RISK ASSESSMENT AND MANAGEMENT IN THE OCCUPATIONAL MEDICINE

UDC 614.2+618

REGULATORY AND LEGAL FRAMEWORK FOR PREVENTION OF VIOLATIONS OF THE REPRODUCTIVE HEALTH OF WORKERS OCCUPIED IN HAZARDOUS INDUSTRIES IN THE RUSSIAN FEDERATION

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The article represents the legal documents, the requirements that are aimed to protect female workers' reproductive health. The basic requirements of domestic documents, that are aimed to prevent the reproductive disorders, adverse pregnancy outcomes and neonatal health, are reported. It is shown that in the legal documents of the Russian Federation, the prevention of reproductive health of workers occupied in hazardous industries, in particular women, has been covered enough, and if compare with the international standards on this issue, the prevention is carried out in sufficient volume, except for certain provisions. We have developed the proposals for the revision of a number of legal instruments in order to preserve the reproductive health of female workers of the harmful and hazardous industries, as well as improving the health of future generations.

Key words: female worker, reproductive health, reprotoxicants, regulatory documents.

The relevancy of topic is determined by the decisions taken by the governmental committee on the citizen health protection "On labor protection, including at the harmful and hazardous productions" (2014) according to which at the end of 2014 – beginning of 2015 it is necessary to submit to the government the offers on the improvement of legislative regulation in the field of occupational safety and hygiene which provide the transition from the absolute safety concept to the occupational risk assessment as well as on the development of compulsory social insurance against the industrial accidents and occupational diseases.

It is considered that the criteria of nonharmful labor conditions are the preservation of life, health, functional abilities of body, future duration of life and the health of future generations. As of now it is proved that the long-term exposure to the harmful occupational factors can cause the disorders of somatic and reproductive health (RH) both for man and women as well as for the health of their children. The nature and extent of the damage to health determine the levels of morbidity [13].

The reproductive outcomes when exposed to the harmful factors can be clinically expressed by different gynecological disorders, pathologies of pregnancy and delivery, disorders of development and health of newborns and remote consequences during the moving into adulthood.

Russia uses the regulatory legal documents the requirements of which are aimed at the provision of protection to the health of population, including the reproductive.

The laws of the Russian Federation, orders of the Ministry of Health of the Russian Federation on the solution of medical issues are based on the Constitution of Russia [1].

The Labor Code of the Russian Federation (LC RF) contains the health and labor protection stan-

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dards. Herewith there are the special standards in relation to the protection of labor of women adopted taking into account the physiological features of female body. Conventionally they can be divided into two groups: 1) standards covering all the working women, and 2) standards containing the additional warranties aimed at the preservation of the health of women performing the maternity function, ri.e. the standards aimed at the prevention of disorders in the future generations. The state acknowledges and legally protects additionally the pregnant working women and the working women who recently gave birth to a child or are breastfeeding, because they are the groups of increased occupational risk in relation to the safety of health both to the women themselves and their children.

The solution of issue on possibility of work of woman at heavy works, in the harmful or hazardous working conditions shall be based on the medical and social conclusions (medical – clinical diagnosis, morphological and functional indicators; social – profession, nature and conditions of labor).

The working conditions according to the Federal Law of the Russian Federation No. 426-FZ dd. December 28, 2013 "On the special assessment of working conditions" [4] are assessed using the set of methods "Special assessment of working conditions" (SAWC) that allows for inclusion of the certain working conditions into the class of harmfulness in accordance with R 2.2.2006-2005 [11]. This manual terminologically determines the harmful factor as the factor the impact of which on the worker can cause the occupational disease or other health disorder and damage to the health of children. Especially this relates to the protection of health of working women who, in particular, are planning the pregnancy, pregnant and breastfeeding women.

