

REGULATION OF THE COUNCIL OF MINISTERS

of 6 August 2002

on the instances in which practices involving the risk of exposure to ionising radiation are not subject to the licensing or reporting requirement, and instances in which the said practices may be conducted based on a report.

(Journal of Laws no. 137, item 1153)

Pursuant to art. 6 item 1 of the Atomic Energy Law of 29 November 2000 (Journal of Laws of 2001, no. 3, item 18, no. 100, item 1085, no. 154, item 1800, of 2002, no. 74, item 676), the following is ordained:

§ 1. This regulation determines:

- 1) instances in which practices involving the risk of exposure to ionising radiation, hereinafter referred to as "exposure", are not subject to the licensing or reporting requirement;
- 2) instances in which practices involving the risk of exposure may be conducted based on a report;
- 3) maximum values of total activity and concentration of radioactive isotopes as a criterion required for the release from the licensing or reporting requirement.

§ 2. The following types of practices are not subject to the licensing or reporting requirement:

- 1) manufacture, processing, turnover, storage, transport and application of substances which contain radioactive isotopes whose total activity or concentration of radioactive isotopes does not exceed the values set in the annex hereto, subject for the provisions of item 4 hereof;
- 2) application of devices which comprise a sealed radioactive source whose total activity or concentration of radioactive isotopes exceed the values set in the annex hereto, if the following requirements are met:
 - a) the device has been manufactured and introduced for turnover under a license issued to the organisational entity which manufactures or introduces the said device for turnover or if the type of the device has been approved by a member state of the European Union,
 - b) during the application of the device, the radiation dose rate at the distance of 0.1 m from any accessible surface of the said device does not exceed 1 microsievert per hour (mSv/h),
 - c) the body of the device is clearly marked to indicate that the device contains a radioactive source and that it must be operated in accordance with instructions of use,
 - d) the instructions of use attached to the device clearly specify:
 - - name of the manufacturer and distributor, number of the license to manufacture or sell the device,
 - - information on the radioactive source (type and activity of radioactive isotope and date of activity determination),
 - - maximum dose rate as per item b) above,
 - - information that the operation of the device in accordance with the instruction of use does not pose a threat and does not require a license,
 - - manner of handling the device and the contained source after ending the operation;
- 3) manufacture, processing, turnover, storage, transport and application of materials, raw materials and waste, in particular mineral raw materials, artificial fertilisers, clay, ash, slag and mining deposits containing natural radioactive isotopes, if the average radioactive concentration of the said isotopes does not exceed the values specified in the annex hereto, and the maximum radioactive concentration resulting from the non-homogeneity of

material does not exceed the said values by more than 10 times in respect of a representative sample of 1 kg.

- 4) practices as per point 1 where total activity or radioactive concentration of radioactive isotopes does not exceed the values specified in the annex hereto by more than 100 times, or when it involves radioactive isotopes not specified in the annex hereto, if all of the below requirements are met:
 - a) the effective dose resulting from given type of practice, which may be received by an individual does not exceed 10 mSv in the calendar year,
 - b) the total collective effective dose, defined as the product of the mean value of the collective effective dose expressed in sieverts (Sv) for persons and the group exposed during the said practice and the number of persons in the group, resulting from given type of practice over a period of one calendar year, does not exceed 1;
- 5) practices involving:
 - a) premeditated addition of radioactive substances in the manufacturing process of mass consumption products and medical products, including the turnover of such products,
 - b) premeditated administration of radioactive substances to people and animals for the purpose of medical or veterinary diagnostics, treatment or scientific research,
 - if total activity or radioactive concentration of radioactive isotopes contained in the said substances does not exceed 0.1 of the values specified in the annex hereto;
- 6) application of image projecting lamps or other electrical devices operating with a potential difference not exceeding 30 kV, if during standard operation of the device, the dose rate at the distance of 0.1 m from any accessible part of device surface does not exceed 1 mSv/h;
- 7) application of electrical devices other than specified in point 6 above, admitted for operation under separate provisions, if during standard operation of the device, the dose rate at the distance of 0.1 m from any accessible part of device surface does not exceed 1 mSv/h.

§ 3. Practices:

- 1) involving the manufacture, processing, turnover, storage, transport and application of substances containing radioactive isotopes, including fissile isotopes, whose total activity or radioactive content exceeds the values specified in the annex hereto by more than 100 times, if the requirements set forth in §2 point 4 letters a and b are not met;
- 2) as defined in §2 point 5, if total activity or concentration of radioactive isotopes in radioactive substances to which the said activity relates is higher than 0.1 of the values specified in the annex hereto, but does not exceed those values
 - may be performed based on a report.

§ 4. 1. During the performance of practices as per §2 point 1, 3-5 and §3, the total activity of radioactive isotopes specified in the annex hereto and their concentration relate to total activity of the isotope and its concentration at any time in reference to the performed practices, subject to the provisions of section 2.

2. During the performance of practices involving radioactive sources and nuclear materials containing various isotopes, the total ratio of concentrations of radioactive isotopes or the total ratio of isotope activity to respective maximum values specified in the annex hereto will not exceed 1.

§ 5. This regulation becomes effective 14 days from publication.

President of the Council of Ministers: *L. Miller*