

Pursuant to Article 16(1) of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (Official Gazette of BiH 88/07) and Article 61(2) of the Law on Administration (Official Gazette of BiH 32/02 and 102/09), the director of the State Regulatory Agency for Radiation and Nuclear Safety issues the

REGULATION
on the medical surveillance of occupationally exposed workers

PART ONE – GENERAL PROVISIONS

Article 1
(Subject)

This regulation provides for the requirements that must be met by health-care institutions in order to conduct health checks of the workers occupationally exposed to ionizing radiation (hereinafter: exposed workers), apprentices, high-school and university students; the criteria for establishing the state of health of exposed workers and their fitness for work; the procedure and deadlines for all types of medical examinations; the way of assessing the exposed workers' fitness for work; the maintaining and keeping of medical records, and also other matters of importance for the medical surveillance of exposed workers, apprentices, high-school and university students.

Article 2
(Definitions)

The terms used in the regulation mean:

- a) *Authorized health-care institution* – A health-care institution registered for the practice of occupational medicine that establishes general and specific health checks of exposed workers, apprentices, high-school and university students as authorized by the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency).
- b) *Biodosimetry* – The laboratory or clinical methods used to measure or estimate ionizing radiation dose, i.e. the absorbed energy. Biodosimetry measures the dose of external and internal exposure in internal organs and tissues.
- c) *Deterministic effects of radiation* – Health effects of radiation for which a threshold level of dose exists above which the severity of the effect increases at higher doses.
- d) *Medical doctor – occupational medicine specialist* (hereinafter: occupational medicine specialist) – Within the meaning of this regulation, a doctor entitled to conduct health check of exposed workers, apprentices, high-school and university students, and who has completed a training in ionizing radiation protection in accordance with applicable legislation.
- e) *Apprentice, high-school or university student* – Any person receiving training within or outside an institution in order to gain competence for a profession directly or indirectly connected with the activities that include exposure to ionizing radiation.
- f) *Annual dose limits for exposed workers* – The effective dose of 20 mSv, the equivalent dose of 20 mSv for the lens, and the equivalent dose of 500 mSv for skin or extremities: the hands, forearms, feet and ankles.
- g) *Occupational exposure* – Exposure of an exposed worker during the performance of duties with ionizing radiation sources.

- h) *Exposed worker* – An individual working with radiation sources or in a radiation field at work, who may be subject to an exposure liable to result in the doses exceeding the dose limits for public exposure.
- i) *Category A exposed worker* – An exposed worker who, due to the working conditions, is liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year for the lens of the eye or greater than 150 mSv per year for skin and extremities (the hands, forearms, feet and ankles).
- j) *Category B exposed worker* – An exposed worker who is not classified as Category A exposed worker.
- k) *Duties involving radiation sources* – The duties involving exposure to ionizing radiation that could result in a dose to exposed workers exceeding any of the population dose limits.
- l) *Stochastic effects of radiation* – Health effects of radiation the severity of which is independent of dose, and the probability of occurrence is proportional to the dose, without a dose threshold.
- m) *Expertise* – A particular knowledge or familiarity with a field, which allows a professional authority to assess and interpret results and findings that are the subject of expertise, with the known mechanisms and procedures for using the expertise. The expertise result must be documented in the form of a report.

Article 3
(Health check of exposed workers)

- (1) The health check of exposed workers categories A and B is based on general principles of occupational medicine.
- (2) The health check of Category A exposed workers is conducted by an authorized health-care institution, and it consists of:
 - a) a pre-employment medical examination before the employment or classification into Category A in order to determine fitness for a job position of Category A exposed workers.
 - b) a periodic medical examination of Category A exposed workers, conducted at least once a year to determine whether these workers have remained fit to perform their work duties. The nature of such examination depends on the type of job and the individual state of health of exposed workers.
 - c) an extraordinary examination in case the conditions referred to in Article 12 are met.
- (3) The authorized health-care institution may indicate continuation of checking the state of health of a Category A exposed worker after cessation of work or as long as it considers necessary to safeguard the health of the exposed worker.

