HJ

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Requirements of radiation safety and protection for radiotherapy

放射治疗辐射安全与防护要求

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Requirements of radiation safety and protection for radiotherapy

1 Scope

This standard specifies the radiation safety and protection requirements for medical institutions to carry out radiotherapy.

This standard applies to radiation safety and protection management of radiation workers and the public, in radiation therapy-related activities in medical institutions.

This standard does not apply to radionuclide therapy, patch therapy, radioactive seed implantation therapy, boron neutron capture therapy, radiotherapy simulation diagnosis.

The production, commissioning, repair and maintenance activities and scientific research activities of radiotherapy equipment can be carried out, with reference to this standard.

2 Normative references

This standard refers to the following documents or their clauses. For dated references, only the dated version applies to this standard. For undated references, the latest edition (including all amendments) applies to this standard.

GB 18871-2002 Basic standards for protection against ionizing radiation and for the safety of radiation sources

"Radioactive waste classification" (Announcement of Ministry of Environmental Protection, No.65 of 2017)

3 Terms and definitions

The following terms and definitions apply to this standard.

3.1

Radiation worker

Those who are or may be exposed to ionizing radiation, in medical institutions, engaged in radiation therapy-related activities, including physicians, medical physicists, technicians and nurses, as well as formal staff, temporary staff and interns,

such as radiation therapy equipment installation and commissioning engineers, maintenance engineers, radiation protection managers, etc.

3.2

Survey system

A system, through which the radiation workers use reset buttons and other methods to clear and inspect the areas accessible to personnel in the accelerator hall or treatment room according to a certain line sequence, meanwhile verify personnel retained or other abnormal situations, before the beams of large accelerator devices, such as proton/heavy ion accelerators, are released. It is generally set up in areas related to large accelerators, such as proton/heavy ion accelerators.

4 General requirements

4.1 Medical institutions, that are engaged in radiotherapy, shall be fully responsible for the radiation safety and protection of radiotherapy activities; achieve the goal of protecting radiation workers engaged in radiotherapy, public health and environmental safety.

4.2 Medical institutions engaged in radiation therapy shall establish a sound radiation safety and protection management system; formulate a radiation safety and protection program; implement management systems such as job responsibilities and operating procedures.

4.3 In the process of planning, designing, constructing radiotherapy workplaces and carrying out radiotherapy activities, medical institutions engaged in radiotherapy shall follow the justification of practice, optimization of safety and protection, dose limitation and potential exposure risk limitation, to ensure that radiation doses exposed by the radiation workers and the public involved in the treatment are at a safe and reasonable level.

4.4 Medical institutions engaged in radiotherapy shall set up appropriate multi-layer protection and safety measures, according to the potential exposure hazard level of radiotherapy activities and the principle of defense in depth, so as to ensure that when a certain level of defense measures fails, the defensive measures of the next level are used for remedy or correction, so as to:

a) Prevent accidents that may cause false exposure;

b) Mitigate the radiological consequences of accidents;

c) Restore radiotherapy equipment to a safe state.

4.5 The items constituting the safety interlocking system of radiotherapy-related

radiation workplaces shall meet the following requirements:

a) It shall meet the redundancy requirements; the items used shall be the minimum number of items necessary to complete a certain safety function, so as to ensure that the whole function will not be lost, when an item fails or does not work during operation;

b) It shall meet the diversity requirements, including system diversity and multiple dose monitoring, using different operating principles, different physical variables, different operating conditions, different components, etc.;

c) It shall meet the independence requirements. When a certain safety component fails, it will not cause the failure or loss of function of other safety components;

d) It shall meet the requirements of failure safety. When a certain safety item or component fails, it shall ensure that the radiotherapy device returns to a safe state.

4.6 Medical institutions engaged in radiotherapy shall standardize the collection, proper temporary storage, disposal of radioactive waste, which is generated in radiotherapy activities.

4.7 Medical institutions engaged in radiotherapy shall conduct regular radiation monitoring and evaluation of the radiotherapy site and surrounding environment, to prove the effectiveness of the radiation safety and protection measures taken.

4.8 The radiation exposure of radiation workers and members of the public shall comply with the relevant requirements on dose limits in GB 18871-2002.

4.9 The dose constraint values for occupational exposure of staff engaged in radiotherapy and public exposure shall meet the following requirements:

a) In general, the dose constraint value for occupational exposure of workers engaged in radiotherapy is 5 mSv/a.

b) The dose constraint value for public exposure shall not exceed 0.1 mSv/a.

