АФНОР/ДИН/БСИ/СВЕДАК Контракт н. 2009/214-140 Проект финансируется Европейским Союзом



Approximation of EU and RF technical regulation, standardization and certification systems

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FEDERAL LAW NO. 184-FZ OF DECEMBER 27, 2002 ON TECHNICAL REGULATION

(including the Amendments and Additions of May 9, 2005, May 1, December 1, 2007, July 23, 2008, July 18, November 23, December 30, 2009)

Adopted by the State Duma on December 15, 2002 Approved by the Federation Council on December 18, 2002

ATTENTION: this text has been edited for the purpose of readibility. The font has been converted to times new roman and bullet point have been added where appropriate.

Chapter 1 General Provisions

Article 1. Sphere of Application of This Federal Law

- **1.** This Federal Law regulates relations originating from:
 - the elaboration, acceptance, application of and compliance with obligatory requirements for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, sale and reclamation;
 - the elaboration, acceptance, application of and compliance with on a voluntary basis of the requirements for products, processes of design (including survey works), production, construction, installation and adjustment, operation, storage, transportation, sale, reclamation, performance of works and rendering of services;
 - compliance evaluation.
- This Federal Law also determines the rights and duties of participants in the relations regulated by this Federal Law.
- **2.** The requirements for the functioning of the unified communication network of the Russian Federation, associated with guarantees to be provided for the integrity and stability of the functioning of the said communication network and with its safety, relations, associated with guarantees to be provided for the integrity of the unified communication network of the Russian Federation and with the utilisation of the radio frequency spectrum, are, respectively, laid down and regulated by the legislation of the Russian Federation in the sphere of communications.
- **3.** The operation of this Federal Law shall not extend to socio-economic, organizational, sanitary, therapeutic and rehabilitative labour protection measures, to federal state educational standards, accounting regulations (standards) and auditor activity rules (standards), standards for the issue of securities and of prospectuses for the issue of securities.

- **4.** This Federal Law shall not regulate the relations connected with the following:
 - taking measures aimed at the prevention of contraction and spreading of mass infectious human diseases, prevention of human diseases, rendering medical aid (except for the cases of development, adoption, application and observance of obligatory requirements for products, including medicinal agents, medical equipment and foodstuffs);
 - taking measures aimed at the protection of the soil, atmospheric air, bodies of water of health resorts and places intended for tourism and mass recreation.

Article 2. Basic Notions

For the purposes of this Federal Law the following basic notions shall be used:

accreditation - official recognition by the agency for accreditation of a natural person's or legal entity's authority to perform works in a certain sphere of compliance evaluation;

the safety of products, production processes, operation, storage, transportation, sale and reclamation (hereinafter referred to as safety) - a condition ruling out the possibility of inadmissible risk, associated with harm to be caused to individuals' life or health, a natural person's or legal entitiy's property, state or municipal property, the environment, to the life or health of animals or plants;

veterinarian-and-sanitary and phyto-sanitary measures - requirements and compulsory procedures that are established for the purposes of protection from risks arising in connection with the penetration, consolidation or spread of harmful organisms, diseases, carriers of diseases or causative organisms, including if they are carried or spread by animals and/or plants, with products, loads, materials, motor vehicles, with the presence of additives, pollutants, toxins, pests, weeds, causative organisms, including food products or feeds, and also requirements and compulsory procedures that are established for the purposes of ruling out other damage, associated with the spread of harmful organisms;

declaration of compliance - a form confirmation of the products' compliance with the requirements of technical regulations;

compliance declaration - a document certifying that the products released for circulation comply with the requirements of technical regulations;

applicant - a natural person or legal entity which in order to prove compliance adopts the compliance declaration or applies for or receives a compliance certificate;

mark of circulation on the market - a device used to inform purchasers that an object releaved for circulation complies with the requirements of technical regulations;

compliance mark - a device used to inform purchesers that a certificate object complies with the requirements of a voluntary certification system or national standard;

control (supervision) over compliance with the requirements of technical regulations - verification of compliance by the legal entity or businessman with the requirements of technical regulations for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, sale and

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reclamation, with measures adopted according to the results of verification;

international standard - a standard accepted by an international organisation;

national standard - a standard approved by a national body of the Russian Federation for standardisation;

certification agency - a legal entity or a businessman, accredited in established procedure to perform work in the sphere of certification;

compliance evaluation - direct or indirect determination of an object's compliance with the requirements;

compliance confirmation - certification by documents of compliance of the products or other objects, processes of design (including survey works), production, construction, installation and adjustment, operation, storage, transportation, sale and reclamation, performance of works or rendering of services with the requirements of technical regulations, provisions of standards, sets of rules or terms of contracts;

products - the result of activity represented in the form of materials or articles and intended for further utilisation for economic or other purposes;

risk - probability of harm to be caused to people's life or health, natural persons' or legal entities' property, state or municipal property, the environment, the life or health of animals and plants taking account of the gravity of this harm;

certification - a form of confirmation by the certification agency of objects' compliance with the requirements of technical regulations, provisions of standards, sets of rules or terms of contracts;

compliance certificate - a document certifying object's compliance with the requirements of technical regulations, provisions of standards, sets of rules or terms of contracts;

certification system - the sum total of rules for the performance of works in the sphere of certification, its participants and rules for functioning of the certification system as a whole;

standard - a document which establishes, for the purposes of voluntary and repeated utilisation, the characteristics of products, rules for the operation of and characteristics of processes of design (including survey works), production, construction, installation and adjustment, operation, storage, transportation, sale and reclamation, performance of works or rendering of services. A standard may also contain rules for, and methods of, examination (tests) and measurement, rules for selection of samples, requirements for terms, symbols, packing, marking or labels and rules for

affixing them;

standardisation - activity for the establishment of rules and characteristics for the purposes of their voluntary and repeated utilisation aimed to ensure orderliness in the spheres of manufacture and circulation of products and to raise the level of competitiveness of products, works or services;

technical regulation - legal regulation of relations in the sphere of establishment, application and meeting of the obligatory requirements for products or for processes of design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale and reclamation connected with them, and also in the sphere of establishment and application on a voluntary basis of the requirements for products, processes of design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale and reclamation, performance of works or rendering of services, and legal regulation of relations in the sphere of compliance evaluation;

technical regulations - a document adopted by an international treaty of the Russian Federation ratified in the procedure established by the legislation of the Russian Federation or an intergovernmental agreement made in the procedure established by the legislation of the Russian Federation, or the federal law, or a decree of the President of the Russian Federation, or by a decision of the Government of the Russian Federation, or by a regulatory legal act of the federal executive power body in charge of technical regulation and which establishes requirements to be necessarily applied to and met by to the objects of technical regulation (products, including buildings, structures and constructions, or processes of design (including survey works), production, construction, installation and adjustment connected with requirements for products, operation, storage, transportation, sale and reclamation);

form of compliance confirmation - a certain procedure for certification by documents of compliance of products or other objects, processes of design (including survey works), production, construction, installation and adjustment, operation, storage, transportation, sale and reclamation, performance of works or rendering of services with the requirements of technical regulations, provisions of standards or terms of contracts;

scheme for confirming compliance - a list of actions of participants in confirmation of compliance whose results are regarded by them as proof of the compliance of products and other objects with established requirements;

set of rules - the standardization document which contains technical rules and/or a description of the processes of design (including survey works), making, construction, installation, adjustment, operation, storage, transportation, sale and reclamation of products and which is applicable on a voluntary basis for the purpose of observing the requirements of technical standing orders;

regional standardisation organization - an organization whose members are national standardization agencies (organizations) pertaining to the same geographic region of the world and/ or the group of countries which are in the process of economic integration in compliance with international treaties;

standard of a foreign state - a standard adopted by a national (competent) standardisation agency (organization) of a foreign state;

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regional standard - a standard adopted by a regional standardization organization;
rule book of a foreign state - a rule book adopted by a competent body of a foreign state;
regional rule book - a rule book adopted by a regional standardization organization.

Article 3. Principles of Technical Regulation

Technical regulation shall be carried out in accordance with the following principles:

- application of unified rules for the establishment of requirements for products, or processes
 of design (including survey works), production, construction, installation and adjustment
 connected with them, operation, storage, transportation, sale and reclamation, performance
 of works or rendering of services;
- correspondence of technical regulation to the development level of the national economy, the material-and-technical facilities and also of scientific-and technological progress;
- independence of accreditation and certification agencies from producers, sellers, manufacturers and purchasers;
- a unified accreditation system and rules;
- unified rules and methods of research (tests) and measures for carrying out obligatory compliance procedures;
- unified application of the requirements of technical regulation, regardless of the kinds and specific features of transactions:
- inadmissibility of any restrictions to competitiveness for accreditation and certification;
- inadmissibility of combined powers to be exercised by the state control (supervision) body and the certification agency;
- inadmissibility of combined powers of accreditation and certification being exercised by the same body;
- inadmissibility of extra-budgetary funds being assigned to the bodies of state control (supervision) over compliance with the requirements of technical regulations;
- inadmissibility of concurrent imposition of the same powers on two and more bodies of state control (supervision) over the observance of requirements of technical regulations.

Article 4. Legislation of the Russian Federation on Technical Regulation

- **1.** The legislation of the Russian Federation on technical regulation consists of this Federal Law, federal laws adopted in keeping with it and other decrees of the Russian Federation.
- 2. The provisions of federal laws and other decrees of the Russian Federation referring to the sphere of application of this Federal Law (including directly or indirectly stipulating for control (supervision) over compliance with the requirements of technical regulations) shall be applied in the

part not conflicting with this Federal Law.

- **3.** Federal executive bodies shall issue acts in the sphere of technical regulation of a solely recommendatory nature, unless stipulated otherwise by Article 5 and 9.1 of this Federal Law.
- **4.** If rules are established by an international treaty of the Russian Federation in the sphere of technical regulation other than those stipulated by this Federal Law, the rules of the international treaty shall be applied, and if it follows from the international treaty that for its application the issue of a national state act is required, the rules of the international treaty and the laws of the Russian Federation, adopted on its basis, shall be given priority.
- Article 5. The Specifics of Technical Regulation in Respect of Defence Products (Works and Services) Supplied within the Framework of the State Defence Order, Products (Works and Services) Used for the Protection of Data Constituting a State Secret or Other Classified Information Protected in Compliance with the Legislation of the Russian Federation, Products (Works and Services) Data on Which Constitute State Secret, Products (Works, Services) and Objects for Which Requirements Are Established Connected with Ensuring Nuclear and Radiation Safety in the Field of Atomic Power Use, of the Process of Design (Including Survey Works), Production, Construction, Installation, Adjustment, Operation, Storage, Transportation, Sale, Reclamation, Disposal of the Said Products and the Said Objects
- 1. In respect of defence products (works and services) supplied within the framework of the state defence order, products (works and services) used for the protection of data constituting a state secret or other classified Information protected in compliance with the legislation of the Russian Federation, products (works and services) data on which constitute a state secret, products (works, services) and facilities for which requirements are established connected with ensuring nuclear and radiation safety in the field of atomic power use, of the processes of design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale, reclamation and disposal of accordingly the said products and objects as obligatory requirements along with the requirements of technical regulations shall be deemed the requirements established by state customers, the federal executive power bodies authorized in respect of security, defence, foreign intelligence, resistance to technical reconnaissance and technical information protection, governmental management of atomic power use, governmental safety regulation of atomic energy use and/or by state contracts (agreements).
- 2. The specifics of technical regulation in the field of development and establishment of obligatory requirements by state customers, the federal executive bodies authorized in respect of security, defence, foreign intelligence, resistance to technical reconnaissance and technical information protection, governmental management of atomic power use, governmental safety regulation of atomic energy use, in respect of the products (works and services), objects cited in item 1 of this article, as well as of the processes of their design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale, reclamation and disposal shall be established by the President of the Russian Federation and the Government of the Russian Federation in compliance with the scope of authority thereof.
- 3. The specifics of standardization of the products (works and services) and the units cited in item 1 of this article, as well as accordingly the processes of their design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale,

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reclamation and disposal shall be established by the Government of the Russian Federation.

