

11 Which special approvals must be obtained from the authorities and which inspections have to be passed and why?

Besides the ordinary official approvals for buildings used for medical treatment, a proton therapy facility can only start operating after it has been granted approval from the Department of Radiation Protection at the Federal Office for Health. This approval process is identical to the approval process for putting into operation a conventional radio therapy center with X-rays and electron radiation. The point of such an approval process is to guarantee the legally prescribed radiation protection measures so that radiation cannot be released from the center. It also ensures that all required quality assurance measures have been carried out correctly. The approval process ensures that a proton therapy center cannot be built until the radiation protection calculations have been successfully checked and the relevant approval has been granted. All the requirements are in line with internationally agreed radiation protection guidelines. As the relevant regulatory agency has already collected relevant experience in connection with the approval procedure for the clinical operation at the Paul Scherrer Institute (PSI), it may be assumed that the approval process will be straightforward.