does not exceed 3 percent of the focal spot to image receptor distance, and the total sum of these distances between the points of intersection does not exceed 4 percent of the focal spot to image receptor distance;

(ii) keeping the air kerma in free air (hereinafter referred to as the "air kerma") in the primary protection shielding of the image receptor at a distance of 10 centimeters from the accessible surface of the unit at or below 1.0 microgray per exposure; and

(iii) installing box-shaped shielding around the irradiated object, and keeping the air kerma at a distance of 10 centimeters from the shielding at or below 1.0 microgray per exposure; provided, however, that this does not apply when persons engaging in the operation of an X-ray unit or other operations can easily evacuate outside the room at the time of irradiation.

(5) A therapeutic X-ray unit (excluding brachytherapy unit) must be that for which the damage prevention measures provided for in paragraph (1) have been taken and that equipped with an interlock which blocks the generation of X-rays when the filter is removed.

(Protection of Medical High-energy Radiation Generators)

Article 30-2 A medical high-energy radiation generator must be that for which the following damage prevention measures have been taken:

(i) shielding the container of the generator tube so that the radiation dose other than that of usable beams will be one-thousandth or less of the radiation dose of usable beams;

(ii) taking appropriate protective measures to reduce exposure to unnecessary radiation immediately after irradiation ends;

(iii) installing an apparatus which automatically indicates the generation of radiation at the time thereof; and

(iv) when the entrance to the room for using medical high-energy radiation generators is open, installing an interlock which blocks the generation of radiation.

(Protection of Medical Particle Beam Irradiation Apparatuses)

Article 30-2-2 The provisions of the preceding Article apply mutatis mutandis to medical particle beam irradiation apparatuses. In this case, the term "generator tube" in item (i) of the same Article is deemed to be replaced with "irradiation tube," the term "the generation of radiation" in item (iii) of the same Article is deemed to be replaced with "irradiation," and the terms "the room for using medical high-energy radiation generators" and "the generation of radiation" in item (iv) of the same Article is deemed to be replaced with "the room for using medical particle beam irradiation apparatuses" and "irradiation," respectively.