the CNAO accelerator, which aims to load the equipment with the relevant settings depending on the planned cycles to be executed and to monitor the achievement of the planned results. All the settings for each planned treatment have to be kept into a repository that is part of the Control System.

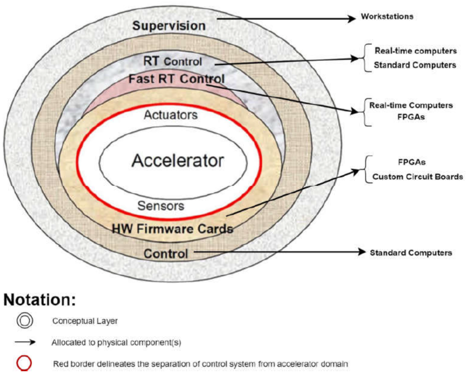

Figure 1: The main Control System Layers.[3]

Moreover, the whole Control System is divided into subsystems, which contain parts that are logically or physically linked or belong to a single domain of interest. Besides, each subsystem is further decomposed into Equipment Components which can be accessed through a Human Machine Interface (HMI), that presents all the properties and operations of the specific Equipment Components to the user.

3. Medical Devices Certification

The control system software is categorized as medical software and it has to comply with the according standards.
As a consequence, the accelerator control system follows the regulatory standards for medical software. Under the regulatory environment for this software in member states of European Union, certification is accredited on the basis of complying with the development process defined in several accepted standards. The work of the thesis focuses on these three standard regulations:

- MDR 2017/745,
- IEC 62304,
- ISO 14971.

After verifying all the criteria for the certification, the manufacturer of medical devices is obliged to create a collection of documents and information, also known as the technical file, an important document that is examined by the Notified Bodies responsible for issuing the CE certification.[4]

3.1. The *Agile* Development Approach

For controlling and supervising the facilities in the center, a set of quality assurance actions has been tightened in the entire activity period of CNAO, and new software applications are being created in order to facilitate the operations.
For this purpose, a project named CF2020 (CNAO Framework 2020s) was established aiming to create an integrated development environment supporting an *Agile* development approach, capable of guaranteeing very strict quality requirements of complex *Mission Critical* systems for specific domains.[1]
These domains can include run-time frameworks, tools to assist domain experts and developers in specifying and maintaining relevant information at a high level of abstraction, and tools to generate part of the implementation-level artifacts from the high-level specifications. Moreover, an extensive set of execution support libraries that implement recurrent tasks for the target domain and application models/templates to grant homogeneous and more robust development are also included. Thereafter, these domains contain even automatic tools to produce documentation and tools to produce test specifications.

3.2. The Product Line Architecture

A complex medical device is very similar to a production line and, therefore, the research is fully applicable to any production plant that has the need for strict quality requirements and where high software/hardware integration is mandatory.
The strategy of the product line can be compared to an umbrella under which a range of techniques and methods can be assembled. *Agile* development methods, domain analysis, model-driven architectures, and generative programming can all be part of a successful product line organization. The Product Line Control System, carried out by the author of the thesis during the research, is shown in Fig.2.

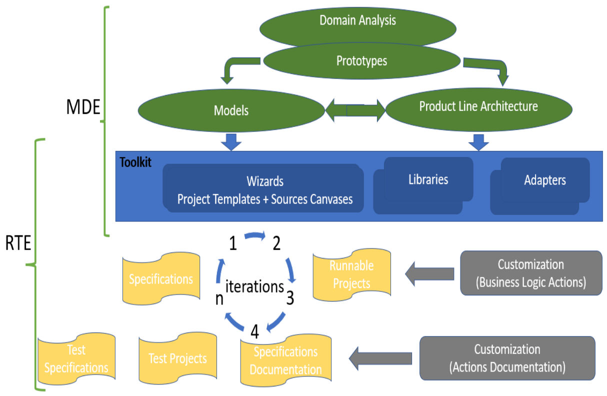

Figure 2: Build a Product Line Control System

Two of the models used in the Product Line Control System are the MDE (Model Driven Engineering) and the RTE (Round Trip Engineering). On the one hand, the MDE approach is meant to increase productivity by maximizing compatibility between systems, simplifying the process of design, and promoting communication between individuals and teams working on the system. On the other hand, the RTE is a functionality of software development tools that synchronizes two or more related software artifacts. This approach is used when the same information is present in multiple artifacts to avoid inconsistency if not all artifacts are updated to reflect a given change.
The Product Line Architecture defined by the author of the thesis is the NGCS architecture, stands for "Next Generation Control System". The philosophy of the NGCS Product Line is based on making more efficient computers and digital tools.