Speaking about the protection of health for the working population and first of all about the women as the keepers of the national genetic material forming the demographical picture of the country, it should be noted that the adopted Federal Law No. 323n "On the basics of protection of health for citizens of the Russian Federation" (dd. November 21, 2011) and explaining Order of the Ministry of Health and Social Development of Russia No. 302n "On approving the lists of harmful and (or) hazardous occupational factors and works during the performance of which the initial and periodical medical examinations (diagnostic studies) are conducted, and procedure for carrying out the mandatory the initial and periodical medical examinations (diagnostic studies) of workers engaged at heavy works and works with harmful and (or) hazardous working conditions" (dd. April 12, 2011) and the Order No. 417n of the Ministry of Health and Social Development of the Russian Federation (dd. April 27, 2012) "The list of occupational diseases" allow for the practitioners to act according to the requirements of legal documents aimed at the preservation of the health of workers associated with heavy, harmful and hazardous working conditions.

In the conditions of transient economy in Russia the previously created system of labor protection and, in particular, of chemical safety does not provide completely the preservation of health, including reproductive, during the work with chemical substances affecting the reproductive function.

Regardless of the fact that about 850 000 of workers are exposed to the chemical substances the consequences are the most unfavorable. The manual R 2.2. 2006-05 (annex 4) contains the list of substances hazardous for the reproductive health of human.

The Russian Federation applies the Sanitary Regulations and Standards 2.2.0.555-96 "Hygienic requirements to the working conditions of women" [12] containing the list of chemical substances potentially hazardous for reproductive health which includes 156 chemical elements and compounds able to have the negative impact on the reproductive function of human.

The list of chemical substances hazardous for reproductive health provided in this document shall be revised because the substances included into it require the additional justifications from the points of view of the evidence-based medicine, classification of substances under their action and degree of their hazard as it is made, for example, in the EU lists of reprotoxicants.

Recently new version of SanPiN 2.2.0.555-96 in accordance with principles of the evidence-based medicine and taking into account the analysis of international databases and lists of reprotoxicants provided the harmful chemical substances causing the known impact on the reproductive function of human with proved (66 substances) and expected risk (16 substances).

This list contains the classes of hazard for substances, rated values (maximum permissible concentrations for the air of working zone) and main types of clinical substances with codes in accordance with MKB-10.

The most important supplements in the revised document (SanPiN for women) are as follows:

– in case of pregnancy (at any term confirmed by the certificate from the obstetrician-gynecologist) or when planning the pregnancy it is necessary to carry out the repeated assessment of risk to the health of pregnant woman and her children. If the risk is present, the employer shall provide the pregnant woman with working place without the harmful occupational factors; if it is established that all the factors of the working place of pregnant woman comply with hygienic standards, the woman can stay at the previous working place with reduced working load;

– for the pregnant working women, women recently given birth to a child or breastfeeding woman it is necessary to exclude completely the contact with substances having the gonadotropic, embryotropic, mutagenic and teratogenic effect; with carcinogens, antitumoral drugs, endocrine disruptors, estrogen hormones, nanomaterials and nanoparticles. The occupational contact of women with chemical substances penetrating the breast milk and with it the body of breastfed child as well as with substances deteriorating the compositions and biological properties of breast milk is not permitted during the whole period of breastfeeding;

– it is forbidden for pregnant to work with substances marked by: "chemical products with proved or expected impact on the reproductive function (chemical products having the teratogenic and/or gonadotropic and/or embryotropic effect) or having the impact on lactation or through it".

The statistical assessment of relationship between the health disorders and work (SAR) (method developed by professor E.I. Denisov) evidences that the pregnancy disorders and birth defects in the working women have the average degree of relationship with working conditions (class of working conditions 3.1-3.2), but the health of newborns is assessed under the category of very high degree of relationship with pathology of pregnancy, delivery and the work of mother, respectively. Herewith the etiological share of the harmful working conditions of mother in the development of health disorders of child was almost 78%. The pathology of newborns was represented pby the different nosological forms of health disorders (low Apgar score during delivery, hypoxia during delivery, low body weight, low hemoglobin, etc.).

The obtained results confirm the previously obtained data on the highest vulnerability of the

body of child to the exposure of harmful factors with which the mother contacts during her working activity. The categories of risk of occupationally conditioned disorders in the reproductive health of working women were developed based on the obtained materials.

