

## 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"> <li>1. The installation of medical particle therapy equipment shall meet one of the conditions below:               <ol style="list-style-type: none"> <li>(1) Medical center in the Hospital Accreditation or Emergency care response hospitals(level 3) in the Grading and evaluation of hospitals' emergency medical competency.</li> <li>(2) Hospitals of the university with a medical department.</li> </ol> </li> <li>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"> <li>(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.)</li> <li>(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).</li> </ol> </li> <li>3. The positions set forth in Subparagraph 1 and 2 of the preceding point may be served by the same person.</li> <li>4. The list and qualification of full-time operators shall be reported to the central authority before the test run.</li> <li>5. The list and qualification of permanent particle accelerator engineer shall be reported to the central authority within one month since the test run.</li> </ol>	The so-called particle refers to proton or light/heavy-charged particle, but not electron.