4. The specifics of assessment of the compliance of the products (works and services) and the units specified in item 1 of this article, as ell as accordingly the processes of their design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale, reclamation and disposal shall be established by the Government of the Russian Federation.

Article 5.1. The Details of Technical Regulation in the Area of Building/Installation Safety

The details of technical regulation in the area of building/installation safety are established by the Federal Law "The Technical Rules Governing the Safety of Buildings and Installations".

Chapter 2 Technical Regulations

Article 6. Goals of Technical Regulations

- 1. Techincal regulations are adopted to attain the following goals: protection of individuals' life or health, of natural persons' or legal entities' property and of state or municipal property; protection of the environment, the life or health of animals or plants; prevention of actions misleading purchasers; ensuring of energy efficiency.
 - **2.** Technical regulations shall not be adopted for any other purposes.

Article 7. Content and Application of Technical Regulations

- **1.** Technical regulations taking account of the degree of the risk of harm to be caused shall establish minimum necessary requirements providing guarantees for:
 - radiation safety;
 - biological safety;
 - safety from explosion;
 - mechanical safety;
 - industrial safety;
 - thermal safety;
 - chemical safety;
 - electric safety;
 - nuclear and radiation safety;
 - electromagnetic compatibility in the part of guarantees for the safe operation of instruments

and equipment;

- unified measurements;
- other kinds of security for the purposes corresponding to Item 1 of Article 6 of this Federal Law.
- **2.** The requirements of technical regulations shall not serve as an obstacle to entrepreneurial activity to a greater extent than is minimally necessary for the attainment of the goals indicated in item 1 of Article 6 of this Federal Law.
- **3.** Technical regulations shall contain a list and/or a description of technical regulation objects, requirements for these objects and rules for their identification for the purpose of application of the technical regulations. Technical regulations shall contain rules for, and forms of, compliance assessment (in particular, technical regulations shall contain schemes for compliance confirmation, a procedure for extending the duration of an issued compliance certificate) defined subject to the risk degree, deadlines for compliance assessment in respect of each technical regulation object and/or requirements for terms, packing, marking or labels and for the rules for affixing them. A technical standing order must contain requirements of energy efficiency.

The compliance evaluation shall be made carried out in the forms of state control (supervision), accreditation, testing, registration, compliance confirmation, approval and putting into operation of a project completed in construction and in a different form.

The obligatory requirements of technical regulations for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, sale and reclamation, the rules and forms of compliance evaluation, identification rules, requirements for terms, packing, marking or labels and for the rules for drawing them shall have a direct effect on the entire territory of the Russian Federation and shall be changed solely by introduction of amendments and addenda to the respective technical regulations.

The requirements for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, processes of production, operation, storage, transportation, sale and reclamation, the rules for and forms of compliance evaluation, identification rules, requirements for terms, packing, marking or labels and for the rules for drawing them, not included in technical regulations, shall not be regarded as obligatory.

- **4.** Technical regulations shall contain requirements for the characteristics of products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, sale or reclamation, but they shall not contain requirements for the design and manufacture, unless, in the absence of requirements for the design and manufacture taking account of the degree of risk of harm to be caused, guarantees are provided for the attainment of the goals of adoption of the technical regulations, indicated in item 1 of Article 6 of this Federal Law.
- **5.** Technical regulations taking account of the degree of risk of harm to be caused, may contain special requirements for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, sale and reclamation, requirements for terms, packing, marking or labels and for the rules for drawing them providing guarantees for the protection of individual groups of private persons (minors, pregnant women, nursing mothers and the disabled).
- **6.** Technical regulations shall be applied uniformly and in equal measure, regardless of the country and/or place of origin of products, or of carrying out processes of design (including survey

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works), production, construction, installation and adjustment connected with requirements for products, operation, storage, transportation, sale and reclamation, the kinds or special features of transactions and/or natural persons and/or legal entities acting as manufacturers, executors, sellers and purchasers taking account of the provisions of item 9 of this Article.

- 7. Technical regulations shall not contain requirements for products causing harm on the individuals' life or health which was accumulated as a result of the protracted use of these products and which depends on other factors precluding the possibility of determination of the degree of admissible risk. In such cases technical regulations may contain a requirement referring to the need to inform the purchasers about possible harm and about factors on which it depends.
- **8.** International standards must be used in full or in part as the basis for elaborating draft technical standing orders, except for the instances if certain international standards or parts thereof would be inefficient or unfit for achieving the purposes established by Article 6 of this Federal Law, including in consequence of the climatic and geographical peculiarities of the Russian Federation, or technical and/or technological peculiarities.

National standards may be used in full or in part as a basis for developing draft technical regulations.

9. Technical regulations may contain special requirements for products, or processes of design (including survey works), production, construction, installation and adjustment connected with them, operation, storage, transportation, ale and reclamation, terms, marking or labels and rules for drawing them, applied in an individual place of origin of products, if the absence of such requirements, by virtue of climatic and geographic special features, leads to failure to attain the goals, mentioned in item 1 of Article 6 of this Federal Law.

Technical regulations also establish a minimum of necessary veterinary and sanitary and phyto-sanitary measures in relation to products originating from individual countries and/or places, including restrictions imposed on importation, utilisation, storage, transportation, sale and reclamation, providing guarantees for biological safety (regardless of the methods for ensuring safety used by the manufacturer).

Veterinary-and-sanitary and phyto-sanitary measures may provide for requirements for products, methods of their treatment and production, procedures for testing the products, inspection, compliance confirmation, quarantine rules, including requirements associated with the transportation of animals and plants, materials necessary for the provision of guarantees for the life or health of animals and plants in the period of their transportation, and also methods and procedures for the selection of tests, methods for the study and evaluation of risk and other requirements of technical regulations.

Veterinary-and-sanitary and phyto-sanitary measures shall be elaborated and applied on the basis of scientific data and also taking account of the respective international standards, recommendations and other documents of international organisations for the purposes of compliance with the necessary level of veterinary-and-sanitary and phyto-sanitary protection to be determined taking account of the degree of actual science-based risk. The provisions of

international standards, recommendations of international organisations of which the Russian Federation is a member, the incidence of diseases and pests and also measures adopted by suppliers for combating diseases and pests, ecological conditions, economic consequences associated with the possibility of harm, the amounts of spending on measures to prevent harm shall be taken into account in the evaluation of the degree of risk.

If there is a need for urgent veterinary-and-sanitary and phyto-sanitary measures to be applied in order to attain the goals of veterinary-and-sanitary and phyto-sanitary protection, but the respective science-based substantiation is either insufficient or cannot be obtained within the necessary time limits, the veterinary-and-sanitary or phyto-sanitary measures, stipulated by technical regulations in relation to certain kinds of products, shall be applied on the basis of the information obtained, including information obtained from the respective international organisations, the authorities of foreign states, information about the respective measures applied by other states or other information. Pending the adoption of the respective technical regulations in the cases established by this paragraph, veterinary-and-sanitary and phyto sanitary measures shall operate in accordance with item 5 of Article 46 of this Federal Law.

Veterinary-and-sanitary and phyto-sanitary measures shall be applied taking account of the respective economic factors, potential damage from the reduced volume of output or sales in the event of penetration, consolidation or spread of some kind of pest or disease, spending on combating them or on their liquidation, effective application of alternative measures to restrict the risks and also of the need to bring to a minimum the effect of the pest or disease on the environment, manufacture and circulation of products.

- 10. Technical regulations, adopted by a federal law, by a decision of the Government of the Russian Federation or by a regulatory legal act of the federal executive power body in charge of technical regulation, shall take effect no earlier than in six months from the day of their official publication.
- 11. The Government of the Russian Federation or, where it is provided for by Article 9.1 of this Federal Law, the federal executive power body in charge of technical regulation prior to the date of entry into force of technical regulations shall endorse in compliance with the requirements of the measurement insurance legislation of the Russian Federation a list of standardization documents containing the rules for, and methods of, investigations (tests) and measurements, including the rules for selection of samples which are required for application and implementation of adopted technical regulations and conformity assessment. Where there are no cited standarisation documents as applied to some requirements of technical regulations or technical regulation objects, the Government of the Russian Federation or, where it is provided for by Article 9.1 of this Federal Law, the federal executive power body in charge of technical regulation, prior to the date of entry into force of the technical regulations shall endorse in compliance with the requirements of the measurement insurance legislation of the Russian Federation the rules for, and methods of, investigations (tests) and measurements, in particular the rules for selection of samples which are necessary for application and implementation of adopted technical regulations and conformity assessment. Drafts of such rules and methods shall be elaborated by the federal bodies of executive power in accordance with their competence or, where it is provided for by Article 9.1 of this Federal Law, by the federal executive power body in charge of technical regulation with the use of standardization documents, shall be published in the print of the federal body of executive power in charge of technical regulation and inserted in a general-use information system in the electronicdigital form at latest thirty days before the approval of the said rules and methods.

The said rules may not impede the exercise of business activities to a greater extent that it is necessary for attaining the aims cited in item 1 of Article 6 of this Federal Law.

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12. The Government of the Russian Federation shall elaborate proposals on the provision of guarantees for technical regulations to meet the interests of the national economy and be in line with the development level of the material-and technical base and with scientific and technological progress and also to comply with internationals norms and rules. With these aims in view the Government of the Russian Federation shall approve the programme for the elaboration of technical regulations (indicating forms for their adoption) whose implementation shall be financed in full or in part out of the federal budget and which shall be adjusted and published every year. Technical regulations may be devised outside an endorsed programme.

The federal executive body authorized by the Government of the Russian Federation shall make arrangements on a permanent basis for the records and analysis of all cases of harm caused as a result of violation of the requirements of technical regulations the individuals' life or health, natural persons' or legal entities' property, state or municipal property, to the environment, the life or health of animals or plants with account of the degree of this harm and also steps shall be taken to inform purchasers, manufacturers and sellers about the situation in the sphere of compliance with the requirements of technical regulations.

Article 8. Abrogated.

Article 9. Procedure for the Elaboration, Adoption, Amendment and Cancellation of Technical Regulations

1. Technical regulations devised in the procedure established by this article shall be adopted by a federal law or a decision of the Government of the Russian Federation in the procedure established accordingly for adoption of federal laws and decisions of the Government of the Russian Federation subject to the provisions of this Federal Law.

Abrogated.

- 2. Any person may act as the developer of draft technical regulations.
- **3.** The notification of the elaboration of technical regulations shall be carried in the publication of the federal executive body for technical regulations and in the public information system in digital electronic form.

The notification of the elaboration of draft technical regulations shall contain information about the kind of products, or processes of design (including survey works), production, construction, installation and adjustment connected with the requirements for them, operation, storage, transportation, sale and reclamation the elaborated requirements shall refer to with a brief outline of the goal of these technical regulations, grounds for the need to elaborate them and with an indication of the elaborated requirements which differ from the provisions of the respective international standards or obligatory requirements operating on the territory of the Russian Federation at the time of elaboration of the draft technical regulations in question and information

about the method for familiarisation with the draft technical regulations, the name or the surname, name and patronymic of the developer of the draft technical regulations in question, the postal address and e-mail address, if any, to which interested persons' remarks shall be sent in written form.

4.Interested persons shall gain access for familiarisation to the respective draft technical regulations from the time of publication of the notification of the elaboration of draft technical regulations. The developer shall present a copy of the draft technical regulations at the interested person's request. The charges for the supply of the given copy shall not exceed the cost of its manufacture.

The developer shall finish the draft technical regulations taking account of interested persons' remarks, obtained in written form, hold public discussion of the draft technical regulations and compile a list of the interested persons' remarks, obtained in written form, with a brief outline of the content of those remarks and of the results of their discussion.

The developer shall preserve the interested person' remarks, obtained in written form, until the day of entry into effect of the technical regulations, adopted by the respective decree, and present them to the State Duma deputies, representatives of federal bodies and executive bodies and to commissions of experts for technical regulation, mentioned in item 9 of this Article, at their request.

The time limit for public discussion of the draft technical regulations from the day of publication of the notification of the elaboration of draft technical regulations to the day of publication of the notification of the completion of public discussion shall not exceed two months.

5. The notification of the completion of the public discussion of the draft technical regulations shall include information about the method for familiarisation with the draft technical regulations and with the list of the interested persons' remarks, obtained in written form, and also the name or surname, name and patronymic of the developer of the draft technical regulations, his postal address and e-mail address, if any, which may be used to communicate with the developer.

