In 2000, the PROSCAN project, the extension of the medical proton therapy facility at PSI, was launched. PROSCAN encompasses the installation of a dedicated compact cyclotron for medical therapy (COMET) including beam lines to the existing Gantry 1, which has been in use for patient treatment since 1996, as well as to new treatment areas which could be used for a second Gantry 2 and two horizontal beam ports.

One of the major milestones will be the delivery of the superconducting proton cyclotron COMET in summer 2003. PSI placed the purchase order for COMET with ACCEL Instruments in Germany in May 2001.

In contrast to the widespread medical electron accelerators (about 35 are operational in Switzerland), official regulations for proton therapy systems are lacking. This might be due to the low number of such facilities worldwide and the highly varying technology being used in these installations, which are mainly home-made without commercial intentions. As an example, the operating approval for the PSI spot-scanning Gantry 1, which was given by the Swiss Federal Office of Public Health BAG (Bundesamt für Gesundheit, Bern) as the responsible public authority, is essentially based on the “Elektronenbeschleunigerverordnung” from 1980. A limited number of site-specific regulations and local directives has been added during the approval process by the BAG.

A similar procedure will be necessary for the commissioning of the new cyclotron COMET and its appendant beam lines. Consequently, inspectors from the BAG have been invited several times for discussions and reviews already in the early phase of the PROSCAN project.

A few months after delivery of COMET, the first start-up of the machine will be possible. In due time before commissioning, a safety report has to be prepared and submitted to the BAG. We expect to receive preliminary operating approval for COMET and the first part of the PROSCAN beam line in autumn 2003.

Some of the topics which will be essential parts of the PROSCAN safety report are mentioned below:

- A description of the systems and their specific functions.
- A description of the safety goals.
- The personnel safety system (PSA). The PSA concept for PROSCAN has already been prepared by the PSI Division of Radiation Safety and Security (ASI).
- Calculations concerning radioactive shielding and activation (of components, floor, cooling water, air and other gases etc.), based on conservative assumptions for beam losses and the duty cycle of COMET. These are necessary in order to estimate possible radiation hazards for the environment of the facility and also to be prepared for later disposal of the whole facility after its final shutdown.
- The definition of radioactive zones including the concept of dosimetric supervision of personnel and facilities.
- Preventive measures concerning electric power breakdown. For example, activity measurements of the exhausted air have to be continued at any time.
- Helium safety: Since COMET is a superconducting cyclotron; large amounts of helium gas could be released during a quench event. Preventive measures against suffocation of personnel will be required.
- A detailed description of the different parts of the control system, each of which can switch off the proton beam using various beam interrupting components.

After successful commissioning, the existing Gantry 1 will be connected to the new cyclotron COMET. Therewith questions of patient safety will arise and the safety report has to be extended accordingly with a chapter describing the patient safety system. Its basic design has already been prepared in close cooperation between the Division of Radiation Medicine (ASM) and the Division of Accelerator Facilities and Systems (ABE).

In addition to the safety report, a special document containing regulations for operation will be required. It will also include concepts for test procedures after system shutdowns or repairs, a quality assurance manual and an organization chart concerning the sources of responsibility for the whole project.

Finally I would like to acknowledge the continuous support by the members of the PROSCAN team and I am looking forward to further and interesting discussions about PROSCAN safety issues.