The results of studies raise the issue on the fundamental revision of approaches to organizing the protection of health for pregnant women engaged in work at the harmful productions (occupational hygiene for women), namely, the planning of pregnancy and possible transfer of the part of maternity leave to the beginning of pregnancy when all the internal organs of future child are formed.

The Federal Law No. 323n "On the basics of protection of health for the citizens of the Russian Federation" (dd. November 21, 2011) [6] determines the population health protection principles in general. One of the main principles (item 8, article 4) of this Law is the prevention and new principle - the children health protection priority This provision is very important because till now the problems of perinatal losses and birth of children with health disorders, including the developmental defects are still current. In the conditions of demographical crisis which continues till now one of the main threats of the economic growth of country is the progressing insufficiency of labor that is directly associated with a number of the born healthy children and, therefore, with the condition of reproductive health and reproductive potential of population.

Regardless of that the article 6 of the Federal Law is dedicated to the protection of health of the mother and child, the issues of family and reproductive health of population, the law does not contain the articles aimed at the women working in the harmful and (or) hazardous working conditions, since almost 50% of women are engaged in the different fields of economy, and among them more than 37 mln. are the women of reproductive age.

We believe that in the practical health protection it is necessary to develop a new statistical form which shall contain the morbidity of newborn and complications of pregnancy for woman working in the harmful conditions, i.e. the indicator "morbidity "mother-newborn" will allow for developing the preventive measures aimed at the decrease of morbidity and delivery of healthy children

To protect the health, according to article 24 of the Law, the employers are entitled to include into staff the positions of health professionals and create the subdivisions (doctor's consulting room, aid post, sick-room, medical division and other structures) providing the medical assistance to the employees of organization. The medical and pharmaceutical staff is approved by the Order of the Ministry of Health and Social Development of the Russian Federation No. 801n dd. July 25, 2011 "On approving the nomenclature of positions of the medical and pharmaceutical staff and specialists with higher and secondary vocational education in the healthcare institutions" [7]. The following professionals perform the examinations (diagnostic studies) of workers engaged in the heavy works and work with harmful and (or) hazardous working conditions: occupational physician, obstetrician-gynecologist of the shop medical post and other professionals.

The Federal Law of the Russian Federartion No. 125-FZ dd. July 24, 1998 "On the compulsory social insurance against the industrial accidents and occupational diseases" [5] established the legal, economic and organizational basics of the compulsory social insurance against the industrial accidents and occupational diseases (OD); the law determines the procedure of the compensation for harm to the life and health of worker, etc.

It is proved that the violations of the working conditions safety are the most often causes of accidents. The remote consequences from the injuries obtained at production are not only the medical but also the social problem. In addition to the physical damage (mutilation) any injury is accompanied by the stress of different degree of manifestation which in future can develop to the psychosomatic pathology.

The occupational injuries can be fatal or serious under the remote consequences for the reproductive health of workers. The desocialization of woman can be manifested in the loss of motivation to labor due to the complete or partial loss of professional skills in connection with occurred disability, development of inferiority feeling because of impossibility of further maternity, mutilation of genital organs, castration and disorder of bedroom duties, etc.

In addition to the law No. 125 there is the Order of the Ministry of Health and Social Development of Russia No. 160 dd. February 24, 2005 "On determining the severity of damage to health at the industrial accidents" [14]. The serious industrial accidents include the interruption of pregnancy (item 3.1 of the order). In addition, the accident which directly does not threaten to the life of injured but has the serious consequences is considered as the serious accident. This is the loss of reproductive

function and reproductive potential (item 3.2 of the order)

For example, if the woman as a result of accident or her use at works forbidden for women suffered from the interruption of pregnancy, the court can award for her the compensation for the violation of this non-material value belonged to her from the birth.