The finished draft technical regulations and the list of the interested persons' remarks, obtained in written form, shall be accessible to interested persons for familiarisation from the day of publication of the notification of the completion of the public discussion of the technical regulations.

- **6.** The federal executive body for technical regulation shall carry in its publication notification of the elaboration of draft technical regulations and of the completion of the draft's public discussion within ten days from the time of payment for the publication of the notifications. The procedure for the publication of the notifications and the charges for their publication shall be fixed by the Government of the Russian Federation.
- **7.** The following documents shall be required by the authorised body to take the legislative initiative of submiting a draft federal law on technical regulations to the State Duma:
 - the justification of the need for adoption of a federal law on technical regulations with indication of the requirements that differ from the provisions of the respective international standards or from the obligatory requirements operating on the territory of the Russian Federation at the time of elaboration of the draft technical regulations;
 - a feasibility study on the adoption of a federal law on technical regulations;
 - documents confirming the fact of publication of the notification of the elaboration of draft technical regulations in accordance with item 3 of this Article;
 - documents confirming the fact of publication of the notification of the completion of the public discussion of the draft technical regulations in accordance with item 5 of this Article;

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• the list of the interested persons' remarks obtained in written form, mentioned in item 4 of this Article.

The draft federal law on technical regulations, submitted to the State Duma, with the documents mentioned in this Item appended, shall be sent by the State Duma to the Government of the Russian Federation. The Government of the Russian Federation shall send to the State Duma within ninety days its judgement of the draft federal law on technical regulations, prepared taking account of the conclusions of the commission of experts on technical regulation. A draft federal law on technical regulations may be considered by the State Duma in the first reading without an opinion of the Government of the Russian Federation being available, if an opinion of the Government of the Russian Federation was not submitted to the State Duma at the said time.

8. Amendments to the draft federal law on technical regulations, adopted at the first reading, shall be published upon expiration of the time limit for their presentation in the public information system in digital electronic form at least a month before consideration by the State Duma of the draft law on technical regulations at the second reading.

The federal executive body for technical regulation shall carry in its publication the draft federal law on technical regulations within ten days from the time of payment for its publication. The procedure for publication of the draft federal law on technical regulations and the charge for its publication shall be fixed by the Government of the Russian Federation.

The draft federal law on technical regulations, prepared for the second reading, shall be sent by the State Duma to the Government of the Russian Federation at least a month before the consideration of the said draft by the State Duma at the second reading.

The draft federal law on technical regulations, prepared for the second reading, shall be sent by the State Duma to the Government of the Russian Federation. The Government of the Russian Federation shall within sixty days send the State Duma its judgement on the draft law on technical regulations prepared taking account of the conclusion of the commission of experts for technical regulation. A draft federal law on technical regulations may be examined by the State Duma in the second reading without an opinion of the Government of the Russian Federation being available, if an opinion of the Government of the Russian Federation was not submitted to the State Duma at the said time.

8.1. A draft decision of the Government of the Russian Federation on technical regulations developed in the procedure established by item 2-6 of this Article and prepared for consideration at a meeting of the Government of the Russian Federation at latest thirty days before the date of its consideration shall be sent for an expert examination to the appropriate expert commission for technical regulation, which is established and exercises its activities in the procedure set up by item 9 of this article. A draft decision of the Government of the Russian Federation on technical regulation shall be considered at a meeting of the Government of the Russian Federation subject to an opinion of the appropriate expert commission for technical regulation.

A draft decision of the Government of the Russian Federation on technical regulations shall be published in the publication of the federal executive power body on technical regulation and placed in electronic form in a general-use information system at latest thirty days before the date of consideration thereof at a meeting of the Government of the Russian Federation. The procedure for publication and placement of said draft decision shall be established by the Government of the Russian Federation.

9. Examination of the draft technical regulations shall be carried out by the commissions of experts for technical regulation, with representatives of federal executive bodies, research institutions, self-supported organisations, public associations of entrepreneurs and consumers among their members acting on an equal basis.

The procedure for the formation and operation of commissions of experts on technical regulation shall be approved by the Government of the Russian Federation. The federal executive body on technical regulation shall approve the personal composition of the commissions of experts on technical regulation and provide support for their activity. The sittings of commissions of experts on technical regulation shall be held in open session.

The conclusions of commissions of experts on technical regulation shall be carried in the publication of the federal executive body for technical regulation and in the public information system in digital electronic form. The procedure for the publication of such conclusions and the charge for their publication shall be established by the Government of the Russian Federation.

10. If the technical regulations conflict with the interests of the national economy, the development of the material and technical base and with the level of scientific progress and also with international norms and rules put into operation in the Russian Federation in the established procedure, the Government of the Russian Federation or the federal executive power body in charge of technical regulation shall start the procedure for the introduction of amendments to the technical regulations or for the cancellation of the technical regulations.

Technical regulations shall be amended, supplemented or canceled in the procedure stipulated by this Article and Article 10 of this Federal Law in the part on elaboration and adoption of technical regulations.

- **Article 9.1.** Procedure for Developing, Adopting, Changing and Canceling Technical Regulations to Be Adopted by a Regulatory Legal Act of the Federal Executive Power Body in Charge of Technical Regulation
- 1. Where it is provided for by the programme of technical regulations' development endorsed by the Government of the Russian Federation in compliance with item 12 of Article 7 of this Federal Law, technical regulations shall be adopted by a regulatory legal act of the federal executive power body in charge of technical regulation. Such technical regulations shall be developed in the procedure established by items 2-6 of Article 9 of this Federal Law and by this article, and shall be adopted in the procedure established for adoption of regulatory legal acts of federal executive power bodies.
- 2. Draft technical regulations adopted in the form of a regulatory legal act of the federal executive power body in charge of technical regulation shall be submitted by the developer thereof to the federal executive power body in charge of technical regulation for adoption, if the following documents are available:

substantiation of the need for adoption of the technical regulations citing the requirements which differ from the provisions of appropriate international standards or mandatory requirements which are effective in the territory of the Russian Federation at the time when the draft technical regulations are being developed;

financial-and-economic substantiation of the technical regulations' adoption;

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documents proving publication of a notice of development of the draft technical regulations in compliance with Item 3 of Article 9 of this Federal Law;

documents proving publication of a notice of completion of public discussion of the draft technical regulations in compliance with Item 5 of Article 9 of this Federal Law;

list of observations of the persons concerned received in writing.

- **3.** Draft technical regulations presented to the federal executive power body in charge of technical regulation together with the documents cited in Item 2 of this article shall be forwarded by the cited body to the technical regulation expert commission established in compliance with Item 9 of Article 9 of this Federal Law for an expert examination.
- **4.** An opinion of the technical regulation expert commission as to the possibility of technical regulations' adoption shall be prepared within thirty days from the date when the draft technical regulations together with the documents cited in Item 2 of this article are received by the federal executive power body in charge of technical regulation, shall be published in the print of the federal executive power body in charge of technical regulation and inserted in the electronic-digital form in a general-use information system.

A procedure for publishing such opinions and the rate of payment for publication thereof shall be established by the Government of the Russian Federation.

- **5.** On the basis of an opinion of the technical regulation expert commission as to the possibility of adopting technical regulations the federal executive power body in charge of technical regulation within ten days from the date when such opinion is received shall render the decision on adoption of the technical regulations or on rejection of the draft thereof. Rejected draft technical regulations jointly with the opinion of the technical regulation expert commission must be returned to the developer thereof within five working days from the date when the decision on rejection of the draft technical regulations is rendered.
- **6.** Adopted technical regulations must be published in the print of the federal executive power body in charge of technical regulation and inserted in a general-use information system in the electronic-digital form. A procedure for such publishing and insertion shall be approved by the federal executive power body in charge of technical regulation.
- 7. The federal executive power body in charge of technical regulation shall provide access on a free-of-charge basis to adopted technical regulations in the electronic-digital form in a general-use information system.
- **8.** Technical regulations adopted by a normative legal act of the federal executive power body in charge of technical regulation shall be subject to the state registration in the established procedure.
 - 9. Technical regulations shall be amended or cancelled in the procedure provided for by this

article and Article 10 of this Federal Law, as regards the development and adoption of technical regulations.";

Article 10. Special Procedure for the Elaboration and Adoption of Technical Regulations

- 1. In exclusive cases of the occurrence of circumstances leading to a direct threat to the life and health of individuals, the environment, the life and health of animals and plants and if it is necessary to adopt immediately the respective decree on technical regulations in order to provide guarantees for the safety of products, or processes of design (including survey works), production, construction, installation and adjustment connected with it, operation, storage, transportation, sale and reclamation, the President of the Russian Federation shall be authorised to issue technical regulations without their public discussion.
- **2.** Technical regulations may be adopted by an international treaty (including by a treaty signed with the members of the Commonwealth of Independent States) to be ratified in the procedure laid down by the legislation of the Russian Federation or an intergovernmental agreement made in the procedure established by the legislation of the Russian Federation. In this case, draft technical regulations shall be elaborated in the procedure stipulated by items 2-6 of Article 9 of this Federal Law.

3. Abrogated.

4. Technical regulations, issued by decree of the President of the Russian Federation, by decision of the Government of the Russian Federation or by a regulatory legal act of the federal executive power body in charge of technical regulation shall be regarded as invalid from the day of enactment of the federal law on respective technical regulations.

Chapter 3 Standardisation

Article 11. Standardisation Goals

Standardisation shall be carried out for the attainment of the following goals:

- a higher level of safety for individuals' life and health, natural persons' and legal entities' property, state and municipal property, facilities taking account of the risk of occurrence of emergency situations of a natural and man-made nature, a higher level of ecological safety, as well as safety for the life and health of animals and plants;
- ensuring competitive ability and high quality of products (works and services), uniformity of measurements, efficient use of resources, exchangeability of technical hardware (machines and equipment, their components, complimentary parts and materials), technological and information compatibility, comparability of the results of examination (tests) and measurements, technical and economics-statistics data, analysis of characteristics of products (works and services), implementation of state orders, voluntary confirmation of the compliance of products (works and services);
- assistance in observance of the requirements of technical regulations;
- establishment of the system of classification and coding of technical economic and social information, of systems of classification of products (works and services), systems of ensuring a high quality of products (works and services), systems of data search and communication, assistance in carrying out unification works.

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Article 12. Standardisation Principles

Standardisation shall be carried out in accordance with the following principles:

- voluntary application of standardization documents;
- elaboration of standards with maximum account of interested persons' interests;
- application of an international standard, unless such application has been recognised as
 impossible since the requirements of international standards conflict with the special
 climatic and geographical features of the Russian Federation, technical and/or technological
 special features or on other grounds or if the Russian Federation has resolved, in accordance
 with established procedures, against the adoption of the international standard or of its
 individual provision;
- inadmissibility of creating obstacles to the manufacture and circulation of products, performance of works and rendering of services to a greater degree than the minimum needed for the attainment of the goals, mentioned in Article 11 of this Federal Law;
- inadmissibility of the establishment of standards conflicting with technical regulations;
- provision of conditions for unified application of standards.

Article 13. Documents in the Sphere of Standardisation

The following documents used on the territory of the Russian Federation shall be regarded as belonging to the standardisation sphere:

- national standards;
- standardisation rules, norms and recommendations in the sphere of standardisation;
- classifications applied in established procedure, all-Russia classifiers of technical-andeconomic and social information;
- standards of organisations;
- sets of rules:
- international standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states registered in the Federal Information Fund of Technical Regulations and Standards;
- properly attested translations into Russian of international standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states registered by the national standardisation agency of the Russian Federation.

