

## **RADIATION SAFETY DIRECTORATE**

Pursuant to Article 26-e, paragraph 1, item 9 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 HEALTH REQUIREMENTS FOR WORKING WITH IONISING RADIATION SOURCES AND ON THE MEASURES, CONTENT AND MANNER OF PERFORMING MEDICAL EXAMINATIONS OF PERSONS WORKING WITH IONISING RADIATION SOURCES**

#### **I. General provisions**

##### **Article 1**

This Rulebook shall prescribe the health requirements for working with ionising radiation sources and the measures, content and manner of performing medical examinations of persons working with ionising radiation sources and of occupationally exposed persons.

##### **Article 2**

The purpose of performing medical examinations of persons working with ionising radiation sources and of occupationally exposed persons (hereinafter referred to as: occupationally exposed persons) shall be:

- to confirm that the occupationally exposed persons are healthy and capable of working with ionising radiation sources and that their health condition and the capacity for work is not an impediment to performing their work;
- to monitor the health condition of the occupationally exposed persons while they are performing their work, especially for the purpose of perceiving any changes in their health condition that may be an impediment to the continuation of their work, and
- to establish the effect of the exposure to ionising radiation on the health of the occupationally exposed persons when the exposure dose level is either exceeded or is considered to be exceeded, in accordance with the regulations on protection against ionising radiation and radiation safety.

##### **Article 3**

The occupationally exposed persons may work or be trained to work with ionising radiation sources if they fulfil the health requirements laid down in the provisions of this Rulebook.

#### **II. Health requirements for working with ionising radiation sources**

##### **Article 4**

When assessing the fulfilment of the health requirements for working with ionising radiation sources on the part of the occupationally exposed persons, particular attention shall be paid to the following health conditions:

1. Blood vessel diseases: refractory anaemia, neutropenia, thrombocytopenia (single or combined);
2. Malign diseases (during the disease and after the therapy);
3. Evolving diseases of the eye lenses, regardless of the reason for the occurrence thereof;

4. Evolving tuberculosis and active tuberculosis;
5. Diseases of the endocrine glands requiring treatment in cases where the application of the latest endocrinological treatments does not result in a satisfactory regulation of a certain pathophysiological condition;
6. Evident permanent skin damage caused by ionizing radiation (necrotic degree of acute radiodermatitis or hyperplastic phase of chronic radiodermatitis);
7. Grave skin diseases (scleroderma, dermatomyositis, pemphigus, etc.);
8. Chronic skin diseases not expected to be fully cured with any known treatment methods, including skin damage caused by ionising radiation;
9. Addictions (alcoholism, pill addiction, drug addiction);
10. Severe mental and nervous diseases: below the average cognitive ability, psychosis and border cases; posttraumatic stress disorders; serious neurosis; personality disorders with an emphasised asocial or antisocial behaviour; acute or severe diseases, injuries or anomalies of the central or the peripheral nervous system; epilepsy and other consciousness disorders;
11. Diseases leading to pulmonary fibrosis, including pneumoconiosis;
12. Severe chronic pulmonary diseases (according to the appropriate acknowledged methodology);
13. Severe kidney diseases (according to the appropriate acknowledged methodology); and
14. Other diseases which contemporary medicine considers an impediment to working with ionising radiation sources.

### **III. Measures, content and manner of performing medical examinations of occupationally exposed persons**

#### Article 5

The legal entity shall provide the performance of medical examinations of all occupationally exposed persons.

The legal entity shall inform an occupational medicine doctor of the performance of the medical examinations referred to in paragraph 1 of this Article by submitting data in writing on the following:

1. The duties of the occupationally exposed person and the workplace conditions;
2. The factors contributing to exposure to ionising radiation; and
3. Risk factors resulting from the person's work or such that might occur for other persons during the performance of their work.

#### Article 6

The medical examinations of occupationally exposed persons shall consist of:

- a pre-employment medical examination, i.e. a pre-examination;
- a regular medical examination, i.e. a periodic examination, and
- an extraordinary control medical examination, i.e. a disease-oriented examination.

The occupationally exposed person shall be provided with a pre-employment medical examination and with a regular medical examination by the legal entity by means of a completed referral form, referred to in Appendix 1, which is a constituent part of this Rulebook.

The referral form referred to in paragraph 2 of this Article shall be completed by the legal entity in two copies, one of which shall be sent to the authorised health institution.

#### Article 7

A pre-employment medical examination shall be performed before starting the employment training or before starting an employment involving work with ionising radiation sources.

The pre-employment medical examination referred to in paragraph 1 of this Article shall include the tests given in Article 10 of this Rulebook.

#### Article 8

A regular medical examination shall be performed on a yearly basis.

The regular medical examination shall provide a continual monitoring of the health condition of occupationally exposed persons for the purpose of determining the existence of any side-effects caused by working with ionising radiation sources.