4.10 Medical institutions carrying out radiotherapy activities shall formulate corresponding emergency plans for radiation accidents; do a good job in emergency preparations, emergency drills, emergency responses for radiation accidents, to ensure effective prevention of radiation accidents or mitigation of the consequences of radiation accidents.

5 Site selection, layout, zoning requirements

5.1 Site selection and layout

5.1.1 The site selection of radiotherapy sites shall fully consider its radiation impact on

structural performance and protective performance; meet the optimization requirements. Neutron shielding must be considered, when using neutron source radiotherapy equipment, proton/heavy ion accelerators or X-ray radiotherapy equipment greater than 10 MV.

6.1.3 When the pipeline passes through the shielding object, the method that does not affect its shielding effect shall be adopted, meanwhile shielding compensation shall be carried out. The overlap between the protective door and the wall shall be fully considered, to ensure that the radiation protection requirements outside the shielding object are met.

6.1.4 Dose control shall meet the following requirements:

a) At 30 cm from the outer surface of the treatment room's wall and entrance door, points of concern adjacent to the treatment room, near the ground and floors outside the roof of the treatment room, built or proposed two-floored buildings above the treatment room or next to the treatment room, or when the height of the adjacent building exceeds the solid angle area spanned by the edge of the inner surface of the roof of the treatment room from the radiation source point, THEN, the surrounding dose equivalent rate, at a distance of 30 cm from the outer surface of the treatment room roof AND the high-rise buildings where personnel reside within the solid angle area, shall meet the dose rate reference control level $\dot{H}_c$, which is determined by the following 1) and 2) at the same time:

1) Using the weekly workload of radiotherapy, the use factor and residence factor of the point of interest (which can be selected according to Appendix A), the derived dose rate reference control level $\dot{H}_{c,d}$ (μSv/h) of the point of interest is obtained, from the following weekly dose reference control level ($\dot{H}_c$):

Radiation workers outside the machine room: $\dot{H}_c \leq 100$ μSv/week;

Non-radiation workers outside the machine room: $\dot{H}_c \leq 5$ μSv/week.

2) Determine the highest dose rate reference control level $\dot{H}_{c,max}$ (μSv/h) of the point of interest, according to the difference of the personnel residence factors in the point of interest:

Places with personnel residence factor T > 1/2: $\dot{H}_{c,max} \leq 2.5$ μSv/h;

Places with personnel residence factor T ≤ 1/2: $\dot{H}_{c,max} \leq 10$ μSv/h.

b) The radiation passing through the roof of the machine room is controlled with an annual dose of 250 μSv to the personnel, who accidentally reach outside the roof of the machine room.

c) For the roof of the machine room that does not require personnel to reach AND can only be accessed with tools, the dose rate reference control level at 30 cm from the outer surface of the roof of the machine room can be controlled at 100 μSv/h (radiation notice boards can be set at the corresponding positions).

6.1.5 The treatment room, where neutron sources are used for after-loading treatment, shall be equipped with necessary emergency source storage pools or polyethylene tanks, that meet neutron shielding measures, to ensure the safe temporary storage of radioactive sources. Meanwhile, it shall implement double-person double-lock management.

6.2 Requirements for safety protection facilities and measures

6.2.1 In the radiotherapy workplace, obvious ionizing radiation warning signs and working status indicators shall be set up:

a) Ionizing radiation warning signs shall be provided, at the entrance of the radiotherapy workplace; ionizing radiation signs and warning instructions in Chinese shall be provided, on the outer surface of the source storage vessel;

b) Ionizing radiation warning signs and working status indicator lights shall be installed, at the entrance and exit of the controlled area of the radiotherapy workplace and other appropriate locations;

c) The control room shall be equipped with a video device, that can observe the status of the patient, the treatment room and the labyrinth area during the treatment process. Meanwhile, it shall set up a two-way communication intercom system.

6.2.2 Proton/heavy ion accelerator halls and treatment rooms, radiation treatment rooms containing radioactive sources, medical electron linear accelerator treatment rooms (generally at the inner entrance of the labyrinth) shall be equipped with fixed radiation dose monitors, which have the alarm function under abnormal situations. The display unit is set in the control room or near the door of the machine room.