Article 14. National Body of the Russian Federation for Standardisation, Technical Committees for Standardisation

- **1.** The national body of the Russian Federation for standardisation (hereinafter referred to as the national body for standardisation) shall:
 - approve national standards;
 - adopt a programme for the development of national standards;
 - organise examination of draft national standards, as well as of standards and rule books presented for registration in compliance with item 4 of Article 44 of this Federal Law;
 - ensure compliance of the national standardisation system with the interests of the national economy, the condition of the material-and technical base and with scientific and technological progress;
 - keep records of standardization documents in the Federal Information Fund of Technical Regulations and Standards and ensure access thereto for persons concerned;
 - set up technical committees for standardisation, endorse regulations on them and coordinate their activity;
 - organise the official publication and distribution of the national standards, all-Russia classifications of technical-and-economic and social information, standardisation rules, norms and recommendations in the field of standardisation in the print publication and in the information system for general use in the electronic-digital form;
 - take part in accordance with the charters of international organisations in the elaboration of international standards and provide guarantees for the interests of the Russian Federation to be taken into account in their adoption;
 - approve the representation of mark of compliance with national standards;
 - represent the Russian Federation in international organisations operating in the standardisation sphere;
 - ensure, in the general-use information system, gratuitous access to the standardization documents whose application on the voluntary basis results in the observance of the requirements of adopted technical regulations, and which contain the rules for and methods of investigations (tests) and measurements, including the rules for selection of samples necessary for application and observance of adopted technical regulations and the assessment of conformity, except as provided for by item 9 of Article 19 of this Federal Law;
 - furnish information and documents in the field of standardisation in accordance with the obligations of the Russian Federation ensuing from the international treaties of the Russian Federation in the sphere of technical regulation;
 - register in the Federal Information Fund of Technical Regulations and Standards international standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states;
 - enter to the records properly attested translations into Russian of international standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states.
- **2.** The Government of the Russian Federation shall determine the body authorised for the performance of the functions of the national body for standardisation. ¹
- **3.** For the purposes of this article publication of national standards by the national body for standardisation shall be understood to mean publication of the national standard in Russian in a printed publication and in the public information system in digital electronic form.

¹ Decision of the Government of the Russian Federation No. 316 of June 2, 2003 designated the State Committee of the Russian Federation for Standardisation and Metrology as the body authorised to perform the functions of the national body of the Russian Federation for standardisation

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4. Representatives of federal executive bodies, research organisations, self-supported organisations, profit-making and non-profit organisations and of public associations of entrepreneurs and consumers may act as members of technical committees for standardisation on an equal and on a voluntary basis.

The procedure for the establishment and operation of technical committees for standardisation shall be approved by the national body for standardisation.

The sittings of technical committees for standardisation shall be held in open session.

Technical committees for standardization shall exercise their activities in compliance with regulations on them.

Article 15. National Standards, All-Russia Classifiers of Technical-and-Economic and Social Information

- 1. Participants in standardization works, as well as national standards, all-Russia classifiers of technical-economic and social information, rules for their development and application, standardization rules, norms and recommendations in the field of standardization, and sets of rules form the national standardisation system.
- **2.** National standards shall be elaborated in the procedure established by this Federal Law. National standards shall be approved by the national body for standardisation in accordance with the standardisation rules, norms and recommendations in this sphere.

A national standard shall be applied on a voluntary basis in the same way and in an equal measure, regardless of the country and/or place of origin of the products, methods for the processes of production, operation, storage, transportation, sale and reclamation, performance of works and rendering of services, the kinds and special features of transactions and/or persons acting as manufacturers, executors, sellers and purchasers.

Application of national standards shall be confirmed by the mark of compliance with the national standard.

3. All-Russia classifiers of technical-and-economic and social information (hereinafter referred to as All-Russia classifiers) are normative documents distributing technical-and-economic and social information in accordance with its classification (classes, groups, kinds and so on) and which are obligatory for application for the establishment of state information systems and information resources and for interdepartmental exchange of information.

The procedure for the elaboration, adoption, bringing into effect, keeping and application of all Russia classifiers in the socio-economic sphere (including in the sphere of forecasts, statistical records, banking, taxation, for interdepartmental exchange of information, establishment of information systems and information resources) shall be established by the Government of the Russian Federation.

Article 16. Rules for the Elaboration and Approval of National Standards

- 1. The national body for standardisation shall elaborate and approve the programme for the elaboration of national standards. The national body for standardisation shall ensure interested persons' access for familiarisation to the programme for the elaboration of national standards.
 - **2.** Any person may act as the developer of a national standard.
- **3.** The notification of the elaboration of a national standard shall be sent to the national body for standardisation and carried in the public information system in digital electronic form and in the publication of the federal executive body for technical regulation. The notification of the development of a national standard shall contain information about provisions in the draft national standards that differ from the provisions of the respective international standards.

The developer of a national standard shall ensure interested persons' access to the draft for familiarisation. The developer shall present a copy of the draft national standard to an interested person at his request. The developer's charges for the supply of said copy shall not exceed the cost of its manufacture.

If the developer of a national standard is a federal executive body, the charges for the supply of the copy of the draft national standard shall be paid to the federal budget.

4. The developer shall finish the draft national standard taking account of any interested person's remarks obtained in written form, hold public discussion of the draft national standard and compile a list of the interested persons' remarks, obtained in written form, with a brief outline of the content of the given remarks and of the results of their discussion.

The developer shall preserve the interested persons' remarks, obtained in written form, pending the approval of the national standard and present them to the national body for standardisation and technical committees for standardisation at their requests.

The time limit for public discussion of the national standard from the day of publication of the notification of the development of a draft national standard to the day of publication of the notification of the completion of the public discussion shall not exceed two months.

5. The notification of the completion of the public discussion of the draft national standard shall be carried in the publication of the federal executive body for technical regulation and in the public information system in digital electronic form.

Interested persons shall have access for familiarisation to the finished draft national standard and to the list of the interested persons' remarks, obtained in written form, from the day of publication of the notification of the completion of the public discussion of the draft national standard.

- **6.** The procedure for the publication of the notification of the development of a draft national standard and of the notification of the completion of the public discussion of the draft national standard and of charge for their publication shall be established by the Government of the Russian Federation.
- 7. The draft national standard together with the list of the interested persons' remarks, obtained in written form, shall be presented by the developer to the technical committee for standardisation which shall organise examination of the given draft.

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8. On the basis of the documents, mentioned in item 7 of this Article, and taking account of the results of the examination, the technical committee for standardisation shall prepare a justified proposal on approval or rejection of the draft national standard. This proposal shall be sent simultaneously with the documents, mentioned in item 7 of this Article, and the results of the examination to the national body for standardisation.

The national body for standardisation shall adopt a decision on the basis of the documents, presented by the technical committee for standardisation, on approval or rejection of the national standard.

Notification of the approval of the national standard shall be carried in the publication of the federal executive body for technical regulation and in the public information system in digital electronic form within thirty days from the day of approval of the national standard.

If the national standard is rejected, the supported decision of the national body for standardisation, with the documents mentioned in item 7 of this Article appended, shall be sent to the developer of the draft national standard.

8.1. National standards shall be amended in the procedure established by this article for development and endorsement of national standards.

9. Abrogated.

10. Where there are no national standards as applied to individual requirements of technical regulations or objects of technical regulation, sets of rules shall be developed for the purpose of ensuring the compliance with the requirements of technical regulations for products or for processes of design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale and reclamation connected with them.

Sets of rules shall be developed by federal executive bodies within the scope of their authority. A draft set of rules shall be placed in a public-use information system in electronic form at latest sixty days before the date of its endorsement. The procedure for development and endorsement of a set of rules shall be determined by the Government of the Russian Federation on the basis of the provisions of items 3-6 of this Article.

Article 16.1. Rules for Composing a List of Standardisation Documents Whose Application on a Voluntary Basis Results in the Observance of Technical Regulations' Requirements

- 1. The national standardization agency at latest thirty days before the date when technical regulations enter into effect shall endorse, publish in the print of the federal executive power body in charge of technical regulation and insert in a general-use information system in the electronic-digital form a list of standardization documents whose application on a voluntary basis results in the observance of the requirements of adopted technical regulations.
 - 2. The list cited in item 1 of this Article may comprise national standards and rule books, as

well as international standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states, provided that the cited standards and rule books are registered in the Federal Information Fund of Technical Regulations and Standards. International standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states shall be registered in the Federal Information Fund of Technical Regulations and Standards in the procedure established by Article 44 of this Federal Law.

- **3.** National standards and rule books may cite the requirements of technical regulations for whose satisfaction national standards and/or rule books are applied on a voluntary basis.
- **4.** The application on a voluntary basis of the standards and/or rule books included into the list of standardization documents cited in item 1 of this Article shall be seen as the sufficient condition of satisfying the requirements of appropriate technical regulations. In case of applying such standards and/or rule books for satisfaction of the technical regulations' requirements, the conformity to the technical regulations' requirements may be assessed on the basis of confirmation of their compliance with such standards and/or rule books. Non-application of such standards and/or rule books may not be regarded as a failure to satisfy the requirements of technical regulations. On such occasion, it shall be allowed to apply other documents for assessing conformity to the technical regulations' requirements.
- **5.** The standardisation documents included into the list cited in item 1 of this Article shall be subject to verification and, where necessary, to reviewing and updating at least once every five years.

Article 17. Standards of Organisations

1. Standards of organisations, including commercial, public, research organisations, self-supporting organisation, and associations of legal entities may be developed and approved by them on their own proceeding from the need to apply these standards for the purposes mentioned in Article 11 of this Federal Law for the improvement of production and for the provision of guarantees for the quality of products, performance of works, rendering of services and also for popularisation and utilisation of the results of research (tests), measurement and development, obtained in various fields of knowledge.

The procedure for the development, approval, recordsing, amendment and cancellation of organisations' standards shall be established by them on their own taking account of the provisions of Article 12 of this Federal Law.

An organisation's draft standard shall be presented by the developer to the technical committee for standardisation which shall organise examination of the given draft. On the basis of the results of the given draft's examination the technical committee for standardisation shall prepare a conclusion and send it to the developer of the draft standard.

2. Abrogated.

Chapter 4 Compliance Confirmation

Article 18. Goals of compliance confirmation

Compliance shall be confirmed for the attainment of the following goals:

• to certify the compliance of the products, design (including survey works), production,

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construction, installation, adjustment, operation, storage, transportation, sale and reclamation, works, services or other objects with technical regulations, standards, sets of rules and terms of contracts.

- to assist the purchaser in the competent choice of products, works and services;
- to raise the level of competitiveness of products, works, services on the Russian and world markets:
- to create conditions for ensuring free transportation of goods across the territory of the Russian Federation and also for international economic, scientific and technological cooperation and world trade.

Article 19. Compliance Confirmation Principles

- 1. Compliance confirmation shall be carried out on the basis of the following principles:
- free access for interested persons to information about the procedure for the confirmation of compliance;
- obligatory confirmation shall not be applied to objects in the absence of the requirements of technical regulations applying to them;
- determination of the list of forms and schemes for the obligatory confirmation of compliance in relation to certain kinds of products in the respective technical regulations;
- reduction of the time limits for the obligatory confirmation of compliance and of the applicant's expenses;
- inadmissibility of coercion to be used for voluntary confirmation of compliance, including in a certain system of voluntary certification;
- protection of the applicant's property interests, observance of commercial secrets in relation to information obtained in the process of confirmation of compliance;
- inadmissibility of the replacement of the obligatory confirmation of compliance by voluntary certification.
- 2. Compliance confirmation shall be elaborated and applied in the same way and in equal measure, regardless of the country and/or place of origin of the products, methods for the processes of design (including survey works), production, construction, installation, adjustment, operation, storage, transportation, sale and reclamation, performance of works and rendering of services, the kinds and special features of transactions and/or persons who are represented by manufacturers, contractors, sellers and purchasers.

Article 20. Forms of Compliance Confirmation

1. Compliance confirmation on the territory of the Russian Federation may of a voluntary or obligatory nature.

- 2. Voluntary confirmation of compliance shall be carried out in the form of voluntary certification
- **3.** Obligatory confirmation of compliance shall be carried out in the following forms: adoption of a declaration of compliance (hereinafter referred as the declaration of compliance); obligatory certification.
- **4.** The procedure for the application of the forms of obligatory confirmation of compliance shall be laid down by this Federal Law.

Article 21. Voluntary Confirmation of Compliance

1. Voluntary confirmation of compliance shall be carried out at the applicant's initiative on the terms of a contract between the applicant and the certification body. Voluntary confirmation of compliance may be carried out for the determination of compliance with national standards, organisations' standards, sets of rules, voluntary certification systems, terms of contracts.

