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## **RADIATION SAFETY DIRECTORATE**

Pursuant to Article 26-e, paragraph 1, point 5 of the Law on Ionising Radiation Protection and Radiation Safety ("Official Gazette of the Republic of Macedonia" no. 48/02 and 135/07), the Director of the Radiation Safety Directorate, hereby adopts a

### **RULEBOOK ON THE CONTENTS OF THE RADIATION PROTECTION PROGRAMME, THE RADIATION EMERGENCIES PLAN AND THE PROGRAMME FOR QUALITY ASSURANCE AND SAFETY CONTROL**

#### Article 1

This Rulebook shall prescribe the content of the Radiation Protection Programme, the Radiation Emergencies Plan and the Programme for Quality Assurance and Safety Control.

#### Article 2

The provisions of this Rulebook shall not apply to export and import of ionizing radiation sources.

#### Article 3

The content of the Radiation Protection Programme shall depend upon the type of the ionizing radiation source and its activity.

The Radiation Protection Programme for performing activities with ionizing radiation sources shall contain:

- Internal working procedures and supervision;
- Plan for individual monitoring in accordance with the regulations on ionizing radiation protection and radiation safety;
- Plan for monitoring of the working environment and zones classification (controlled and supervised zone), and
- Plan for medical exposure, where appropriate.

The Radiation Protection Programme, depending on the activity carried out should include, where appropriate, additional areas regarding:

- Transport of radioactive sources - procedures when carrying out transportation and Plan for emergency events during transportation, according to the regulations on ionizing radiation protection and radiation safety;
- Transfer and acquisition of radioactive sources - procedures for performing a transfer and acquisition according to the regulations on ionizing radiation protection and radiation safety;

- Plan for discharge of radioactive substances into the environment, according to the regulations on ionizing radiation protection and radiation safety, and
- Radioactive waste management plan and/or used (disused sources) sources of ionizing radiation.

#### Article 4

The internal working procedures and supervision referred to in Article 3 paragraph 2 indent 1 of this Rulebook shall contain:

- Internal organisation and regulation: description of the system of organisation and management, awarding responsibilities and clear division of the authorisations of persons involved in activities with sources of ionizing radiation that relate to the ionizing radiation protection, radiation safety and security;
- Duties and responsibilities of the person responsible for radiation protection: authorisation to terminate unsafe operations, staff training, keeping records, keeping register, etc.;
- Plan and procedures for protection of employees - pregnant women: notification, acceptance of working conditions to protect the fetus/embryo and instructions provided to them;
- Description of the procedures and actions in performing an activity with ionizing radiation sources;
- Description of the Programme for optimisation of the exposure at work and exposure of the population, according to the principle of optimisation (ALARA principle) with an assessment of the nature and size of the radiation risk;
- Procedures for entering the controlled zone;
- Monitoring of the worker's health condition;
- Manner of informing the employees on issues concerning ionizing radiation protection and radiation safety, as well as the health risks and
- Manner of informing the patients about the medical exposure and informing regarding accidental medical exposure.

#### Article 5

The Plan for individual monitoring referred to in Article 3 paragraph 2 indent 2 of this Rulebook shall contain:

- Manner and procedure of determining the persons occupationally exposed to radiation and their classification;
- Ensuring individual monitoring of persons occupationally exposed to radiation and annexed document by authorised professional technical service;

- Keeping records in accordance with the regulations on ionizing radiation protection and radiation safety;
- Manner and procedure for informing the persons occupationally exposed to radiation regarding the results of the individual monitoring;
- Procedure when exceeding the investigation levels, in accordance with the regulations on ionizing radiation protection and radiation safety, and
- List of personal protective equipment for workers (lead gloves, aprons, shields).

