ABSTRACT

A Linear Proton Accelerator with a beam current lower than 10 nA in average, and an energy up to 150 MeV, has to be sited at the Frascati ENEA Research Center, in Italy. The accelerator will be part of the TOP-IMPLART project that will reach 250 MeV of proton energy for deep tumors treatment.

The accelerator is composed by a sequence of linear sections and it operates currently at a maximum energy of 18 MeV. The upgrade, from this energy to 85 MeV, required important modifications of the bunker and of the accelerator linear dimension. The safety solutions for the operators and the population were implemented accordingly. Therefore a specific project and a licensing process were developed. The license was obtained three years after the request.

In this paper the project upgrade is outlined and the legal and technical aspects of the licensing process in Italy and in Europe are described and discussed. The specific licensing process is analyzed considering the local legislation. The administrations involved in the process are identified and their roles are briefly described. The main technical issues important in the licensing enquiry are present and discussed.

The licensing process for operating the TOP-IMPLART facility up to 85 MeV has been completed and now the next step to reach the energy of 150 MeV is starting.

The paper ends with final considerations about time and procedure of the licensing in Italy and in the rest of the Europe.

KEYWORDS

Proton Accelerator, licensing, proton therapy

1. INTRODUCTION

The TOP-IMPLART project [1, 2] is going on at the Frascati ENEA Research Centre with the aim of realizing an innovative proton therapy facility. TOP-IMPLART are the acronym of Terapia Oncologica con Protoni (Oncological Therapy with Protons) and Intensity Modulated Proton Linear Accelerator for Therapy. The accelerator constitutes the main peculiar characteristic of this design, it is a linear accelerator, or, better to say, a sequence of linear accelerators.

The project is aimed to develop a proton irradiation facility that could be devoted to different applications taking advantage of the modular nature of the linear accelerators. The use of a linear machine instead of a compact circular accelerator (synchrotrons and cyclotrons), permits the possibility to proceed by steps in the construction and operation process and makes it possible the combined use of different irradiation stations at various energies. At the ENEA Frascati Research Centre, the modules of the accelerator are
added to the injector, in a step by step process, leading the energy of the proton beam from 7 to 30, 85 and 150 MeV.

Figure 1. Main layout of the accelerators building: the current setup.

Figure 2. Layout of the accelerators building in the final design.

Figure 1 shows the current layout of the first floor of the accelerator’s building. In this configuration TOP-Implant accelerator can operate with a proton beam energy up to 85 MeV. In order to achieve a proton energy of 150 MeV an important modification of the layout is needed, as it is shown in figure 2.
The present study is finalized to the analysis of the licensing process required in Italy to get the permit for constructing and operating the facility in the different modes.

2. ITALIAN AND EUROPEAN LICENSING PROCESSES

On 17 January 2014 Europe has issued a new directive related to the protection against the dangers arising from exposure to ionising radiation, the Directive 2013/59/EURATOM. An European Directive is a legal act of the European Union, which requires member states to achieve a particular result without dictating the means of achieving that result. It is not directly applicable. It has to be implemented into member state law. Each member state, and its courts, may interpret or adapt slightly differently from the Directive itself. The new Directive recommends to the EU Member States a graded approach to regulatory control. They require that the practices must be subject to regulatory control for the purpose of radiation protection, by way of notification, authorization and appropriate inspections. In particular Member States shall require either registration or licensing of the operation of accelerators, or radioactive sources, for medical or non-medical exposures. According to the statements of the EU Directive, Italian legislation requires that for constructing and operating a proton accelerator that is likely to produce an annual average neutron yield higher than $10^4 \text{n s}^{-1}$, a formal preventative permit is needed. The complete scheme, showing the three different levels of authorization for using a radiological device, is reported in figure 3.

![Diagram](image)

**Figure 3.** Scheme of the levels of authorization. The information is extracted from the Italian decree n. 230 issued in 1995, and the subsequent modifications and integrations.

The assessment of the neutron flux produced by TOP-Implant accelerator has shown that even at the preliminary stage, namely the 7 MeV injector alone, the average annual neutron yield is higher than $10^7 \text{n}$.
According to the advice of the Italian regulatory authority, the average is calculated dividing by the working hours conventionally included into one year (2000 h/y), the total number of neutrons potentially produced in the year. Each design evolution for TOP-Implart requires therefore a permit of category "A".