In case of diagnosing a disease which is a side-effect caused by working with ionising radiation sources, the capacity of working with ionising radiation sources of the occupationally exposed person shall be re-assessed.

#### Article 9

An extraordinary control medical examination shall be performed:

- for occupationally exposed person who has received a dose level exceeding the dose limit established in accordance with the regulations on protection against ionising radiation and radiation safety;
- on the basis of a suggestion by an occupational medicine doctor or by a chosen doctor from the ranks of the primary health care, and
- upon request from the Radiation Safety Directorate.

#### Article 10

A pre-employment medical examination shall consist of the following:

- 1) Medical history: employment medical history, disease-oriented medical history – such as gynaecological information on women, chief complaints, history of the present illness, family diseases, past medical history, social and epidemiological history;
- 2) Review of systems and anthropometry (body mass, height and BMI);
- 3) Basic laboratory SE, KS, (Er, Hgb, Htc, Le) analyses, determining the number of reticulocytes, trombocytes, leukocytary formula, glycaemia, cholesterol, triglycerides, urine (sugar, proteins, billirubin, urobillinogen, sediment);
- 4) Ophthalmological examination: eye function examination: distance and proximity sharpness of vision, examination of optical media by means of pupil dilation;
- 5) Audiometry;
- 6) Spirometry;

- 7) 12-lead ECG;
- 8) Radiophotography of the thorax, by decision of a doctor;
- 9) Analysis of chromosome aberrations, by decision of a doctor, and
- 10) Gynaecological examination of the reproductive function, by decision of a doctor.

#### Article 11

A regular medical examination shall consist of the following:

- 1) Medical history: employment medical history, medical history with a specific target – such as gynaecological information on women, chief complaints, history of the present illness, family diseases, past medical history, social and epidemiological history;
- 2) Review of systems and anthropometry (body mass, height and BMI);
- 3) Basic laboratory SE, KS, (Er, Hgb, Htc, Le) analyses, determining the number of reticulocytes, trombocytes, leukocytary formula, glycaemia, cholesterol, triglycerides, urine (sugar, proteins, billirubin, urobillinogen, sediment);
- 4) Ophthalmological examination: eye function examination: distance and proximity sharpness of vision, examination of optical media by means of pupil dilation;
- 5) Audiometry;
- 6) Spirometry;
- 7) 12-lead ECG;
- 8) Radiophotography of the thorax, by decision of a doctor;
- 9) Analysis of chromosome aberrations, by decision of a doctor;
- 10) Psychological observations (psychological and physiological capacities and personality characteristics); and
- 11) Gynaecological examination of the reproductive function, by decision of a doctor.

#### Article 12

An extraordinary control medical examination shall consist of the following:

- 1) Medical history: employment medical history, medical history with a specific target – such as gynaecological information on women, chief complaints, history of the present illness, family diseases, past medical history, social and epidemiological history;
- 2) Review of systems and anthropometry (body mass, height and BMI);
- 3) Basic laboratory SE, KS, (Er, Hgb, Htc, Le) analyses, determining the number of reticulocytes, trombocytes, leukocytary formula, glycaemia, cholesterol, triglycerides, urine (sugar, proteins, billirubin, urobillinogen, sediment);
- 4) Ophthalmological examination: eye function examination: distance and proximity sharpness of vision, examination of optical media by means of pupil dilation;
- 5) Audiometry;
- 6) Spirometry;
- 7) 12-lead ECG;
- 8) Radiophotography of the thorax, by decision of a doctor;

- 9) Analysis of chromosome aberrations, by decision of a doctor;
- 10) Psychological observations (psychological and physiological capacities and personality characteristics); and
- 11) Other examinations and tests depending on the reason for the referral.

#### Article 13

When determining the health capacity to carry protective equipment for the respiratory system, medical examinations that include checks of the functioning of the lungs shall be performed.

In the case of occupationally exposed persons who have skin diseases, the decision on their health condition shall depend on the nature, phase and evolution of the disease, as well as on the nature of the work being performed.

Occupationally exposed persons who have the diseases referred to in paragraphs 1 and 2 of this Article shall not be exempted from working with unsealed radioactive sources if the appropriate preventive measures have been taken.

In the case of occupationally exposed persons who have psychological disorders, the decision on the health condition shall take into consideration the safety implications of the symptomatic stages of the disease, the primary aim being to determine whether these employees are a danger to themselves or to other employees.

#### Article 14

The occupational medicine doctor may suggest that the medical examinations be continued even after the termination of the work with ionising radiation sources, as long as s/he considers it necessary for the protection of the person's health.

#### Article 15

Medical examinations of occupationally exposed persons shall be performed on the basis of the professional principles of occupational medicine and of evidence-based medical practice.

