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## REGULATION OF THE MINISTER OF HEALTH<sup>1)</sup>

of 22 December 2006

### **on the supervision and control of compliance with the conditions of radiation protection in organisational units using X-ray equipment for medical diagnostics, interventional radiology, surface radiotherapy and radiotherapy of non-cancerous diseases**

Pursuant to Article 63 Section 3 of the Act of 29 November 2000 - Atomic Law (Journal of Laws of 2004, No. 161, Item 1689, as amended<sup>2)</sup>) it is hereby ordered as follows:

Article 1. The Regulation defines the method of supervising and carrying out inspections of the compliance with the conditions of radiation protection in organisational units using X-ray equipment for medical diagnostics, interventional radiology, surface radiotherapy and radiotherapy of non-cancerous diseases, hereinafter referred to as "inspected entities", by the regional public sanitary inspector, military commander of the preventive medicine centre or state sanitary inspector of the Ministry of Internal Affairs and Administration, hereinafter referred to as "supervisory authorities".

Article 2. 1. As part of the supervision, the supervisory authority:

- 1) Organises an inspection in case of obtaining information of a breach of the principles of radiation protection resulting in a threat to life or health;
- 2) Cooperates with the competent regional consultants in the field of radiology and diagnostic imaging, radiation oncology and nuclear medicine.

2. The planned inspection of compliance with regulatory requirements for radiation protection shall be carried out not less than once every 4 years or upon submission of a request by the inspected entity to the supervisory authority.

Article 3. Actions taken during the inspection, hereinafter referred to as "inspection activities" should be carried out in a manner:

- 1) Ensuring an objective determination of the facts and their reliable documentation, allowing for the evaluation of the method of operation of the inspected entity;
- 2) Not interfering significantly with the activities conducted by the inspected entity, in particular the implementation of its obligations to third parties.

Article 4. 1. An employee or employees authorised by the supervisory authority to carry out the inspection, hereinafter referred to as the "inspectors", shall carry out the inspection on the basis of the authorisation, referred to in the separate provisions, upon the presentation to the head of the inspected entity of ID cards and making an entry in the sanitary inspection logbook, specifying the subject-matter and scope of the inspection.

2. If, in the course of the inspection, it becomes necessary to extend the duration of the inspection, change its subject-matter or scope or its location, the inspectors shall immediately inform the inspected entity, by submitting the appropriate authorisation to conduct the inspection.

Article 5. 1. The inspection begins on the date on which the authorisation for the inspection was presented, but not earlier than the date specified in the authorisation for the inspection.

2. The date of completion of the inspection shall be the date of signing the report by the inspectors and the head of the inspected entity, and if the head of the inspected entity refuses to sign the report, the date of completion of the inspection shall be the date on which the final activity of the inspection was carried out.

3. Upon completion of the inspection, the inspectors shall make an entry in the sanitary inspection logbook.

4. The head of the inspected entity shall be notified about the completion of the inspection.

Article 6. The head of the inspected entity shall provide the conditions and measures for the inspectors which are necessary for the efficient carrying out the inspection, in particular:

- 1) Make the facilities and rooms available;
- 2) Provide access to all documents relevant to the subject-matter of the inspection;
- 3) Provide oral or written explanations on matters relating to the subject-matter of the inspection;
- 4) Provide means of communication at its disposal, to the extent necessary for the performance of inspection activities;
- 5) Provide access for the inspectors, as far as possible, to its technical equipment used to improve the performance of inspection activities, including making copies of documents.

Article 7. 1. The inspectors determine the facts, relying in particular on:

- 1) The documents and information included in the explanations provided by the head

<sup>1)</sup> The Minister of Health manages the department of government administration - health, on the basis of Article 1 Section 2 of the Regulation of the President of the Council of Ministers of 18 July 2006 on the detailed scope of responsibilities of the Minister of Health (Journal of Laws No. 131, Item 924).

<sup>2)</sup> Amendments to the Act were published in the Journal of Laws of 2004, No. 173, Item 1808, of 2005, No. 163, Item 1362 and of 2006, No. 52, Item 378, No. 104, Item 708, No. 133, Item 935 and No. 170, Item 1217.

of the inspected entity and employees of the inspected entity or other persons who may contribute in a significant manner to the establishment of the facts;

2) Visual examination.

2. If the information collected during the inspection is insufficient to show compliance with the conditions of radiation protection, the inspectors may check the status of this protection by:

- 1) Performing dosimetric measurements;
- 2) Performing measurements of compliance of physical parameters of newly installed X-ray machines or X-ray machines after repairs for the fulfilment of the requirements of acceptance tests specified in regulations issued pursuant to Article 33c Section 9 of the Act of 29 November 2000 - Atomic Law, hereinafter referred to as "the Act";
- 3) Performing measurements of compliance of physical parameters of X-ray machines for the fulfilment of the requirements of basic and specialised tests specified in regulations issued pursuant to Article 33c Section 9 of the Act.

Article 8. 1. The results of the inspection conducted along with post-inspection recommendations are presented by the inspectors in the inspection report.

2. The inspection report shall include in particular:

- 1) An indication of the (company) name or the first and last name and address of the inspected entity;
- 2) The date of commencement and completion of the inspection;
- 3) First name(s), last name(s) and position(s) of the inspectors;
- 4) determination of the subject matter and scope of the inspection;
- 5) Description of the facts established during the inspection, taking into account the violations found;
- 6) A list of attached documents;
- 7) Information about instructing the head of the inspected entity about the right to file objection to the report and the right to refuse to sign the report.

Article 9. 1. The inspection report shall be signed by the head of the inspected entity and the inspectors.

2. After the head of the inspected entity is given the report to be signed, within 7 days he may submit objections to the report in writing, or refuse to sign the report, giving a written explanation on the refusal to sign the report.

3. If the objections are made, referred to in Section 2, the inspectors will carry out their analysis and, if necessary, undertake additional checks. If it is found that the objections are valid, the inspectors will amend or supplement the relevant part of the inspection report.

4. The refusal to sign the inspection report by the head of the inspected entity will be mentioned in the report by the inspectors.

5. The refusal to sign the inspection report does not constitute an obstacle to its signing by the inspectors.

6. After preparing the inspection report in duplicate, one copy of the report is left with the head of the inspected entity.

Article 10. After the transfer of the inspection report to the head of the inspected entity, no further amendments and additions can be made, with the exception of annotations relating to the refusal to sign the report by the head of the inspected entity or his representative, authorised in writing.

Article 11. 1. In the event of obstacles preventing the inspection to be carried out, the inspection must be carried out at the earliest possible date after the obstacles are removed.

2. If the obstacles preventing the inspection are caused by the inspected entity, the inspection must be repeated with the possible participation of representatives of other inspection authorities.

Article 12. This Regulation shall enter into force after 14 days from the date of publication.

Minister of Health: *Z. Religa*