

Appendix for Article 4

Type of the hazardous medical device	Qualification for the physician in charge	Requirements for the installed institution	Remark
Medical particle therapy device	Full-time Radiation Oncology Specialist	<ol style="list-style-type: none"> 1. The installation of medical particle therapy equipment shall meet one of the conditions below: <ol style="list-style-type: none"> (1) Medical center in the Hospital Accreditation or Emergency care response hospitals(level 3) in the Grading and evaluation of hospitals' emergency medical competency. (2) Hospitals of the university with a medical department. 2. In addition to the physician qualification and above regulation, the installation of medical particle accelerator shall also meet conditions below: <ol style="list-style-type: none"> (1) One or more full-time operators as set forth in the Ionizing Radiation Protection Act (foreigners shall have least 3 months training on the same type of equipment and acquired a certificate.) (2) One or more permanent particle accelerator engineers (domestic permanent engineer shall have at least 3 month training and acquired a certification. The permanent engineer from the original manufacturer shall provide a training certificate for the same type of equipment). 3. The positions set forth in Subparagraph 1 and 2 of the preceding point may be served by the same person. 4. The list and qualification of full-time operators shall be reported to the central authority before the test run. 5. The list and qualification of permanent particle accelerator engineer shall be reported to the central authority within one month since the test run. 	The so-called particle refers to proton or light/heavy-charged particle, but not electron.