The norms for lifting and transportation of loads are developed for woman (the Resolution of the Government of the Russian Federation No. 105 "On new norms of the maximum permissible loads for women during the manual lifting and transportation of loads" dd. February 6, 1993) [3]. If they are not observed, the woman can suffer from the development of occupational disease (during the establishment of diagnosis the conclusion of the obstetrician-gynecologist shall be available). The Order of the Ministry of Health and Social Development of Russia (dd. April 27, 2012) "The list of occupational diseases" in section IV "Diseases associated with physical overloads and functional stresses of the separate organs and systems" states that "the physical overloads and functional stress of the separate organs and systems of the relevant location at the lifting and transportation of loads combined with the forced working position "the descent and falling of womb and walls of vagina" is the occupational disease of the reproductive system of women (MKB-10 No. 81)" that will be considered as the insurable event [8].

The studies conducted at our institute are the evidence. Thus, the falling of womb and walls of vagina prevailed for pressers the work of which is associated with the lifting and transportation of loads $(46.3\pm3.6 \text{ versus } 28.8\pm5.1 \text{ cases per } 100 \text{ examined women, } p < 0.05)$ [2].

"The list of heavy works and works with harmful and hazardous working conditions during the performance of which it is forbidden to use the work of women" [10] currently does not comply with the modern requirements and shall be revised. Our offers are submitted to the Ministry of Labor of Russia.

The well-adjusted system for the protection of health and labor of the working population is developed and applied in the Russian Federation.

In addition to this provision there is the Order of the Ministry of Health and Social Development of the Russian Federation No. 302n dd. April 12, 2011 which approved the lists of harmful and (or) hazardous occupational factors and works during the performance of which it is necessary to conduct the mandatory initial and periodical medical ex-

aminations (diagnostic studies) and procedure of the conduction of these examinations (diagnostic studies) for workers engaged in the heavy works or works with harmful and (or) hazardous working conditions [9].

The employers shall provide the conditions for passing by workers of the medical examinations and medical surveillance as well as provide freely the leave for their passing to the workers.

"The list of general medical contraindications to the permit for works with harmful and (or) hazardous occupational factors" contain the indications for women: birth defects, deformations, chromosomal abnormalities with stable significant disorders of the organs and systems; pregnancy and lactation period; habitual miscarriage and fetal abnormalities in the anamnesis of the women of childbearing age; the progressing diseases of endocrine system with the signs of damage to the other organs and systems and violation of their function of the 3–4 category; malignant neoplasms of any location.

Therefore, the prevention of the reproductive health disorders in the workers of harmful productions, in particular, in women is illustrated adequately in the regulatory legal documents of the Russian Federation, and compared to the international requirements to this problem it is performed in a sufficient volume, except for some provisions. The revisions of a number of legal documents and their execution will contribute to the improvement of the reproductive health of workers and the health of their children.