The objects of voluntary confirmation of compliance shall be represented by products, processes of production, operation, storage, transportation, sale and reclamation, works and services and also other objects, with requirements for them established by standards, voluntary certification systems and contracts.

The certification agency shall:

- carry out confirmation of the compliance of the objects of voluntary confirmation of compliance;
- issue compliance certificates for objects which have undergone the procedure for voluntary certification;
- grant authority to the applicants for the application of the compliance mark, if application of a compliance mark is stipulated by the respective voluntary certification system;
- suspend or terminate operation of the compliance certificates issued by it.
- **2.** A voluntary certification system may be established by a legal entity and/or businessman and/or businessmen.

The person or persons who have set up a voluntary certification system shall compile a list of objects to be certified and of their characteristics, with voluntary certification to be carried out for compliance with them, establish rules for performance of the works provided for by the given voluntary certification system, and the procedure for payment for them and determine participants in the given voluntary certification system. The voluntary certification system may provide for the application of a compliance mark.

3. The voluntary certification system may be registered with the federal executive body for technical regulation.

The following documents shall be presented to the federal executive body for technical regulation for registration of the voluntary certification system:

- the certificate of the legal entity's or businessman's state registration;
- the rules for the functioning of the voluntary certification system which provide for the provision of item 2 of this Article;
- the representation of a compliance mark applied in this voluntary certification system, if application of the compliance mark is provided for, and the procedure for the application of the compliance mark
- the document confirming payment has been made for registration of the voluntary

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certification system.

The voluntary certification system shall be registered within five days from the time of presentation of the documents, stipulated by this Item for registration of the voluntary certification system, to the federal executive body for technical regulation. The procedure for registration of the voluntary certification system and the charge for the registration shall be established by the Government of the Russian Federation. The charge for registration of the voluntary certification system shall be paid to the federal budget.

4. Refusal to register the voluntary certification system shall be admissible solely in the event of non-presentation of the documents, stipulated in item 3 of this Article, or if the name of the system and/or representation of the compliance mark and the name of the system and/or representation of the compliance mark of a voluntary certification system registered earlier are identical. The notification of the refusal to register the voluntary certification system shall be sent to the applicant within three days from the day of adopting the decision on the refusal to register this system with indication of the grounds for the refusal.

The refusal to register a voluntary certification system may be appealed in judicial procedure.

5. The federal executive body for technical regulation shall keep a unified register of registered voluntary certification systems with information about the legal entities and/or businessmen who have created voluntary certification systems, about the rules for functioning of the voluntary certification systems which stipulate for the provisions of item 2 of this Article, about compliance marks and the procedure for their application. The federal executive body for technical regulation shall ensure that interested persons have free access to information contained in the unified register of registered voluntary certification systems.

The procedure for keeping the unified register of registered voluntary certification systems and the procedure for the supply of information contained in this register shall be established by the federal executive body for technical regulation.

Article 22. Compliance Marks

- 1. Certification objects certified in the voluntary certification system shall be labeled with the compliance mark of the voluntary certification system. The procedure for the application of such a compliance mark shall be established by the rules of the respective voluntary certification system.
- **2.** The mark of compliance with a national standard shall be applied by the applicant on a voluntary basis in any way suitable for the applicant in the procedure established by the national body for standardisation.
 - 3. Objects whose compliance has not been confirmed in the procedure established by this

Federal Law shall not be labeled with the compliance mark.

Article 23. Obligatory Confirmation of Compliance

1. Obligatory confirmation of compliance shall be carried out provided such cases are stipulated by the respective technical regulations and exclusively for compliance with the requirements of technical regulations.

The object of obligatory confirmation shall be solely products put into circulation on the territory of the Russian Federation.

- **2.** The form and schemes of the obligatory confirmation of compliance shall be established solely by technical regulations taking account of the degree of the risk of failure to attain the goals of technical regulations.
- **3.** The declaration of conformity and the certificate of conformity shall have equal legal force and shall be effective on the whole territory of the Russian Federation with respect to each unit of products released into circulation on the territory of the Russian Federation during the effect of a conformity declaration or a conformity certificate, within the working life or service life of products established in accordance with legislation of the Russian Federation.
- **4.** Works for obligatory confirmation of compliance shall be paid for by the applicant. The cost of works for obligatory confirmation of products' compliance shall be determined regardless of the country and/or place of their origin, as well as of the persons who are applicants.

Article 24. Declaration of Compliance

- 1. Compliance shall be declared according to one of the following systems:
- acceptance of the declaration of compliance on the basis of the person's own proof;
- adoption of the declaration of compliance on the basis of the person's own proof and of proof obtained with the participation of certification agency and/or accredited testing laboratory (centre) (hereinafter referred to as a third party).

For a declaration of compliance, the applicant can be represented by a legal entity or a natural person, registered in accordance with the legislation of the Russian Federation on its territory as a businessman or acting as a manufacturer or seller, or performing the functions of a foreign manufacturer on the basis of a contract concluded with the former in the part of provision of guarantees for compliance of the delivered products with the requirements of technical regulations and in the part of liability for noncompliance of the delivered products with the requirements of technical regulations (the person performing the functions of a foreign manufacturer).

The circle of applicants shall be determined by the respective technical regulations.

The system of declaration of compliance with the participation of a third party shall be determined in technical regulations if the absence of a third party leads to failure to attain the goals of confirmation of compliance.²

2. For declaration of compliance on the basis of the applicant's own proof the applicant shall form on his own materials of proof for the purposes of confirmation of the products'

² See Unified List of Products Whose Conformity Is to Be Confirmed in the Form of Acceptance of a Conformity Declaration approved by Decision of the Government of the Russian Federation No. 982 of December 1, 2009

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compliance with the requirements of technical regulations. Technical documents, the results of the applicant's own research (tests) and measurement and/or other documents which serve as a supported basis for confirmation of the products' compliance with the requirements of technical regulation shall be used as materials of proof. The composition of the materials of proof shall be determined by the respective technical regulations.

- **3.** For declaration of compliance on the basis of one's own proof and of those obtained with the participation of a third party, the applicant, at his own choice in addition to his own proof, formulated in the procedure stipulated by item 2 of this Article, shall:
 - include in the materials of proof reports of research (tests) and measurement, carried out in an accredited test laboratory (centre);
 - present the certificate of the quality system with respect to which control (supervision) is stipulated to be exercised by the certification agency, which issued the given certificate, over the certification object.
- **4.** The quality system certificate shall be used as part of the proof for the adoption of a declaration of compliance of any products, unless a different form of compliance confirmation is stipulated for such products by technical regulations.
 - **5.** The declaration of compliance shall be drawn up in Russian and shall contain:
 - the applicant's name and location;
 - the manufacturer's name and location;
 - information about the object of confirmation of compliance making it possible to identify this object;
 - the name of the technical regulations for compliance with whose requirements the products are being confirmed;
 - indication of the scheme of the declaration of confirmation:
 - the applicant's statement of the products' safety for their utilisation in accordance with their goal oriented designation and of the applicant's having adopted measures for ensuring the products' compliance with the requirements of technical regulations;
 - information about the research (tests) and measurement carried out by the applicant, the quality system certificate and also about the documents which served as the ground for the confirmation of the products' compliance with the requirements of technical regulations;
 - the duration of the declaration of compliance;
 - other information stipulated by the respective technical regulations.

The duration of the declaration of compliance shall be determined by technical regulations.

The form of the declaration of compliance shall be approved by the federal executive body for technical regulation.

6. The declaration of compliance, drawn up according to item 5 of this Article, shall be registered with the comprehensive register of declarations of compliance within three days.

A procedure for forming and keeping the comprehensive register of declarations of compliance, a procedure for registration of declarations of compliance and for providing data contained therein shall be determined by the federal executive body authorized by the Government of the Russian Federation.

A procedure for paying for providing data contained in the comprehensive state register of declarations of compliance shall be determined by the Government of the Russian Federation.

7. The declaration of compliance and the documents of the materials of proof shall be kept in storage by the applicant for three years from the time of expiration of the declaration. The second copy of the declaration of compliance shall be kept in storage by the federal executive body authorized by the Government of the Russian Federation.

Article 25. Obligatory Certification

- 1. Obligatory certification shall be carried out by the certification agency on the basis of a contract with the applicant. Certification schemes used for certification of individual kinds of products shall be established by the respective technical regulations.
- **2.** The products' compliance with the requirements of technical regulations shall be confirmed by a compliance certificate, issued to the applicant by the certification agency.

The compliance certificate shall include:

- the applicant's name and location;
- the name and location of the manufacturer of the products which have undergone the certification procedure;
- the name and location of the certification agency which issued the compliance certificate;
- information about the certification object making it possible to identify this object;
- the name of the technical regulations for compliance with whose requirements certification was carried out;
- information about the research (tests) and measurement that were carried out;
- information about the documents presented by the applicant to the certification agency as proof of the products' compliance with the requirements of technical regulations;
- the duration of the compliance certificate.

The duration of the compliance certificate shall be determined by the respective technical regulations.

The form of the compliance certificate shall be approved by the federal executive body for technical regulation.

Article 26. Organisation of Obligatory Certification

- **1.** Obligatory certification shall be carried out by a certification agency, accredited in the procedure established by the Government of the Russian Federation.
 - **2.** The certification agency shall:
 - attract on a contractual basis test laboratories (centres), accredited in the procedure established by the Government of the Russian Federation (hereinafter referred to as accredited test laboratories (centres), for carrying out research (conducting tests) and measurement;

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- exercise control over certification objects, if such control is stipulated by the respective obligatory certification scheme and by the contract;
- keep the register of compliance certificates issued by it;
- inform the respective bodies of state control (supervision) over compliance with the requirements of technical regulations for products which have been presented for certification but have not yet undergone its procedure;
- issue compliance certificates, suspend or cancel compliance certificates issued by it and notify the federal executive body charged with organisation of drawing up and keeping of the comprehensive register of compliance certificates and the state bodies of control (supervision) over compliance with the requirements of technical regulations of this;
- ensure the supply of information to the applicants about the procedure for obligatory certification;
- determine the cost of certification works carried out on the basis of the contract made with the applicant;
- in the procedure established by the appropriate technical regulations renders the decision on extension of duration of the compliance certificate, in particular on the basis of the results of control that has been exercised over certified objects.
- **3.** The procedure for forming and keeping the comprehensive register of compliance certificates, the procedure for presentation of information contained in the said register and the procedure for making payment for the supply of information contained in said register, as well as the federal executive body charged with organisation of drawing up and keeping of said register, shall be determined by the Government of the Russian Federation.
- **4.** Research (tests)into and measurement of products for obligatory certification shall be carried out by accredited test laboratories (centres).

The accredited test laboratories (centres) shall carry out research (tests) into and measurement of products within the sphere of their accreditation on the terms of contracts with certification agencies. Certification agencies shall not supply information about the applicant to the accredited test laboratories (centres).

The accredited test laboratories (centres) shall formalise the results of the research (tests) and measurement in reports, and on their basis the certification agency shall adopt a decision on the issue or on the refusal to issue a compliance certificate. The accredited test laboratory (centre) shall ensure trustworthiness of the results of the research (tests) and measurement.

Article 27. Mark of Circulation on the Market

1. The products whose compliance with the requirements of technical regulations has been confirmed in the procedure, stipulated by this Federal law, shall be labeled with the mark of circulation on the market. The representation of the mark of circulation on the market shall be established by the Government of the Russian Federation. This mark shall not be regarded as a

special protected mark and shall be drawn for information purposes.³

2. The applicant shall label products with the mark of circulation on the market on his own by any method suitable for him. The peculiarities of marking products with a circulation stamp on the market shall be established by technical standing orders.

Products whose compliance with the requirements of technical regulations has not been confirmed in the procedure established by this Federal Law shall not be labeled with the mark of circulation of the market.

Article 28. The Applicant's Rights and Duties in the Sphere of Obligatory Confirmation of Compliance

- **1.** The applicant shall be authorized:
- to choose the form and scheme for the confirmation of compliance, stipulated for certain kinds of products by the respective technical regulations;
- to apply for obligatory certification to any certification agency whose sphere of accreditation extends to the products which the applicant intends to certify;
- to lodge complaints with the accreditation agency against unlawful actions of certification agencies and accredited test laboratories (centres) in accordance with the legislation of the Russian Federation.