PART TWO – MEDICAL EXAMINATIONS

Article 4
(Referral to medical examination)

- (1) The holder of authorization for practices involving radiation sources (hereinafter: authorization holder) sends exposed workers to an authorized health-care institution for:

- a) the pre-employment examination with the referral shown in Annex 1, Form 1;
 - b) the periodic examination with the referral shown in Annex 1, Form 2;
 - c) the extraordinary examination with the referral shown in Annex 3, Form 5.
- (2) The educational institution sends apprentices, high-school and university students for the pre-employment, periodic and extraordinary examinations to an authorized health-care institution with the referrals referred to in paragraph (1).
 - (3) The authorization holder referred to in paragraph (1) and the educational institution fill in the referrals referred to in paragraph (1) in two copies, one of which is sent to the authorized health-care institution and the other one kept in its archive.

Article 5
(Cooperation of institutions in the health checks)

If the authorized health-care institution has established during the procedure of assessing general and specific health circumstances of exposed workers that the earlier medical records are needed to evaluate their fitness, it may request it from the health-care institution that has it.

Article 6
(Change of the authorized health-care institution)

- (1) If the holder of authorization for practices involving radiation sources has engaged a new authorized health-care institution to check the health of exposed workers, that health-care institution requests the previously engaged health-care institution in writing to send original medical records of the previous examinations of exposed workers.
- (2) The previously engaged health-care institution must send the requested records to the newly engaged health-care institution within 30 days from the date of receiving the request and keep a copy of the records in its archive.
- (3) While sending the records referred to in paragraphs (1) and (2), the provisions of the applicable regulations relating to the patient's personal rights, i.e. personal data protection, must be followed.

Article 7
(Pre-employment health examination)

- (1) The pre-employment medical examination is conducted:
 - a) before the training or education for work with radiation sources;
 - b) before the work with radiation sources begins;
 - c) in case of changing the type of job with radiation sources.
- (2) The objective of pre-employment examination is to assess the fitness for job duties of a Category A exposed worker and to determine whether an individual's state of health may require special precaution measures during the work.

- (3) The authorization holder that conducts training or education may not admit an individual to the training or education without the pre-employment examination referred to in paragraph (1)a.
- (4) In addition to the reasons for the pre-employment examination referred to in paragraph (1), a Category A exposed worker with an interruption of work longer than 12 months is also subject to the pre-employment examination.

Article 8
(Special requirements for the pre-employment examination)

The pre-employment examination should pay particular attention to:

- a) the fitness of a Category A exposed worker for wearing respiratory protective equipment if the work duties include the use of such equipment.
- b) the fitness of a Category A exposed worker for work duties with unsealed radiation sources if the worker suffers from a skin disease, such as some types of eczema and psoriasis. In such cases the fitness assessment should be based on the nature and stage of the disease and also on the nature of the job. Exposed workers with these diseases may be fit for work with unsealed radiation sources provided that the activity levels are low and appropriate protection measures are taken, such as covering the exposed body parts.
- c) the fitness of Category A exposed worker to perform job duties if the worker suffers from psychological disorders. In such cases the fitness assessment should take account of safety implications of symptomatic episodes of the disease, with primary concern whether such individual may be a hazard to themselves or their fellow workers.
- d) the fitness of apprentices, high-school and university students to attend training.

Article 9
(Content of the pre-employment examination)

The pre-employment medical examination consists of:

- a) A review of previous medical and non-medical records, and a radiation risk assessment;
- b) Medical history data, which consist of personal, family and occupational medical history, and the information on the current state of health;
- c) A general clinical examination and tests, which consists of:
 - I. A physical examination of organs and organ systems, with particular accent on the skin status,
 - II. Laboratory tests: sedimentation rate, CBC, DBC, blood glucose level, urinalysis, bilirubin, urea, creatinine ALT and AST, ALP, LDH,
 - III. PA chest X-ray, as indicated,
 - IV. Spirometry, as indicated,
 - V. Audiometry,
 - VI. ECG.
- d) A psychological evaluation;
- e) Neurological and psychiatric examinations;
- f) An ophthalmological examination;

- g) A gynecological examination for women as indicated, including Pap test and a clinical examination of breasts;
- h) A capillaroscopy examination for the individuals that could be exposed during the work to a direct beam of X and gamma rays or surface contamination by beta emitters, upon decision of the occupational medicine specialist and in accordance with a risk assessment;
- i) Other examinations as determined in a written explanation by the occupational medicine specialist in order to determine fitness to perform job duties that indirectly affect the safe application of radiation sources.

Article 10
(Periodic medical examination for Category A)

- (1) Periodic medical examinations for Category A exposed workers are conducted every 12 months in order to monitor and evaluate the state of health, i.e. fitness for work in a specific job position.
- (2) Periodic examinations may be conducted more often than specified in the deadline prescribed in paragraph (1) if the occupational medicine specialist in an authorized health-care institution considers it necessary and explains it in writing, depending on the worker's state of health.