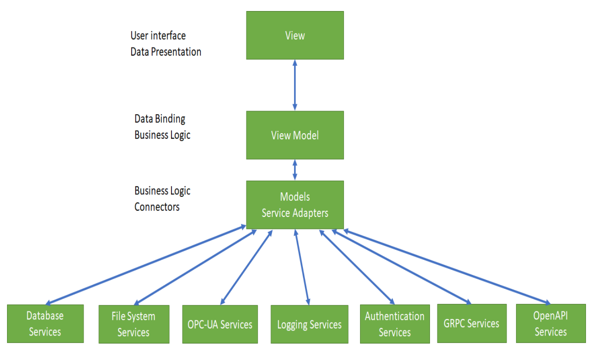

Figure 3: NGCS Architecture scheme

At the basis of the Product Line Architecture and the project, there is the use of a toolkit with libraries and a wizard, which are able to reduce the amount of error made by the developer and the documentation to be produced, improving the rules and functionalities mandatory in the production environment.

4. Project Research

The research, initiated in October 2021 at the CNAO Center, contains the creation of an application documentation, useful for the process, in order to keep the documentation aligned with the artifacts and enable the constructions of tools that verify and validate the final product. An important step of the research is the utilization of a project wizard, useful to select the target operating system on which the application will run, to choose the pages that will be included in the final applications, to assign the model configuration parameters, and to define the menu, its items, the toolbar buttons, and the visual elements included in each page. It is important to say that the wizard could be modified afterwards by the developer, in order to apply changes as requested from the project. The output of the wizard is a Specification File with JSON format that can be used to build a skeleton of an application that is already a running executable.
Consequently, the developer knows that all the connections and interfaces are respected and the basic behavior supplied by the chosen model is fulfilled. Moreover, the developer can add application-level resources which are kept in the Specification File and included into the project source files, when building the application.

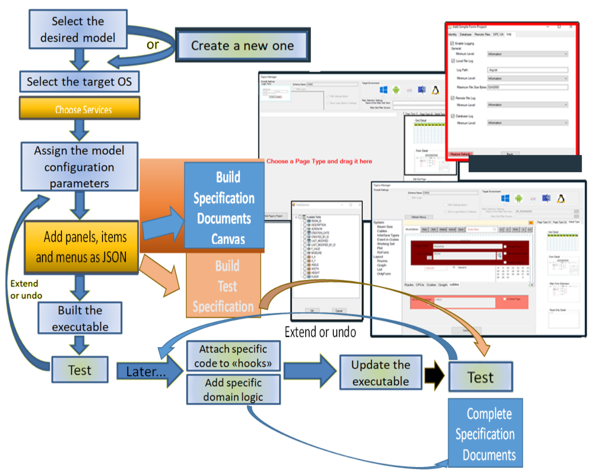

Figure 4: Complete process map

The research is important for future developments in CNAO Center and the complete map of the process, depicted in Fig.4, shows the outcome of the author of the thesis based on the creation of a new block named "Build Specification Document Canvas". This block contains wizards that are targeted to build applications used to manage data contained in a database in order to improve an industrial plant or a production line such as the CNAO accelerator complex.

4.1. Software Validation & Application Development

The applications created by the author of the work are a turning point to validate a general software. The author used a new State Machine, creating at the end of each process a Specification File JSON, important to build the test specifications and all the documentation. During the period of the research, the author created even test cases and their test run, in order to endorse the work done.
Some examples of applications are discussed in this essay in order to explain how the applications done by the author of the thesis.
The "Scheduler Monitor Template Manager" wizard builds an application that monitors the execution of tasks that are planned to be run during a day in a set of resources. Its layout is shown in Fig.5.

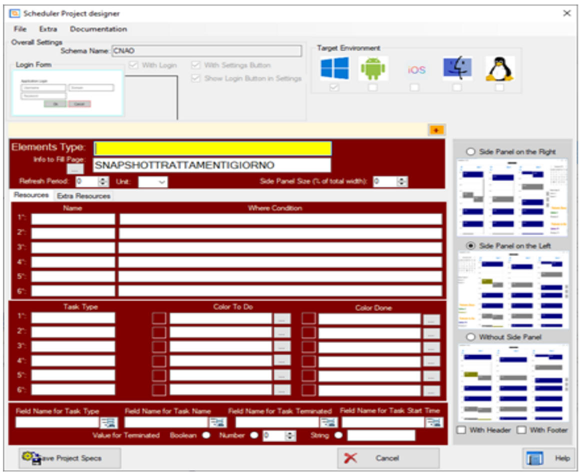

Figure 5: Scheduler Monitor Manager layout

The tasks are listed in an agenda-like grid at the time they are planned and have a color that depends on their state. The application, shown in Fig.6, refreshes the data in the page according to the parameters assigned by the developer.