2. The applicant shall:

- ensure the products' compliance with the requirements of technical regulations;
- put into circulation products subject to the obligatory confirmation of compliance only after having carried out such confirmation of compliance;
- indicate information in the accompanying technical documents and when marking the products about the compliance certificate or about the declaration of compliance.
- present documents to the bodies of state control (supervision) over compliance with the requirements of technical regulations and also to interested persons testifying to the products' compliance with the requirements of technical regulations (declaration of compliance, compliance certificate or copies thereof);
- suspend or terminate the sale of products if the duration of the compliance certificate or of the declaration of compliance has expired or if the compliance certificate or the declaration of compliance has been either suspended or terminated;
- inform the certification agency about amendments introduced to the technical documents or in the processes of production of certified products;
- suspend the manufacture of products which have undergone the procedure of the confirmation of compliance and do not comply with the requirements of technical regulations on the basis of the decision of the bodies of state control (supervision) over compliance with the requirements of technical regulations.

Article 29. Terms for the Importation into the Territory of the Russian Federation of Products Subject to Obligatory Confirmation of Compliance

1. For products subject to obligatory confirmation of compliance to be assigned a customs

³ On the market circulation mark, see Decision of the Government of the Russian Federation No. 696 of November 19, 2003

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regime providing for the possibility of alienation or utilisation of these products in accordance with their designation on the customs territory of the Russian Federation, the declaration of compliance or the compliance certificate or documents of their recognition in accordance with Article 30 of this Federal Law, shall be presented to the customs agencies together with the customs declaration by the applicant or by the person, authorised for the purpose by the applicant. The said documents shall not be presented if the products are assigned the customs treatment of refusal in favour of the state.

For the purpose of the customs clearance of products, the Government of the Russian Federation shall, within thirty days before the day of entry into force of a technical standing order and on its basis, approve lists of products covered by the effect of paragraph one of this Item with indication of the codes of the Commodity Classification of Foreign Economic Activity. The federal bodies of executive power performing the functions in the established sphere of activity shall, jointly with the federal body of executive power authorised in the field of the customs business and with the federal body of executive power performing the functions in rendering state services, managing state property in the sphere of technical regulation and metrology, form the said lists and submit them to the Government of the Russian Federation within sixty days before the day of entry into force of the technical standing order.

If technical regulations are adopted by a regulatory legal act of the federal executive power body in charge of technical regulation, for the purposes of the customs clearance of products the cited federal executive power body jointly with the federal executive power body authorised in respect of customs affairs shall endorse at latest thirty days before the date of technical regulations' entry into force on the basis of them the lists of products whereto Paragraph One of this item extends, citing the CC FEA codes thereof.

- 2. The products, determined in accordance with the provisions of Paragraph 2 of item 1 of this Article and subject to obligatory confirmation of compliance, which are brought into the customs territory of the Russian Federation and assigned customs regimes which do not provide for the possibility of their alienation, shall be released by the customs agencies of the Russian Federation into the territory of the Russian Federation without the need to present the documents of compliance, mentioned in Paragraph 1 of item 1 of this Article.
- 3. The procedure for the importation into the customs territory of the Russian Federation of products subject to obligatory confirmation of compliance and determined in accordance with the provisions of Paragraph 2 of ietem 1 of this Article and taking account of the provisions of item 1 of this Article, shall be approved by the Government of the Russian Federation.

Article 30. Recognition of the Results of the Confirmation of Compliance

Documents of the confirmation of compliance, marks of compliance and reports of research (tests) and measurement of products, obtained outside the Russian Federation, may be recognised in accordance with the international treaties of the Russian Federation.

Chapter 5 Accreditation of Certification Agencies and of TestLaboratories (Centres)

Article 31. Accreditation of Certification Agencies and of Test Laboratories Centres)

- **1.** Certification agencies and test laboratories (centres) shall be accredited for the following purposes:
 - to confirm the jurisdiction of the certification agencies and test laboratories (centres) performing works for the confirmation of compliance;
 - to ensure trust of the manufacturers, sellers and purchasers in the activity of the certification agencies and accredited test laboratories (centres);
 - to create conditions for recognition of the results of activity of the and accredited test laboratories (centres).
- **2.** Certification agencies and test laboratories (centres) performing works for the confirmation of compliance, shall be accredited on the basis of the following principles:
 - accreditation on their own accord:
 - free access to accreditation rules;
 - the accreditation agencies' competence and independence;
 - inadmissibility of restrictions imposed on competitiveness or of obstacles to the use of the services of the certification agencies and accredited test laboratories (centres);
 - provision of equal conditions for persons applying to obtain accreditation;
 - inadmissibility of combining authority for accreditation and for confirmation of compliance;
 - inadmissibility of limits to be imposed on the operation of accreditation documents on individual territories.
- **3.** A procedure and criteria for accreditation of certification agencies and test laboratories (centres) performing works in the sphere of conformity confirmation shall be defined by the Government of the Russian Federation on the basis of the national standards adopted with the account taken of international rules. The Government of the Russian Federation shall appoint accreditation agencies.

Chapter 6 State Control (Supervision) over Compliance with the Requirements of Technical Regulations

Article 32. Bodies of State Control (Supervision) over Compliance with the Requirements of Technical Regulations

- 1. State Control (supervision) over compliance with the requirements of technical regulations shall be exercised by federal executive bodies, the executive bodies of the subjects of the Russian Federation, governmental institutions subordinated to them authorised for state control (supervision) in accordance with the legislation of the Russian Federation (hereinafter referred to as the state control (supervision) bodies).
- 2. State control (supervision) over compliance with the requirements of technical regulations shall be exercised by the officials of state control (supervision) bodies in the procedure established

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by the legislation of the Russian Federation.⁴

Article 33. Objects of State Control (Supervision) over Compliance with the Requirements of Technical Regulations

- 1. State control (supervision) over compliance with the requirements of technical regulations shall be exercised in relation to products, or processes of design (including survey works), production, construction, installation and adjustment connected with requirements for them, operation, storage, transportation, sale and reclamation exclusively in the part of compliance with the requirements of the respective technical regulations.
- **2.** In relation to products, state control (supervision) over compliance with the requirements of technical regulations shall be exercised exclusively at the stage of circulation of products.
- **3.** For the implementation of measures for state control (supervision) over compliance with the requirements of technical regulations the rules and methods of research (tests) and measurement established for the respective technical regulations in the procedure stipulated by item 11 of Article 7 of this Federal Law shall be used

Article 34. Powers of State Control (Supervision) Bodies

- 1. On the basis of the provisions of this Federal Law and of the requirements of technical regulations, state control (supervision) bodies shall be authorised:
 - to demand from the manufacturer (seller, person performing the functions of the foreign manufacturer) presentation of the declaration of compliance or of the compliance certificate confirming the products' compliance with the requirements of technical regulations or of copies thereof, if the application of such documents is stipulated by the respective technical regulations;
 - to implement measures for state control (supervision) over compliance with the requirements of technical regulations in the procedure established by the legislation of the Russian Federation;
 - to issue orders on the removal of the violations of the requirements of technical regulations within the time limits fixed with account of the nature of the violation;
 - to send information about the necessity of suspension or cancellation of the compliance certificate to the certification body that issued it; to issue an order to suspend or cancel the declaration of compliance to the person that has adopted the declaration and to notify the

⁴ Decision of the Government of the Russian Federation No. 294 of June 17, 2004 established that the Federal Agency on Technical Regulation and Metrology shall exercise control and supervision over the observance of the obligatory requirements of the state standards and technical regulations pending the adoption by the Government of the Russian Federation of a decision on the transfer of those functions to other federal bodies of executive power

- federal executive body charged with organisation of forming and keeping the comprehensive register of declarations of compliance of this;
- to bring the manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) to account in accordance with the legislation of the Russian Federation;
- to adopt other measures, stipulated by the legislation of the Russian Federation, for the purposes of ruling out harm
 - **2.** The state control (supervision) bodies shall:
- explain, in the course of measures for state control (supervision) over compliance with the requirements of technical regulations, ways for the application of the legislation of the Russian Federation on technical regulation and supply information about current technical regulations.
- observe commercial secrets and other secrets protected by the law; 5
- comply with the procedure for the implementation of measures for state control (supervision) over compliance with the requirements of technical regulations and for formalisation of the results of such measures established by the legislation of the Russian Federation;
- adopt measures, on the basis of the results of measures for state control (supervision) over compliance with the requirements of technical regulations, for the removal of the consequences of violations of the requirements of technical regulations;
- send information about the products' noncompliance with the requirements of technical regulations in accordance with the provisions of Chapter 7 of this Federal Law.
- exercise other powers stipulated by the legislation of the Russian Federation.

Article 35. Liability of the State Control (Supervision) Bodies and of Their Officials for the Exercise of State Control (Supervision) over Compliance with the Requirements of Technical Regulations

- 1. State control (supervision) bodies and their officials shall bear liability in accordance with the legislation of the Russian Federation in the event of improper performance of their official duties for the implementation of measures in the sphere of state control (supervision) over compliance with the requirements of technical regulations.
- **2.** State control (supervision) bodies shall inform within a month inform the legal entity and/ or individual businessman whose rights and legitimate interests have been violated about measures adopted in relation to the officials of state control (supervision) bodies, guilty of violation of the legislation of the Russian Federation.

Chapter 7 Information about Violation of the Requirements of Technical Regulations and Withdrawal of Products

Article 36. Liability for Non-Compliance of Products or Processes of Design (Including Survey Works), Production, Construction, Installation, Adjustment, Operation, Storage, Transportation, Sale and Reclamation, Connected with Requirements for Them, with the Requirements of Technical Regulations

⁵ On protection by state power bodies of the confidentiality of information, constituting a commercial secret, passed over to them, see Federal Law No. 98-FZ of July 29, 2004

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- 1. The manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) shall bear liability in accordance with the legislation of the Russian Federation for violation of the requirements of technical regulations.
- **2.** In the event of noncompliance with the orders and decision of the state control (supervision) body, the manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) shall bear liability in accordance with the legislation of the Russian Federation.
- **3.** If as a result of the products' noncompliance with the requirements of technical regulations, violations of the requirements of technical regulations for the implementation of processes of design (including survey works), production, construction, installation and adjustment connected with requirements for the products, operation, storage, transportation, sale and reclamation, harm is caused the individuals' life or health, natural persons' or legal entities' property, state or municipal property, the environment, the life or health of animals and plants and if there is a threat of such harm being caused, the manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) shall compensate for the harm done and adopt measures in order to prevent any harm being caused to other persons, their property or the environment in accordance with the legislation of the Russian Federation.
- **4.** The duty to compensate for the harm shall not be restricted by a contract or declaration of one of the parties. Agreements on or declarations of the restriction of liability shall be invalid.

Article 37. Information about Products' Noncompliance with the Requirements of Technical Regulations

1. The manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) who has learned about the fact of noncompliance of products released into circulation with the requirements of technical regulations shall inform the state control (supervision) body in accordance with its jurisdiction about this within ten days from the time of receipt of said information.

The seller (contractor, person performing the functions of the foreign manufacturer) who has received said information shall bring it to the manufacturer's notice within ten days.

2. A person who does not act as the manufacturer (contractor, seller, person performing the functions of the foreign manufacturer) and who has learned about the fact of noncompliance of products released into circulation with the requirements of technical regulations, shall be authorised to send information about the products' noncompliance with the requirements of technical regulations to the state control (supervisions) body.

Upon receipt of such information, the state control (supervision) body shall within five days inform the manufacturer (seller, person performing the functions of the foreign manufacturer) about

Article 38. Duties of the Manufacturer (Seller, Person Performing the Functions of the Foreign Manufacturer) in the Event of Receipt of Information of Products' Noncompliance with the Requirements of Technical Regulations

1. The manufacturer (seller, person performing the functions of the foreign manufacturer) shall verify the trustworthiness of the received information within ten days from the time of receipt of information about the products' noncompliance with the requirements of technical regulations, unless the need for a longer time limit to be fixed follows from the substance of the implemented measures. On the demand of the state control (supervision) body, the manufacturer (seller, person performing the functions of the foreign manufacturer) shall present the materials of said verification to the state control (supervision) body.