The medical examinations referred to in paragraph 1 of this Article shall be performed by occupational medicine doctors in health institutions practising occupational medicine in accordance with the regulations concerning healthcare, authorised by the Radiation Safety Directorate.

#### Article 16

After the completion of the medical examinations, a capacity assessment shall be made within ten days from the date of starting the medical examination and within 30 days at the latest, if additional medical examinations are necessary.

The capacity assessment referred to in paragraph 1 of this Article may be to the effect that the employee is:

- capable of working with ionising radiation sources,
- capable on a conditional basis, and
- incapable of working with ionising radiation sources.

#### Article 17

The capacity assessment shall be entered into an individual medical report, attached in Appendix 2, which is a constituent part of this Rulebook.

The assessments “capable on a conditional basis” and “incapable of working with ionising radiation sources” shall be accompanied by a citation of the provisions of this Rulebook pursuant to which such assessments have been made, and the Radiation Safety Directorate shall be informed thereof by submitting the individual medical report referred to in paragraph 1 of this Article.

#### Article 18

The following entities shall be informed of the capacity assessment:

1. The occupationally exposed person; and
2. The legal entity where the occupationally exposed person is employed.

#### Article 19

The authorised health institutions referred to in Article 15, paragraph 2 of this Rulebook shall keep medical records of each occupationally exposed person, which shall be kept for as long as the person is subjected to medical examinations, in accordance with the regulations on ionising radiation protection and radiation safety.

The medical records referred to in paragraph 1 of this Article shall contain in particular:

- information on the previous professional duties of the occupationally exposed person and the relation with the work that is necessary for monitoring the condition and that may be important for the work with ionising radiation sources;
- information on the nature of the professional duties of the occupationally exposed person;
- the results from all medical examinations;
- information on each additional medical examination of interest, and
- information on any radiotherapy or radionuclide therapy to which the occupationally exposed person has been subjected.

### **IV. Transitional and final provision**

#### Article 20

On the date of entry into force of this Rulebook, the provisions on health conditions and medical examinations of persons that may work with ionising radiation sources of the Rulebook on the medical expertise, health conditions and medical examinations of persons that may work with ionising radiation sources (Official Gazette of the SFRY No. 40/84) shall cease to apply.

#### Article 21

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

No. 01-190/3  
17 February 2010  
Skopje

Director,  
PhD. **Rumen Stamenov**

# Appendix 1

\_\_\_\_\_  
(legal entity)

\_\_\_\_\_  
(registration number)

\_\_\_\_\_  
(address)

\_\_\_\_\_  
(activity code)

/

\_\_\_\_\_  
Referral number (date)

## MEDICAL EXAMINATION REFERRAL FORM

The person

\_\_\_\_\_  
(name, father's name and surname)

born on \_\_\_\_\_, in \_\_\_\_\_  
(place and municipality)

by occupation \_\_\_\_\_, occupying or about to occupy  
the post of \_\_\_\_\_,

is hereby referred to have his/her capacity to work with ionising radiation sources assessed.

Brief description of occupational duties and workplace conditions:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Factors contributing to exposure to ionising radiation

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Risk factors arising from the workplace: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

(Stamp)

\_\_\_\_\_  
Legal  
entity,

## Appendix 2

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(authorised health institution )

(examination date)

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(address)

(ambulance protocol number)

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(medical record number)

### INDIVIDUAL MEDICAL REPORT on a performed medical examination

On the basis of the referral for \_\_\_\_\_  
number \_\_\_\_\_ dated \_\_\_\_\_, a medical examination was  
performed of the person \_\_\_\_\_  
(name, father's name and surname)  
born on \_\_\_\_\_, by occupation \_\_\_\_\_  
who occupies or is about to occupy the post of \_\_\_\_\_  
\_\_\_\_\_

On the basis of the medical examinations performed in accordance with the *Rulebook on the health requirements for working with ionising radiation sources and on the measures, content and manner of performing medical examinations of persons working with ionising radiation sources (Official Gazette of the Republic of Macedonia No. \_\_\_\_)*, the following

#### HEALTH CONDITION ASSESSMENT is being made

1. \* Pathological conditions (diagnoses):

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2.\* Recommendations for the person:

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3. Special conditions and recommendations for the legal entity and information on the existence of occupational diseases and occupational-related diseases: \_\_\_\_\_

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4. Capacity assessment:

The above-mentioned person is:

- **CAPABLE**
- **CAPABLE ON A CONDITIONAL BASIS**
- **INCAPABLE**

of working with ionising radiation sources.

\_\_\_\_\_  
(place)

\_\_\_\_\_  
(signature and facsimile of the occupational  
medicine specialist)

\_\_\_\_\_  
(date) (STAMP)

\* Points 1 and 2 shall not be completed in the copies that are submitted to the legal entity and to the Radiation Safety Directorate.