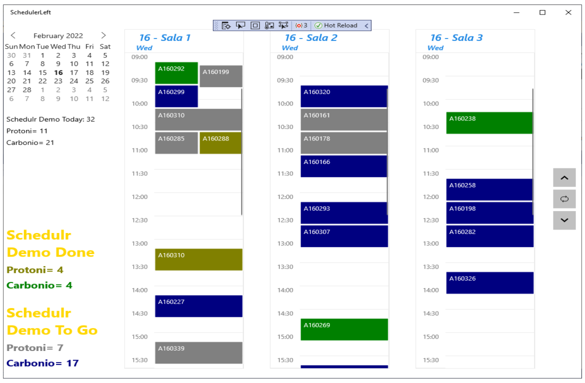

Figure 6: Schedule Monitor

Another example of application made by the author of the thesis is given by the "Procedure Template Manager" wizard which allows building applications that manage the execution of activities on a set of devices. Its layout is shown in Fig.7.

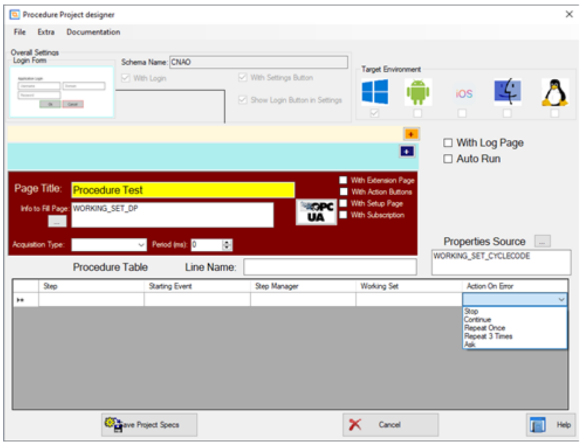

Figure 7: Procedure Project Designer

The activities are grouped into steps which have a working group of devices on which the activities of the step are performed, as shown in Fig.8.

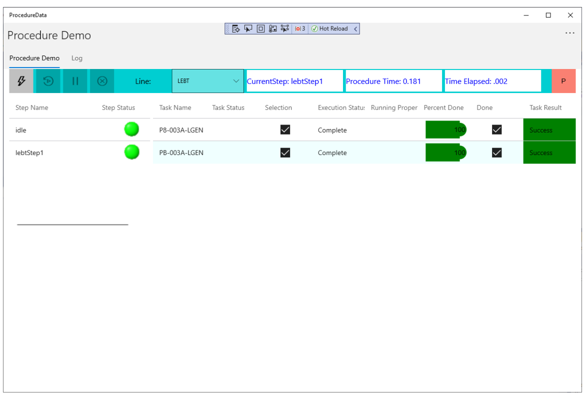

Figure 8: Procedure Project Application

For each application, when the configuration of the wizard is completed, the author saved the project in the JSON Spec. file. Then, the author can generate the code and build the canvas application.
All the applications, created by the author of the thesis himself, have already been tested by the CNAO Center and have already been simulated, stating that they are fully functional and are consistent with the process map, concerning the Product Line Architecture and the *Agile* development approach.
At the end of the process, documents for product validation are generated and the documentation is elaborated with the necessary checks. This iterative approach is based on verifying the coherence of all the documentation with the rest of the work. The documentation, useful for the release of the software, needs to meet certain requirements, drafted by specific staff in the CNAO Center using the Jira platform.
The main purpose of the requirements is to provide a rational explanation and a functional description without defining in depth the characteristics of the software.

4.2. Model-Based Systems Engineering

In order to implement and discuss the *Agile* philosophy in the aeronautical and space field, the author of the work compares the project modeling methodology among both fields and other different industries. To do so, the author describes the Model-Based Systems Engineering, highlighting the peculiarities of this model.[5]
It can be stated that changes are only applied in the industry where this model is the most effective, to ensure that the work is reduced.
Thus, applying a Model-Based Systems Engineering solution and comparing it with the toolkit for accelerator control systems, allows companies to reduce complexity, rework, and quality issues while meeting regulatory compliance and lowering risk.

5. Conclusions

The author of the thesis, at the end of the research, succeeded in creating new applications to facilitate the validation system of a product. This is carried out by using the State Machine wizard and subsequently creating the JSON Specification File. It is also described how *Agile* development methods function, stating that the approach is important to reduce the effort in the CNAO Center in their daily projects, which require software in *Mission Critical* environments.
Several applications set up during the work are to be reviewed. During the development, metrics can be gathered, and the Product Line approach can be further evaluated to provide insight on the impact of the architecture and new wizards, improving the entire system.
Concerning the developments in the aerospace and space fields, the future goal of the author would be to adapt the technical sub-level generated by the JSON Specification File, containing all the documents for the validation of the product, the tests and the codes of the applications in further *Mission Critical* projects, facilitating the work and shortening development times.

6. Acknowledgements

I want to thank Prof. Giovanni Consolati, who showed from the beginning great interest in my thesis, providing me constant availability and attention.
In addition, I would like to thank the CNAO Foundation, with which I have been working for six months, the whole team of the Control Group, but above all my Company Supervisor, Dr. Luigi Casalegno, who gave me a great hand in the elaboration of the thesis and in learning new engineering software.

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