Article 11
(Content of the periodic examination of Category A)

- (1) The periodic medical examination of Category A exposed workers consists of:
 - a) collecting new medical history data and reviewing personal dosimetry report and dosimetry report for the job position for the evaluated period;
 - b) the same clinical examination and tests as in the pre-employment medical examination except for ophthalmological examination, which is in this case conducted every 24 months;
 - c) other examinations as determined by the occupational medicine specialist, as indicated.
- (2) The additional part of the periodic examination, as indicated by the occupational medicine specialist, consists of:
 - a) a capillaroscopy examination for the individuals that could be occupationally exposed to a direct beam of X and gamma rays or surface contamination by beta emitters, as decided by the occupational medicine specialist and in accordance with a risk assessment;
 - b) the measurement of the total radioactivity in the whole body or vital organs in case of indications;
 - c) the measurement of radionuclide concentration in biological samples in case of indications;
 - d) a radiotoxicological test, depending on radiotoxicity and the total radionuclide activity, based on to a risk assessment.

Article 12
(Extraordinary medical examination)

- (1) The extraordinary medical examination is conducted when a Category A exposed worker has received a dose exceeding the annual effective or equivalent dose limit.
- (2) In addition to the cases referred to in paragraph (1), the extraordinary examination is conducted in case of a suspected intake of radionuclides by inhalation or orally, or due to the body contamination by unsealed radiation sources.

Article 13
(Content of the extraordinary examination and therapeutic procedures)

- (1) The extraordinary medical examination consists of:
 - a) medical history data;
 - b) a general clinical examination and indicated laboratory tests;
 - c) biodosimetry by an analysis of chromosome aberrations in case of an exposed worker who has received the effective dose of 200 mSv and above;
 - d) therapeutic procedures in case that the estimated external doses to the whole body or organs are on or above the dose threshold for deterministic effects.
- (2) Other examinations, tests and the way of treatment are determined in a written explanation by the occupational medicine specialist who delivers specific health care of exposed workers, depending on the reasons for referral to the extraordinary medical examination.

PART THREE – MEDICAL RESTRICTIONS AND SPECIAL SURVEILLANCE

Article 14
(Medical restrictions)

- (1) If an exposed worker develops a malignant disease, including the case of having been subjected to a radiotherapeutic treatment, the worker is not considered unfit to work with radiation sources.
- (2) In case referred to in paragraph (1) and also in the cases referred to in Article 8 points a), b) and c), the fitness for work with radiation sources should be assessed individually, taking into account:
 - a) the quality of treatment;
 - b) a general prognosis and other health implications;
 - c) understanding and preferences of the exposed worker;
 - d) the character of work duties.

Article 15
(Advisory and special medical surveillance)

The following exposed workers must be under the constant advisory and special medical surveillance by an authorized health-care institution, i.e. the occupational medicine specialist:

- a) women from the time of conception until the end of the pregnancy;
- b) breastfeeding women;
- c) the workers concerned about being exposed to ionizing radiation;
- d) the Category A workers who are fit, subject to certain conditions and recommendations; for example, the deviation of hematological tests of more than 5% of normal values in a periodic medical examination does not make an individual unfit for the job but requires repeating the test within 30 days, i.e. further medical surveillance;
- e) workers with considerable changes in the state of health;
- f) after cessation of work as long as health consequences may arise from earlier exposure to radiation.

PART FOUR – MEDICAL CLASSIFICATION, ASSESSMENT OF FITNESS AND REPORTS

Article 16
(Medical classification of fitness)

- (1) The following medical classification is established with respect to fitness to perform job duties of Category A exposed worker:
 - a) fit;
 - b) fit, subject to certain condition(s) and a recommendation;
 - c) unfit.
- (2) The fitness classification is recorded in:
 - a) the report on pre-employment medical examination;
 - b) the report on periodic medical examination;
 - c) the medical chart and the record of the authorized health-care institution;
 - d) the report on expert examination in special cases.

Article 17
(Evaluation of fitness)

- (1) The assessment of fitness for the job duties of a Category A exposed worker is conducted in case of:
 - a) professional orientation of high-school and university students for the professions involving exposure to ionizing radiation;
 - b) employment or change of job position;
 - c) the periodic medical examination;
 - d) an emergency;
 - e) suspected or confirmed occupational disease;
 - f) the diseases listed in Article 8 points b) and c).