In the event of receipt of information about products' noncompliance with the requirements of technical regulations, the manufacturer (seller, person performing the functions of the foreign manufacturer) shall adopt the necessary measures to prevent possible harm, associated with the circulation of the given products, from arise before completion of the verification stipulated by Paragraph 1 of this item.

2. Upon confirmation of the trustworthiness of the information about the products' noncompliance with the requirements of technical regulations, the manufacturer (seller, person performing the functions of the foreign manufacturer) shall, within ten days from the time of confirmation of the trustworthiness of such information, elaborate a programme of harm-prevention measures and reach agreement upon it with the state control (supervision) body in accordance with its jurisdiction.

The programme shall include measures for the supply of information to purchasers about the fact of threat of harm and about methods for its prevention and also time-limits for the implementation of such measures. If it is necessary to spend more funds for the prevention of harm, the manufacturer (seller, person performing the functions of the foreign manufacturer) shall implement all measures to prevent harm on his own, and if it is impossible to implement them, announce the products' withdrawal and compensate for the losses inflicted on purchasers in connection with the withdrawal of the products.

The manufacturer (seller, person performing the functions of the foreign manufacturer) shall remove the defects and also deliver the products to the place of removal of the defects and return them to the purchasers at his own expense.

- **3.** If the threat of harm cannot be removed by implementation of the measures, mentioned in item 2 of this Article, the manufacturer (seller, person performing the functions of the foreign manufacturer) shall immediately suspend the products' manufacture and sale, withdraw the products and compensate for the purchasers' losses, inflicted in connection with the withdrawal of the products.
- **4.** The manufacturer (seller, person performing the functions of the foreign manufacturer) shall provide at his own expense the opportunity for the purchasers to gain operative information about the necessary actions throughout the period of operation of the programme of harm-prevention measures.

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about Products' Noncompliance with the Requirements of Technical Regulations

1. If information is received about products' noncompliance with the requirements of technical regulations, the state control (supervision) bodies shall verify the trustworthiness of the received information as soon as possible.

In the course of verification the state control (supervision) bodies shall be authorised:

- to demand from the manufacturer (seller, person performing the functions of the foreign manufacturer) the materials of verification of the trustworthiness of the information about the products' noncompliance with the requirements of technical regulations;
- to request the manufacturer (seller , person performing the functions of the foreign manufacturer) and other persons to supply additional information about the products, or processes of design (including survey works), production, construction, installation and adjustment connected with requirements for them, operation, storage, transportation, sale and reclamation, including the results of the research (tests) and measurement, carried out for the obligatory confirmation of compliance;
- to send inquiries to other federal executive bodies;
- to attract, if necessary, specialists for analysis of the received materials.
- 2. Upon recognition of the trustworthiness of the information about the products' noncompliance with the requirements of technical regulations, the state control (supervision) body shall, in accordance within the sphere of its jurisdiction, issue orders within ten days for the elaboration by the manufacturer (seller, person performing the functions of the foreign manufacturer) of a programme of harm-prevention measures, render assistance in and exercise control over its implementation.

The state control (supervision) body shall:

- promote the spread of information about the time limits and procedure for the implementation of harm prevention measures;
- request the manufacturer (seller, person performing the functions of the foreign manufacturer) and other persons to supply documents confirming implementation of the measures indicated in the programme for harm-prevention measures;
- verify compliance with the time limits, indicated in the programme for harm-prevention measures;
- adopt a decision on filing a court claim for the forcible withdrawal of the products.
- **3.** If the body of state control (supervision) has received information about non-compliance of products with the requirements of technical regulations and it is necessary to take prompt measures aimed at preventing the infliction of harm upon the life and health of citizens by the use of these products or the threat of infliction of such harm, the state body of control (supervision) is entitled to do the following:
 - to issue an order to suspend the sale of the products;
 - to notify acquirers of these products through mass media of noncompliance of these products with the requirements of technical regulations and of the threat of inflicting harm

upon the life and health of citizens by using these products.

4. The manufacturer (the seller, the person exercising the functions of the foreign manufacturer) is entitled to appeal against the actions of the state body of control (supervision) specified in item 3 of this article in a judicial procedure. In the event of the rendering of a judicial decision on unlawfulness of the actions committed by the state body of control (supervision), the harm inflicted upon the manufacturer (the seller, the person exercising the functions of the foreign manufacturer) by actions of the state body of control (supervision) shall be compensated for in the procedure provided for by the legislation of the Russian Federation.

Article 40. Forcible Withdrawal of Products

- 1. I the event of disregard of the order, stipulated by item 2 of Article 39 of this Federal Law, or of non-implementation of the programme for harm-prevention measures, the state control (supervision) body, in accordance with its sphere of jurisdiction, and also other persons who have learned about non-implementation by the manufacturer (seller, person performing the functions of the foreign manufacturer) of the programme for harm-prevention measures, shall be authorised to file a court claim for the forcible withdrawal of the products.
- 2. If the claim for the forcible withdrawal of the products is met, the court shall make it incumbent on the respondent to perform certain actions, associated with the withdrawal of the products, within the time-limit fixed by the court and also bring the court judgement to purchasers' notice via the mass media or in another way within at most one month from the day of its entry into effect.

In the event of the respondent's failure to execute a court decision in due time, the court decision shall be executed in the procedure established by the legislation of the Russian Federation. For this, the claimant is entitled to notify acquirers through the mass media of compulsory withdrawal of products.

3. Measures of criminal liability and of administrative responsibility may be applied in accordance with the legislation of the Russian Federation for violation of the requirements of this Federal Law on the withdrawal of products.

Article 41. Responsibility for Violation of Rules for the Performance of Works in the Sphere of Certification

The certification agency and an official of the certification agency who (which) have violated rules for the performance of works in the sphere of certification, if such violation has involved the release into circulation of products not meeting the requirements of technical regulations, shall bear liability in accordance with the legislation of the Russian Federation and with the contract for works in the sphere of certification.

Article 42. Liability of the Accredited Test Laboratory (Centre)

The accredited test laboratory (centre), experts shall bear liability in accordance with the legislation of the Russian Federation and with the contract for untrustworthy or biased results of the research (tests) and measurement.

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Chapter 8 Information about Technical Regulations and Documents for Standardisation

Article 43. Information about Documents for Standardisation

- 1. National standards and all-Russia classifiers and also information about their elaboration shall be accessible to interested persons.
- 2. Official publication in the established procedure of national standards and all-Russia classifiers shall be carried out by the national body for standardisation. The procedure for the publication of national standards and all-Russia classifiers shall be determined by the federal executive body authorized by the Government of the Russian Federation.

Article 44. Federal Information Fund of Technical Regulations and Standards

1. Technical regulations, documents of the national standardisation system, international standards, standardisation rules, standardisation norms and recommendations on standardisation, national standards of other states and information about international treaties in the sphere of standardisation and compliance confirmation and about the rules of their application constitute the Federal Information Fund of Technical Regulations and Standards.

The Federal Information Fund of Technical Regulations and Standards is a state information resource.

The procedure for the creation and keeping of the Federal Information Fund of Technical Regulations and Standards and also rules for the use of this fund shall be established by the Government of the Russian Federation.

2. A unified information system, designed for the provision of information about documents of the Federal Information Fund of Technical Regulations and Standards, shall be created and shall function in the Russian Federation on the terms established by the Government of the Russian Federation.

Free access to the created information resources shall be ensured for interested persons, unless such access is restricted in the interests of protection of state, official or commercial secrets.

3. International standards, regional standards, regional rule books, standards of foreign states and rule books of foreign states, whose application on a voluntary basis results in the observance of the requirements of adopted technical regulations and which contain the rules for and methods of investigations (tests) and measurements, including the rules for selection of samples required for application and implementation of adopted technical regulations and conformity assessment, shall be subject to registration in the Federal Information Fund of Technical Regulations and Standards.

4. To register the standards and rule books cited in item 3 of this Article in the Federal Information Fund of Technical Regulations and Standards a person concerned shall file with the national standardization agency an application for registration of an appropriate standard or rule book attaching thereto a copy of such document and of a properly attested translation thereof into Russian. Opinions of all-Russia public organizations and of the Chamber of Industry and Commerce of the Russian Federation may be likewise presented jointly with the documents required for registration of a standard or rule book to the national standardization agency. These opinions may contain recommendations as to the application of an international standard, regional standard, regional rule book, standard of a foreign states and a rule book of a foreign state for ensuring the observance on a voluntary basis of adopted technical regulations, for holding investigations (tests) and making measurements, selection of samples required for application and implementation of adopted technical regulations, as well as for conformity assessment.

Within five days from the date when an application for registration of a standard or rule book is received, the national standardisation body shall forward the standard or rule book presented for registration jointly with a properly attested translation thereof into Russian to an appropriate technical standardization committee (technical standardization committees) for issuance of an opinion. If an application for registration of a standard or rule book contains the proposal to include such standard or rule book into the appropriate list of standardization documents whose application on a voluntary basis results in the observance of the requirements of adopted technical regulations and which contain the rules for and methods of investigations (tests) and measurements, in particular the rules for samples' selection which are required for application and implementation of adopted technical regulations and conformity assessment, the technical standardisation committee (technical standardisation committees) shall issue an opinion as to the possibility of applying the standard or rule book for ensuring the observance on a voluntary basis of the requirements of adopted technical regulations or for holding investigations (tests) and measurements, as well as samples' selection required for application and implementation of adopted technical regulations and conformity assessment. A technical standardization committee (technical standardization committees) within thirty days as of the date when the cited documents are received from the national standardization committee shall consider them and forward an opinion to the national standardisation committee

5. The national standardization committee within fifteen days from the date when the opinion of a technical standardization committee (technical standardization committees) cited in item 4 of this Article is received but at latest in forty five days from the date when an application for registration of a standard or rule book is received shall render the decision on registration of the presented standard or rule book or reasonably refuse to register thereof citing the reasons for the refusal.

The national standardization agency within ten days from the date when a standard or rule book is registered shall render the decision to include such standard or rule book in the list of standardization documents whose application on a voluntary basis results in the observance of the requirements of adopted technical regulations, as well as shall forward to the Government of the Russian Federation or to the federal executive power body in charge of technical regulation the proposal to include such standard or rule book into the list of standardisation documents containing the rules for and methods of investigations (tests) and measurements, in particular the rules for selection of samples required for application and implementation of adopted technical regulations and conformity assessment.

- **6.** As the grounds for the refusal to register a standard or rule book shall be deemed the following:
 - failure to satisfy the requirements provided for by item 4 of this Article;

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- reasoned opinion of a technical standardization committee (technical standardization committees) to reject the standard or rule book.
- 7. As the ground for the refusal to include a registered standard or rule book in the list of standardization documents whose application on a voluntary basis results in the observance of the requirements of adopted technical regulations shall be deemed a reasoned opinion of a technical standardization committee (technical standardization committees) that it is impossible to apply it for the purpose of conformity assessment.
- **8.** The national standardization committee within five days from the date when a decision on a standard or rule book presented for registration is adopted shall forward to the person concerned a copy of the decision together with an opinion of a technical standardization committee (technical standardization committees).

The refusal of the national standardization agency to register and/or include a standard or rule book into the list of standardization documents cited in item 7 of this Article may be appealed against judicially.

9. Where the licence agreements made with foreign right holders, as well as international treaties and other international law rules, provide for onerousness and/or inadmissibility of providing free access to standardisation documents, the national standardization agency shall arrange the official publication in the print of the federal executive power body in charge of technical regulation and insertion in a public-use information system in the electronic-digital form data on the rate of payment for providing appropriate documents and of the rules for their distribution.

The national standardisation agency shall provide on a free-of-charge basis standardization documents on demand of state power bodies or at the request of a court.