6.2.3 Radiation workplaces related to radiotherapy shall be equipped with safety interlocking measures, to prevent mis-operation and prevent accidental exposure of staff and the public:

a) The radiotherapy room and the proton/heavy ion accelerator hall shall be equipped with door-machine/source interlocking device. When the protective door is not completely closed, the beam/source cannot be emitted for irradiation. Under the beam emission/source state, if the door is opened, the beam emission stops OR the radiation source returns to a safe location on the therapy equipment. Therapeutic equipment containing radioactive sources shall be equipped with measures, to automatically return the source after power failure;

b) Radiation therapy rooms and proton/heavy ion accelerator halls shall be equipped

7.3 No one is allowed to enter the controlled area without authorization or permission. The staff can enter the radiotherapy room, only after confirming that the radiotherapy or beam flow in the treatment room has been terminated. They must carry a personal dose alarm, before entering the treatment room containing radioactive sources or proton/heavy ion devices. Maintenance personnel shall conduct workplace radiation monitoring, before entering the proton/heavy ion accelerator hall and beam transport channel area, AND they can only enter after the approval of the unit radiation safety management agency. Visitors entering the proton/heavy ion accelerator hall and beam transport channel area must be led by radiation staff.

7.4 The radiation safety management of radioactive source flipping activities shall be strengthened. The flipping work shall be carried out by professionals who have the corresponding ability and have passed the radiation safety assessment. It shall formulate the radioactive source flipping work program; confirm the effectiveness of radiation monitoring and alarming instruments, the partition setting of operation area, the installation of flipping shielding object. When flipping the radioactive source, it shall carry out radiation monitoring, around the flipping hot cell and on the surface of source-containing equipment; pay attention to the radiation protection effect of the flipping source shielding object and the surface contamination of the source-containing equipment; check and record the installed and replaced radioactive sources. After the source flipping is completed, conduct radiation monitoring on the radiotherapy equipment, places and surrounding environment containing radioactive sources.

7.5 During the commissioning and maintenance of the proton/heavy ion accelerator, the management of personnel entering the proton/heavy ion accelerator hall, beam transport channel, treatment room area shall be strengthened. It is strictly forbidden for debugging and maintenance personnel to stay in the control area, when the beam is released. Shielding shall be considered for radiation hotspot areas (such as cyclotrons, energy degraders, beam deflection and lead-out parts, etc.). The exposure dose monitoring equipment, which accesses to personal safety interlock systems should adopt direct-reading instruments.

8 Radioactive waste management requirements

8.1 General requirements

Medical institutions shall minimize the generation of radioactive waste. The generated radioactive waste shall be collected and processed, according to the type of nuclide, activity, half-life, physical-chemical properties.

8.2 Solid waste management requirements

8.2.1 Management requirements for disused radioactive sources

Disused radioactive sources shall be returned to the radioactive source manufacturer or

original exporter, in accordance with laws and regulations. If it is determined that it cannot be returned to the manufacturer or returned to the original exporter, it shall be sent to an organization with corresponding qualifications for storage, and bear the relevant costs.

8.2.2 Other solid waste management requirements

8.2.2.1 During the commissioning and operation of proton/heavy ion accelerators, linear accelerators, other therapeutic devices, such as activated cyclotrons, collimators, beam stoppers, accelerator targets and other components, when replacing or decommissioning, they shall be disposed as radioactive solid waste. After dismantling, put it into a shielded vessel or solid waste temporary storage room, for decay and temporary storage; finally send it to a qualified organization for storage.

8.2.2.2 For the low-level activation components, such as proton/heavy ion accelerator treatment head devices, magnets, etc., as well as waste resin used to treat proton/heavy ion accelerator cooling water, they are placed in the solid waste temporary storage room for temporary decay. Those that exceed the clearance decontrol level (see Appendix B for the activity and activity concentration of radioactive waste exemption) are sent to qualified organizations for storage.

8.2.2.3 Establish a ledger for radioactive solid waste; conduct monitoring before storage and disposal; record the name, quality, radiation category, monitoring equipment, monitoring results (dose equivalent rate), monitoring date, whereabouts and other relevant information. If it is lower than the clearance decontrol level, it can be disposed of as general solid waste, meanwhile archived and recorded.

8.3 Liquid waste management requirements

The activated cooling water of the proton/heavy ion accelerator, in the event of an accident or maintenance, shall be properly collected and stored, in accordance with the management requirements of radioactive waste liquid. After the temporary storage, if it decays below the exemption level, it can be disposed as as ordinary waste liquid, meanwhile the records shall be kept.

8.4 Gaseous waste management requirements

8.4.1 The radiotherapy room shall be equipped with a forced exhaust system, using the ventilation mode of full exhaust and full delivery; the air exchange rate shall not be less than 4 times/h. The exhaust outlet shall not be set in the areas with doors, windows or corridors with large personal flow.

8.4.2 After the proton/heavy ion accelerator is shut down, the accelerator hall shall be enhanced with ventilation and exhaust; take measures to delay the entry of personnel, so as to reduce the induced radioactive level of the activated air, thereby reducing the exposure dose of personnel.

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