- (2) Not any individual may be employed to a Category A job position or categorized as Category A exposed worker for a job position if an authorized health-care institution classified that individual as unfit for that job position.

Article 18
(Medical chart)

In order to monitor the state of health of each Category A exposed worker, the authorized health-care institution, i.e. occupational medicine specialist, keeps a medical chart that includes:

- a) occupational history and the nature of the exposed worker's current job;
- b) the data on pre-employment and periodic medical examinations;
- c) the data on the extraordinary examinations or the tests conducted because of exceeded dose limits, if any;
- d) the results of individual monitoring of exposure of the exposed workers and the monitoring of the workplace;
- e) the data on the diseases that resulted from an exposure to ionizing radiation and on the way of treatment;
- f) other diseases and the way of treatment.

Article 19
(Medical examination report)

- (1) The report on the pre-employment examination and the report on the periodic medical examination of exposed worker, shown respectively in Form 3 and Form 4 in Annex 2, are made in four copies, one of which is sent to the holder of authorization for practices involving radiation sources, the other one to the exposed worker, and the third one remains with the authorized health-care institution.
- (2) One copy of each report and the annual summary report with a data analysis are sent to the Agency.
- (3) The report on medical examination is signed and certified with the scanned signatures of the occupational medicine specialist and the director of the authorized health-care institution.

Article 20
(Expert examination)

- (1) An expert examination is established in the following cases:
 - a) An extraordinary examination;
 - b) After the treatment of diseases that result from occupational exposure to ionizing radiation;
 - c) A suspected or confirmed occupational disease;
 - d) The diseases and injuries resulting in a longer temporary or permanent disability;
 - e) Upon request by the institution that employs the exposed worker.
- (2) The report on expert examination is signed by an expert group established by the authorized health-care institution with the consent of the Agency.

- (3) The expert group referred to in paragraph (2) should consist of:
- a) two occupational medicine specialists, one of whom is employed in the authorized health-care institution in which the medical examination is conducted;
 - b) a medical doctor – specialist in radiation oncology or diagnostic radiology or nuclear medicine;
 - c) a medical physics specialist or a radiation protection expert.
- (4) The report on expert examination is made in five copies and sent to:
- a) the exposed worker;
 - b) the holder of authorization for carrying out practices;
 - c) the Agency;
 - d) the competent ministry of health;
 - e) the archive of the authorized health-care institution.

Article 21

(Temporary or permanent disability of the exposed worker)

- (1) In case of a temporary working disability of exposed worker longer than 12 months, the provisions of applicable law on health insurance will apply, and in case of the permanent disability the provisions of applicable law on pension and disability insurance and the list of occupational diseases will apply.
- (2) In case of a cured or controlled disease that was the reason for establishing disability of an exposed worker to perform job duties, the occupational medicine specialist in an authorized health-care institution reassesses the fitness of the concerned worker, taking into account his or her understanding and preferences.

Article 22

(Deadlines for assessment)

- (1) The reports on pre-employment and periodic medical examinations must be sent within 10 days from the start date of the medical examination, and within 30 days at the latest if an additional medical evaluation is needed.
- (2) The summary annual report must be sent to the Agency by the 31 January of the following year.
- (3) The expert examination report referred to in Article 20 must be sent to the subjects referred to in Article 20(4) within 30 days at the latest.

Article 23

(Keeping of medical records)

- (1) The authorized health-care institution must keep the medical records based on which the classification of exposed worker's fitness has been made, and also other medical records referred to in paragraphs 18, 19, 20 and 21 until the exposed worker has attained 75 years of age but in any case at least 30 years after termination of the work involving occupational

exposure to ionizing radiation.

- (2) The medical records referred to in paragraph (1) must be at disposal of the competent authorities and the exposed worker.

PART FIVE – FINAL PROVISIONS

Article 24 (Appeals of exposed workers)

An appeal against the decisions made by the occupational medicine specialist in accordance with this regulation may be filed under the applicable legislation in Bosnia and Herzegovina that regulates the rights of patients.

Article 25 (Cessation of effect)

On the date of entry into force of this regulation, the "Regulation on the authorization of the legal persons that conduct medical examinations and the way of conducting medical examinations of workers occupationally exposed to ionizing radiation" (Official Gazette of BiH 25/12) ceases to have effect.

Article 26 (Entering into force)

This regulation enters into force on the eighth day following the date of its publication in the Official Gazette of BiH.

No.:

DIRECTOR

Sarajevo, 2015

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