Chapter 9 Financing in the Sphere of Technical Regulation

Article 45. Procedure for Financing Expenditures in the Sphere of Technical Regulation from the Federal Budget

- 1. Outlays on the exercise of state control (supervision) on the federal level over the compliance with the requirements of technical regulations shall be covered from the federal budget. The following outlays may be covered from the federal budget:
 - on establishing and keeping the Federal Information Fund of Technical Regulations and Standards:
 - on implementation of the programme of development of technical regulations and the programme of development of national standards provided for accordingly by item12 of Article 7 and item 1 of Article 16 of this Federal Law, as well as on expert examinations of

- individual draft technical regulations and draft national standards;
- on developing standardization rules, norms and recommendations;
- on developing sets of rules
- on development of rules for, and methods of, examination (tests) and measurement, in particular rules for selection of samples for conducting examination (tests) and measurement which are necessary for application and implementation of technical regulations;
- on devising the normative documents of federal executive bodies specified in Article 5 of this Federal Law;
- on registration of voluntary certification systems and keeping of the comprehensive register of registered voluntary certification systems;
- on devising and keeping all-Russia classifiers;
- on keeping the comprehensive register of compliance certificates and the comprehensive register of declarations of compliance;
- on registration and analysis of cases when harm was inflicted as a result of non-compliance with the requirements of technical regulations;
- on payment of fees to international standardization organisations.
- **2.** The procedure of financing the expenditures, mentioned in item 1 of this Article, shall be determined y the Government of the Russian Federation.

Chapter 10 Concluding and Transitional Provisions

Article 46. Transitional Provisions

- 1. The requirements for products, or processes of design (including survey works), production, construction, installation and adjustment connected with requirements for them, operation, storage, transportation, sale and reclamation, established by decrees of the Russian Federation and by the normative documents of federal executive bodies shall be necessarily met from the day of enactment of this Federal Law pending the entry into effect of the respective technical regulations solely in the part pursuing the following goals:
 - protection of individuals' life or health, of the natural persons' or legal entities' property, state or municipal property;
 - protection of the environment, of the life or health of animals and plants;
 - prevention of actions misleading purchasers;
 - ensuring energy efficiency.
- 1.1. Prior to the date of entry into force of appropriate technical regulations the Government of the Russian Federation and federal executive bodies are entitled, within the scope of authority thereof for the purposes defined by item 1 of Article 6 of this Federal Law, to make amendments in the established procedure subject to the specifics defined by this article to normative legal acts of the Russian Federation applied before the date of entry into force of appropriate technical regulations, and federal executive bodies are entitled to amend normative documents of federal executive bodies applied before the date of entry into force of appropriate technical regulations.

Draft normative legal acts of the Russian Federation and draft normative documents of federal executive bodies on making the said amendments shall be placed in a public-use information system in electronic form at the latest sixty days before the date of adoption thereof. Such drafts completed subject to observations of persons concerned and a list of these observations received in writing shall be sent to an expert commission for technical regulation established in compliance

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with the provisions of item 9 of Article 9 of this Federal Law by the federal executive body charged with the development of such drafts at latest thirty days before the date of adoption thereof. An expert commission for technical regulation shall include on a parity basis representatives of this federal executive body, other federal executive bodies concerned, scientific organizations, self-regulated organizations, public associations of businessmen and consumers. Decisions as to the approval or rejection of such drafts shall be rendered on the basis of an opinion of an expert commission for technical regulation.

2. The obligatory confirmation of compliance shall be carried out solely in relation to products to be released into circulation on the territory of the Russian Federation from the day of enactment of this Federal Law.

Pending the date of entry into force of appropriate technical regulations, the obligatory assessment of compliance, in particular confirmation of compliance and the exercise of state control (supervision), as well as the application of the compliance mark to products, shall be effected in conformity with the rules and procedures established by normative legal acts of the Russian Federation and normative documents of federal executive bodies adopted before the date of entry into force of this Federal Law.

- **3.** Pending the entry into effect of respective technical regulations, the Government of the Russian Federation shall endorse and specify on an annual basis the comprehensive list of products subject to obligatory certification and the comprehensive list of products whose compliance has to be declared.
- **4.** Pending the entry into effect of the respective technical regulations, the scheme for the declaration of compliance on the basis of one's own proof shall be admissible for application solely by the manufacturers or solely by persons performing the functions of the foreign manufacturer.
- **5.** Pending the adoption of the respective technical regulations, technical regulation in the sphere of application of veterinary-and-sanitary and phyto-sanitary measures shall be carried out in accordance with the Federal Law on the Quarantine of Plants and with the Law of the Russian Federation on Veterinary Medicine.
- **6.** Pending the adoption of the technical regulations for nuclear and radiation safety, technical regulation in the sphere of nuclear and radiation safety shall be carried out in accordance with the Federal Law on the Utilisation of Atomic Power and with the Federal Law on Radiation Safety of the Population.
- **6.1.** Before the entry into force of the appropriate technical regulations, the technical regulation in the sphere of application of the energy efficiency requirements, requirements to lighting devices, electric lamps used in alternating current circuits for lighting shall be implemented in compliance with the Federal Law on Energy Saving and Improvement of Energy Efficiency, other federal laws, other normative legal acts of the Russian Federation in the sphere of energy

saving and improvement of energy efficiency adopted in pursuance of them, as well as the normative legal acts of the Russian Federation and normative documents of the federal bodies of executive power mentioned in items 1 and 2 of the present Article and applied where regulation is not provided in the normative legal acts mentioned in the present item. From the day of entry into force of the appropriate technical regulations, the mentioned acts shall apply as obligatory ones where regulation is not provided in the appropriate technical regulations.

- **6.2.** Before the date of entry into force of technical regulations in respect of some kinds of products and of the processes of design (including surveying works), production, construction, installation, adjustment, operation, storage, transportation, sale and utilization connected with the requirements for them the Government of the Russian Federation may introduce in respect of such kinds of products and/or processes the mandatory requirements contained in technical regulations of member-states of the customs union or in the documents of the European Union. When introducing such requirements, the Government of the Russian Federation may establish forms of assessing the conformity to such requirements and to appoint the body authorised to exercise the state control (supervision) over the observance of such requirements.
- **6.3.** Prior to the date of entry into effect of the requirements cited in item 6.2 of this Article the national standardization body shall endorse, publish in the print of the federal executive power body in charge of technical regulation and insert in a general-use information system in the electronic-digital form a list of standarisation documents used in the member-states of the customs union or in the European Union to ensure the observance of the requirements cited in Item 6.2 of this Article, as well as of the documents containing the rules for and the methods of investigations (tests) and measurements, in particular the rules for samples' selection, which are required for application and satisfaction of the cited requirements and conformity assessment. When publishing and placing this list of documents, data on the availability of translations of standards and rule books shall be stated.

The standards and rule books in respect of which data on the availability of their translations is cited in this list of documents may be applied for conformity assessment.

6.4. A person concerned may submit to the national standardisation agency for the purpose of ensuring satisfaction of the requirements cited in item 6.2 of this Article a standard or rule book and a properly attested translation thereof into Russian, if this standard or rule book are included into the list of documents cited in item 6.3 of this Article. A properly attested translation into Russian of a standard or rule book shall be subject to registration by the national standardization body within seven days from the date when it is received.

After properly attested translations of standards and rule books into Russian are presented to the national standardisation agency the cited agency within ten days shall enter to the list of standardization documents provided for by Item 6.3 of this Article data on the availability of such translations.

A procedure for registration of properly attested translations into Russian of standards and rule books and a procedure for providing information about them shall be defined by the federal executive power body in charge of technical regulation.

7. The mandatory requirements cited in item 1 of this Article for products, processes of design (including surveying works), production, construction, installation, adjustment, operation, storage, transportation, sale and utilization in respect of which technical regulations are not adopted shall be in effect pending the date of entry into force of appropriate technical regulations.

Where in respect of products and processes connected with the requirements for them the requirements cited in item 6.2 of this Article are established, an applicant shall be entitled to select

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independently the technical regulation mode in which conformity to the requirements cited in item 1 or in item 6.2 of this Article will be assessed.

When selecting the technical regulation mode, the requirements for products and processes established in compliance with some other mode shall not apply for the purpose of conformity assessment.

In case of selecting the technical regulation mode based on the requirements cited in item 6.2 of this Article, the conformity shall be assessed in compliance with the effective rules and procedures established by regulatory legal acts of the Russian Federation and regulatory documents of federal executive power bodies.

- **7.1.** The requirements for energy efficiency, as well as the requirements for lighting facilities and electric lamps used for lighting in alternating-current mains, which are established in compliance with item 6.1 of this Article, shall be subject to mandatory application pending the date of entry of appropriate technical regulations into force, and from the date when they enter into force they shall be subject to obligatory application in the area which is not regulated by appropriate technical regulations.
- **8.** Documents of accreditation, issued in established procedure to certification agencies and to accredited test laboratories (centres), pending the enactment of this Federal Law, and also documents confirming compliance (compliance certificate, declaration of compliance) and adopted before the enactment of this Federal Law shall be regarded as valid until the expiration of their time limit.
- **9.** For the purpose of carrying out the works aimed at proving conformity to the requirements and the standardization documents cited in items 6.2 and 6.3 of this Article, the certification agencies and testing laboratories (centers) shall apply to the accreditation body for the accreditation certificate proving an appropriate accreditation area or expansion of the accreditation area.

Article 47. Bringing Decrees into Line with This Federal Law

The following normative documents shall be regarded as invalid from the day of enactment of this Federal Law:

- Law of the Russian Federation No. 5151-I of July 10, 1993 on Certification of Products and Services (Vedomosti Syezda narodnykh deputatov i Verkhovnogo Soveta Rossiiskoi Federatsii, No. 26, 1993, Item 966);
- Decision of the Supreme Soviet of the Russian Federation No. 5153-I of June 10, 1993 on the Enactment of the Law of the Russian Federation on Certification of Products and Services (Vedomosti Syezda narodnykh deputatov i Verkhovnogo Soveta Rossiiskoi Federatsii, No. 26, 1993, Item 967);
- Law of the Russian Federation No. 5154-I of June 10, 1993 on Standardisation (Vedomosti

- Syezda narodnykh deputatov i Verkhovnogo Soveta Rossiiskoi Federatsii, No. 25, 1993, Item 917);
- Decision of the Supreme Soviet of the Russian Federation No. 5156-I of June 10, 1993 on the Enactment of the Law of the Russian Federation on Standardisation (Vedomosti Syezda narodnykh deputatov i Verkhovnogo Soveta Rossiiskoi Federatsii, No. 25, 1993, Item 918);
- Items 12 and 13 of Article 1 of the Federal Law No. 211-FZ of December 27, 1995 on the Introduction of Amendments and Addenda to Individual Legislative Acts of the Russian Federation in Connection with the Enactment of the Federal Law On Fire Safety (Sobraniye zakonodatelstva Rossiiskoi Federatsii, No. 1, 1996, Item 4);
- Item 2 of Article 1 of the Federal Law No. 30-FZ of March 2, 1998 on the Introduction of Amendments and Addenda to Individual Legislative Acts of the Russian Federation in Connection with the Adoption of the Federal Law on Advertising (Sobraniye zakonodatelstva Rossiiskoi Federatsii, No. 10, 1998, Item 1143);
- Federal Law No. 154-FZ of July 31, 1998 on the Introduction of Amendments and Addenda to the Law of the Russian Federation on Certification of Products and Services (Sobraniye zakonodatelstva Rossiiskoi Federatsii, No. 31, 1998, Item 3832);
- Article 2 of the Federal law No. 87-FZ of July 10, 2002 on the Introduction of an Amendment to Article 6 of the Federal Law on the Principles of Social Services in the Russian Federation and of an addendum to Article 2 of the Law of the Russian Federation on Standardisation (Sobraniye zakonodatelstva Rossiskoi Federatsii, No. 28, 2002, Item 2791);
- Article 13 and 14 of the Federal Law No. 116-FZ of July 25, 2002 on the Introduction of Amendments and Addenda to Certain Legislative Acts of the Russian Federation in Connection with the Improvement of State Administration in the Sphere of Fire Safety (Sobraniye zakonodatelstva Rossiiskoi Federatsii, No. 30, 2002, Item 3033).

Article 48. Enactment of This Federal Law

This Federal Law shall take effect upon the expiration of six months from the day of its official publication.

President of the Russian Federation Vladimir Puti	n
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Moscow, the Kremlin December 27, 2002 No. 185-FZ