References

- 1. Konstitucija Rossijskoj Federacii [Constitution of the Russian Federation]. Moscow, 2007.
- 2. Morozova T.V., Fesenko M.A. Professional'nyj risk i reproduktivnaja patologija rabotnikov polimerperera-batyvajushhej promyshlennosti [Professional risk and reproduductive pathology of the workers of polymer processing industry]. *Zhizn' bez opasnostej. Zdorov'e. Profilaktika. Dolgoletie*, 2012, no. 3, pp. 76–80.
- 3. O novyh normah predel'no dopustimyh nagruzok dlja zhenshhin pri pod#eme i peremeshhenii tjazhesti vruchnuju. Postanovlenie Pravitel'stva RF ot 6 fevralja 1993 g. № 105 [On the new norms for maximum allowed load for women during manual weight lifting and carrying. The Russian Federation Government Regulation dated February 6, 1993. № 105].
- 4. O special'noj ocenke uslovij truda. Federal'nyj zakon ot 28 dekabrja 2013 g. N 426-FZ [On the special assessment of working conditions. Federal law dated December 28, 2013 N 426-Φ3].
- 5. Federal'nyj Zakon ot 24 ijulja1998g. № 125-FZ. Ob objazatel'nom social'nom strahovanii ot neschastnyh sluchaev na proizvodstve i professional'nyh zabolevanij [Federal Law dated July 24, 1998. № 125-Ф3. On compulsory social insurance against industrial accidents and occupational illnesses].
- 6. Federal'nyj zakon ot 21.11.2011 N 323-FZ. Ob osnovah ohrany zdorov'ja grazhdan v Rossijskoj Federacii [Federal Law dated 21.11.2011 N 323-Φ3. On the fundamentals of citizens' health care in the Russian Federation].
- 7. Ob utverzhdenii nomenklatury dolzhnostej medicinskogo i farmacevticheskogo personala i specialistov s vysshim i srednim professional'nym obrazovaniem uchrezhdenij zdravoohranenija. Prikaz Minzdravsocrazvitija RF №801n ot 25.07.2011 [On the establishment of the positions nomenclature of medical and pharmaceutical personnel and specialists with higher and secondary vocational education in health care institutions. Order of the Ministry of Public Health and Social Development of the Russian Federation №801н dated 25.07.2011].
- 8. Ob utverzhdenii perechnja professional'nyh zabolevanij. Prikaz Ministerstva zdravoohranenija i social'nogo razvitija RF ot 27 aprelja 2012 g. N 417n. [On the establishment of the list of occupational diseases. Order of the Ministry of Public Health and Social Development of the Russian Federation dated April 27, 2012. N 417H].
- 9. Ob utverzhdenii perechnej vrednyh i (ili) opasnyh proizvodstvennyh faktorov i rabot, pri vypolnenii kotoryh provodjatsja objazatel'nye predvaritel'nye i periodicheskie medicinskie osmotry (obsledovanija), i porjadka provedenija objazatel'nyh predvaritel'nyh i periodicheskih medicinskih osmotrov obsledovanij) rabotnikov, zanjatyh na tjazhelyh rabotah i na rabotah s vrednymi i (ili) opasnymi uslovijami truda. Prikaz Minzdravsocrazvitija Rossii ot 12.04.2011 N 302n (red. ot 05.12.2014) [On the establishment of the list of harmful and (or) dangerous industrial factors and works, which require compulsory preliminary and periodical medical examinations (checkups), and procedures for the conduction of compulsory, preliminary and periodical medical examinations (checkups) of people performing heavy works or working under harmful and (or) dangerous working conditions. Order of the Ministry of Public Health and Social Development of the Russian Federation dated 12.04.2011 N 302H].
- 10. Perechen' tjazhelyh rabot i rabot s vrednymi i opasnymi uslovijami truda, pri vypolnenii kotoryh zapreshhaetsja primenenie truda zhenshhin [The list of heavy works with harmful and dangerous working conditions for the execution of which female work is prohibited]. Approved by the Russian Federation Government Regulation dated February 25, 2000 № 162.
- 11. Rukovodstvo po gigienicheskoj ocenke faktorov rabochej sredy i trudovogo processa. Kriterii i klassifikacija uslovij truda. Rukovodstvo 2.2.755-99 [Guidance on the hygienic assessment of working environment and

process factors. The criteria and classification of working conditions. Guidance 2.2.755-99]. Moscow: Federal'nyj centr gigieny i jepidemiologii Rospotrebnadzora, 2005. 142 p.

- 12. Gigienicheskie trebovanija k uslovijam truda zhenshhin. SanPiN 2.2.0.555-96 [Hygienic requirements to women's working conditions. SanPiN 2.2.0.555-96]. Approved by the Resolution of Goskomsanepidnadzor dated October 28, 1996. № 32. Separate edition. Moscow, 1997.
- 13. Sivochalova O.V., Fesenko M.A., Golovaneva G.V., Denisov Je.I. Sohranenie i ukreplenie reproduktivnogo zdorov'ja rabotnikov professij vysokogo riska: problemy i perspektivy [Reproductive health maintenance and promotion in workers of high risk professions: problems and perspectives]. *Vestnik RGMU*, 2013, no. 5–6, pp. 73–78
- 14. Shema opredelenija stepeni tjazhesti povrezhdenija zdorov'ja pri neschastnyh sluchajah na proizvodstve. Prikaz Ministerstva zdravoohranenija i social'nogo razvitija Rossijskoj Federacii ot 24 fevralja 2005 g. № 160 [The scheme for determining the severity of health damage from industrial accidents. Order of the Ministry of Public Health and Social Development of the Russian Federation dated February 24, 2005. № 160].