#### Article 6

The Plan for monitoring of the working environment and zones classification referred to in Article 3 paragraph 2 indent 3 of this Rulebook shall contain:

- Manner and frequency of conducting working environment monitoring;
- Plan with clearly indicated points where the monitoring is conducted;
- Magnitudes measured;
- Reference values and measures taken in cases of exceeding the reference values;
- dosimetry equipment and programme for calibration of the same, together with calibration certificates provided by an authorised professional technical service, depending on the activity with ionizing radiation sources;
- Zones classification procedure (controlled zone, supervised zone and population zone) and manner of marking the zones;
- Means for marking the workspace when working on site and a description of the marking procedure, and
- Procedure for notification of persons not covered in the working process and individuals of the population, with particular emphasis when working on site.

#### Article 7

The plan on medical exposure referred to in Article 3 paragraph 2 indent 4 of this Rulebook shall contain:

- Justification of the exposure to ionizing radiation during medical treatment or the diagnostic or therapeutic procedure, persons who assess the justification of medical exposure, as well as persons who carry out the procedure;
- Protocol for performing x-rays on patients;
- Information provided to patients, individuals who assist patients, pregnant women and/or persons voluntarily exposed to ionizing radiation for medical and biomedical scientific research;
- Information and/or instructions provided to patients undergoing treatment with open

radioactive sources, and the manner of their delivery;

- Procedures, where appropriate, in case of a medical exposure for reasons of a medical or biomedical research;
- Optimisation of the medical exposure (use of diagnostic reference levels, treatment planning, selection of new equipment, etc.), and
- Procedures in case of exposure of individuals as part of medical procedures prescribed by general regulations.

#### Article 8

The radiation emergencies plan shall contain:

- Description and identification of possible radiation emergencies and radiation accidents and procedures in the event of a radiation emergency and/or radiation accident, according to the regulations on ionizing radiation protection and radiation safety;
- plan and procedures for action in case of a radiation emergency (potential damage to the source, security system failure, loss of a source or source protection, sabotage, theft, persons with high level of harmful exposure, and less likely events that may occur, such as contamination, fires, floods, explosions which involve radioactive sources, etc.), persons responsible for their implementation and updating, their appropriate training and carrying out practical exercises in a certain time interval;
- Correct safety procedures, protective equipment and protective measures taken before the implementation of the plans/procedures and the equipment which will be used;
- Way of communication in case of a radiation emergency;
- Urgent procedures undertaken in the event of a radiation emergency;
- Investigating procedure in the event of a radiation emergency;
- Investigation in the event of an accidental medical exposure;
- List of telephone numbers of persons reporting emergencies;
- The person performing a risk assessment and consequences of a radiation emergency;
- List of other institutions involved in dealing with the situation;
- Manner of notifying the Radiation Safety Directorate and
- List containing data on persons familiar with the Radiation Emergency Plan. The list is available to these persons.

#### Article 9

The Programme for Quality Assurance and Safety Control shall contain:

- Description of the Programme for periodic review and updating of the Radiation Protection Programme and working procedures;
- Training programme for the personnel involved in activities with ionizing radiation sources and the person responsible for radiation protection;
- Description of the training programme which ensures that all personnel is properly trained regarding correct operating procedures;
- Programme for quality control of the equipment, in accordance with the regulations on ionizing radiation protection and radiation safety, as well as a report on quality control;
- Keeping records of the personal exposure: current records and previous work history;
- Keeping records of reports of conducted assessment of radiation exposure;
- Keeping records of certificates for calibration of measuring instruments;
- Keeping records of review and revision of the Radiation Protection Programme;
- Keeping records of reports concerning radiation emergencies;
- Keeping records of reports concerning maintenance and servicing of equipment;
- Keeping records of changes that would affect the radiation safety and ionizing radiation protection ;
- Keeping records of reports concerning personnel trainings that have been provided;
- Keeping records of the health monitoring of persons occupationally exposed to radiation;
- Keeping records regarding information about the transfer of ionizing radiation sources;
- Keeping records of the estimated dose for patients in the case of a medical exposure;
- Keeping records of the parameters for performing x-rays on patients and
- Keeping records of the daily, weekly, monthly and annual checks of the equipment and the procedures undertaken by the operator before and after completion of the use of the source.

#### Article 10

This Rulebook shall enter into force on the eight day from the date of its publication in the Official Gazette of the Republic of Macedonia.

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Director  
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