HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

HERCA Practical Document

Proton Therapy Licensing and Inspection Resume

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This practical document was approved by the HERCA WGMA in February 2021

Introduction

Proton therapy is a topic of interest for the WGMA members (authorization and inspection processes) as in 2018, at least seven countries had plans to develop or were in the process of developing proton therapy facilities. Therefore, the WGMA created a task group for proton therapy and charged Dr. Nicolas Stritt (Switzerland) to chair it. This task group has elaborated a practical document on "Proton therapy licensing and inspection", which is intended for internal use within the competent authorities of HERCA. For information and training purpose, this document is also available on demand for other authorities' outside HERCA in the field of proton therapy. An official demand should be addressed to the secretary of the HERCA Board of Head.

The scope and aim of this document is to:

- **provide information about the needed competences of the competent authority;**
- **provide a set of best practices for the supervision of a proton therapy facility;**
- **assist the competent authority in addressing the challenges of the licensing procedure for a new proton therapy facility and;**
- **outline the procedure for routine surveillance once a proton facility is operational.**

Depending on the national legislation and practical situations, the implementation of all of the recommendations in the document might not be possible in each HERCA member state. However, it is the task group's opinion that HERCA MS should adopt the regulatory processes as given in this document where possible taking into account the putative differences in the national legal frameworks in each MS.

Due to the diverse challenges that a proton therapy facility poses to the licensing and inspection processes as well as the rapid development in the field, the task group will revise and improve the document in order to provide a comprehensive and up to date account to the HERCA member states.

Key messages

Due to the complexity of proton therapy facilities and the higher risks for the staff, the patients, the general population and the environment compared to conventional radiotherapy units, all stakeholders as well as the competent radiological protection authority should dedicate effort and resources for the safe operation of proton therapy facilities.

The task group for proton therapy identified the following key aspects that the competent radiation protection authority should consider in the licensing and inspection of a proton therapy facility.

1. **Competences and qualifications of the authorities**
   In order to review the licensing process and decide on the issuing of a license for a proton therapy facility, the competent authorities need certain competences and qualifications. The document identifies the necessary competences and provides a tentative list training opportunities for the competent authority's personnel. The competent authority needs to know the radiation protection issues related to the installation, operation and decommissioning of a particle accelerator.

   This includes knowledge of accelerator physics, nuclear and particle physics, medical physics with focus on radiation oncology, complex shielding calculations and treatment planning with particle transport simulations, activation and safe handling of radioactive materials, radiation measurement techniques, personal and environmental dosimetry, environmental discharge of radioactive material, radioactive waste management, etc.

The task group emphasizes the importance of keeping the full knowledge and expertise in-house to ensure a completely independent review of the licensing applications. However, the competent authority might also find the need of an external consultancy. In this case, the competent authority has to pay particular attention to the cluster risk of expertise in the different fields. The task group believe as well that the competent authority need to plan and allocate the necessary resources for the supervision of a proton therapy facility.

2. **Licensing process**
   The task group outlines the different steps and phases during the installation and operation of a proton therapy centre and the corresponding types of licenses. The full licensing process involves different stakeholders and licensees, most prominently the user (a hospital, university or other research facilities) and the manufacturer but also radiation protection experts. The current document clarifies their roles.

   The task group stresses the fact that due to the complexity of a proton therapy facility and the lack of stringent legal requirements when compared to conventional radiotherapy, a close collaboration with all stakeholders and a good communication with designated points of contact are indispensable for a trouble-free licensing process and supervision.

3. **Documentation**
   During the licensing process, the licensees need to provide all relevant documentation, which the competent authority will have to evaluate. The document lists the necessary documentation, i.e. a safety report, acceptance test and commissioning instructions, maintenance documentation, QA manuals, operating instructions or SOP as well as a declaration of conformity with industry standards and norms, and outlines in detail the content thereof. The task group highlights the fact that the documentation, in particular the safety report, can undergo various changes during the licensing process and the competent authority needs to be able to evaluate and judge efficiently such changes.

   An important aspect is the organisational structure of a proton therapy facility. The document therefore comments on the roles of different professional groups and in particular of radiation protection officers, radiation protection experts and medical physics experts. Furthermore, the working group encourages the competent authorities to set up regular technical discussions and meetings with the user outside the more formal framework of an authorization procedure or inspection.

4. **Inspection themes and tools**
   The document lists in detail the possible themes for inspections and supervision of a proton therapy facility from its construction to its routine operation. This includes radiation protection for accelerators, accelerator and beam line operation, medical physics and clinical as well as operational aspects. Furthermore, the task group encourages the competent authorities to engage with the user on a regular basis and outside the more formal setting of a licensing procedure or inspection.

5. **References**
   Finally, the document lists useful references for regulating and supervising proton therapy facilities.