3. CATEGORY “A” PERMIT FOR THE TOP-IMPLART ACCELERATOR

Taking advantage of the modular structure of TOP-Implart facility, the licensing process was divided into subsequent phases. The first step was devoted to the licensing of the 7 MeV ignitor, together with additional modules, to achieve a total energy of 20 MeV. The second request was finalized to achieve the permit for operating with an energy up to 85 MeV. The third step is still in the design stage and will permit the production of a proton beam with a maximum energy of 150 MeV. The first application of the accelerator will be the medical proton therapy. The clinical installation will be located at IFO Hospital in Rome. In this configuration the linear accelerator will reach an energy of 250 MeV and this will require a brand new permit of category “A”.

The applications for the achievement of the permit of category “A”, and for the subsequent modifications, were sent to the Italian Ministry of Economic Development as first recipient and to the Ministry of Environment, to the Ministry of Labour and Social Security, to the Ministry of Health, to the Ministry of Interior, to the Institute for Environmental Protection and Research (ISPRA, Italian technical body for nuclear safety), and to the Lazio Region where the facility is installed.

The request of licensing to construct and operate the accelerator is accompanied by a specific technical report undersigned by the responsible for the facility and by the so called Qualified Expert. This professional is specifically defined by law and has many attributions related to the radiological protection of workers and population. The technical report required by the procedure has to include at least the following:

- Description of the installation, structures and systems
- Suitability of the area, buildings and structures
- Radioprotection structures and organization
- Operation program and procedure
- Qualification of personnel
- Accident analysis and relevant consequences
- Radioactive wastes assessment and management

The documents are examined by the involved administrations that have to provide their advice to the Ministry of Economic Development. The Ministry of Health and the Ministry of Interior, for the technical aspects, make reference to their agencies. The first one, in this process, is mainly responsible for controlling the fire protection characteristics and therefore asks a technical advice to the firemen local department. The other makes reference to the Institute for the Safety at Work that is imbedded into the INAIL (Italian Institute for the Insurance for Accidents at Work). Sometime one or more authorities require some clarification to the licensee that has to provide additional documents. The Ministry of Economic Development, once obtained the positive advice from all the other Ministries and Organizations involved, issues the licensing permit for construction and operation, accompanied by specific prescriptions relevant to design, construction, commissioning, operation, maintenance and decommissioning of the facility.

The whole process is summarized in figure 4.

The analysis of the technical documents usually requires more than one year and sometime it could last even more than three years. Italian regulations does not limit the technical investigation period for this procedure.
The main technical aspects that are considered by the authorities for giving a judgment on the installation, are related to the level of protection guaranteed to workers and to population during normal and accidental situations. All the radiation protection principles are taken into account: justification, optimization and dose limitation. It is not the scope of this study going through the above principles, but it could be useful report the recent position of the EU community about the dose limits. The legal statement of the more recent EU Directive [4] says that the limit on the effective dose for occupational exposure shall be 20 mSv in any single year. However, in special circumstances or for certain exposure situations, specified in national legislation, a higher effective dose, of up to 50 mSv may be authorized by the competent authority in a single year, provided that the average annual dose over any five consecutive years, including the years for which the limit has been exceeded, does not exceed 20 mSv. The Italian legislation is more stringent in this sense, it requires the respect of the effective dose limit of 20 mSv in any single year without any exception.

The critical aspect about the population safety in the Italian legislation is related to the release of radioactive waste into the environment. In this frame the licensee has to demonstrate that the following options are observed:

- For solid and liquid waste the release is possible without any further authorization if both:
  - the radionuclides have a half life lower than 75 days
  - and their activity concentration is lower than 1 Bq/g
- In general it is possible demonstrate the "not radiological relevance" of a release, mainly for the gaseous ones, and the release is permitted if both:
  - the effective dose is not exceeding 10 μSv per year to the most exposed individuals of the population
  - the collective effective dose is not exceeding 1 Sv per person for the population living around the installation
4. CONCLUSIONS

The TOP-Implart design was completed until 85 MeV of maximum energy, since 2012. The personnel and population safety was demonstrated both for normal and accidental situations. The licensing process for this phase was completed only some months ago, it required a time period of about 3 years. This is the maximum time period usually required for achieving such a permit. Usually a time from 1 to 3 years is required. In Italy more flexibility and collaboration among facilities and authorities could improve and speed up the licensing process.

REFERENCES