Registered with the Ministry of Justice of the Russian Federation on March 19, 2012, No. 23509

FEDERAL ENVIRONMENTAL, INDUSTRIAL AND NUCLEAR SUPERVISION SERVICE OF RUSSIA

ORDER

of February 07, 2012, No. 85

ON APPROVAL OF FEDERAL CODES AND REGULATIONS IN THE FIELD OF ATOMIC ENERGY USE "REQUIREMENTS FOR QUALITY ASSURANCE PROGRAMS OF NUCLEAR FACILITIES"

Pursuant to Article 6 of the Federal Law of November 21, 1995, No. 170-FZ "On Use of Atomic Energy" (Code of laws of the Russian Federation, 1995, No. 48, article 4552; 1997, No. 7, article 808; 2001, No. 29, article 2949; 2002, No. 1, article 2; No. 13, article 1180; 2003, No. 46, article 4436; 2004, No. 35, article 3607; 2006, No. 52, article 5498; 2007, No. 7, article 834; No. 49, article 6079; 2008, No. 29, article 3418; No. 30, article 3616; 2009, No. 1, article 17; No. 52, article 6450; 2011, No. 29, article 4281; No. 30, article 4590; No. 30, article 4596; No. 45, article 6333; No. 48, article 6732; No. 49, article 7025), item 5.2.2.1 of Provisions on the Federal Environmental, Industrial and Nuclear Supervision Service of Russia of July 30 2004, No. 401 (Code of laws of the Russian Federation 2004, No. 32, article 3348; 2006, No. 5, article 544; No. 23, article 2527; No. 52, article 5587; 2008, No. 22, article 2581; No. 46, article 5337; 2009, No. 6, article 738; No. 33, article 4081; No. 49, article 5976; 2010, No. 9, article 960; No. 26, article 3350; No. 38, article 4835; 2011, No. 6, article 888; No. 14, article 1935; No. 41, article 5750; No. 50, article 7385), the following order is issued:

1. To approve the attached federal codes and regulations in the field of atomic energy use entitled as "Requirements to quality assurance programs of nuclear facilities" (NP-090-11).

2. The issued order shall come into effect since coming into effect of the resolution of the Government of the Russian Federation on introduction of respective changes into the List of federal codes and regulations in the field of atomic energy use approved by the resolution of the Government of the Russian Federation of December 1, 1997, No. 1511 (Code of laws of the Russian Federation, 1997, No. 49, article 5600; 1999, No. 27, article 3380; 2000, No. 28, article 2981; 2002, No. 4, article 325; No. 44, article 4392; 2003, No. 40, article 3899; 2005, No. 23, article 2278; 2006, No. 50, article 5346; 2007, No. 14, article 1692; No. 46, article 5583; 2008, No. 15, article 1549).

Chairman

N. KUTIN

Approved by
Order of the Federal
Environmental, Industrial
and Nuclear Supervision Service
of February 07, 2012, No. 85

FEDERAL CODES AND REGULATIONS IN THE FIELD OF ATOMIC ENERGY USE "REQUIREMENTS TO QUALITY ASSURANCE PROGRAMS OF NUCLEAR FACILITIES" (NP-090-11)

I. Purpose and Scope of Application

1. The federal code and regulation in the field of atomic energy use entitled as "Requirements to quality assurance programs of nuclear facilities" (hereinafter referred to as "the Regulation") have been written in accordance with the Federal Law of November 21, 1995, No. 170-FZ "On Atomic Energy Use" (Code of laws of the Russian Federation, 1995, No. 48, article 4552; 1997, No. 7, article 808; 2001, No. 29, article 2949; 2002, No. 1, article 2; No. 13, article 1180; 2003, No. 46, article 4436; 2004, No. 35, article 3607; 2006, No. 52, article 5498; 2007, No. 7, article 834; No. 49, article 6079; 2008, No. 29, article 3418; No. 30, article 3616; 2009, No. 1, article 17; No. 52, article 6450; 2011, No. 29, article 4281; No. 30, article 4590; No. 30, article 4596; No. 45, article 6333; No. 48, article 6732; No. 49, article 7025), resolution of the Government of the Russian Federation of December 1, 1997, No. 1511 "On approval of the Provisions on development and approval of federal codes and regulations in the field of atomic energy use and of the list of federal codes and regulations in the field of atomic energy use" (Code of laws of the Russian Federation, 1997, No. 49, article 5600; 1999, No. 27, article 3380; 2000, No. 28, article 2981; 2002, No. 4, article 325; No. 44, article 4392; 2003, No. 40, article 3899; 2005, No.

23, article 2278; 2006, No. 50, article 5346; 2007, No. 14, article 1692; No. 46, article 5583; 2008, No. 15, article 1549).

2. The Regulation sets requirements to the structure, content and the procedure of development of quality assurance programs (hereinafter referred to as "QAP") to be applied at nuclear facilities.

3. The terms and definitions used are given in the Appendix to this Regulation.

II. General Provisions

4. QAPs for nuclear facilities are comprised of:

1) general QAP, which applies to all the works and services related to the safety of a nuclear facility during all life-cycle stages;

2) specific QAPs of the organizations that carry out activities related to the safety of a nuclear facility at a particular life-cycle stage and (or) when they fulfill a licensable activity in the field of atomic energy use.

5. The operating organization (or the leading design organization - regarding ships and other means of transportation or mobile objects with nuclear installations) shall perform the following activities:

1) organization of development, approval, putting into force, fulfillment, verification of fulfillment and efficiency assessment of the general QAP;

2) agreeing upon, control of fulfillment and efficiency assessment of QAPs of organizations performing works and rendering services to the operating organization.

6. The organization performing works in the field of atomic energy use shall carry out the following activities:

1) organization of development, approval, putting into force, fulfillment, verification of fulfillment and efficiency assessment of its own specific QAP;

2) agreeing upon, control over fulfillment and efficiency assessment of specific QAPs of its subcontractors.

7. Development of one QAP for several types of activities in the field of atomic energy use regarding one or several nuclear facilities, where the given activities are performed, as

well as development of one specific QAP during design (elements design) and/or during manufacture of several items delivered to a nuclear facility, or during performance of works (providing services) at different nuclear facilities shall be justified in a respective QAP.

8. QAP shall be approved and put into effect in the organization before the beginning of activity in the field of atomic energy use to which it applies.

9. Administrative and technical, and other quality assurance activities mentioned in the QAP shall be based on a differentiated approach considering safety classification of systems (elements) and structures of the nuclear facility according to the federal codes and regulations in the field of atomic energy use.

III. Requirements to Content of Quality Assurance Programs

10. The general QAP shall have to the following content:

1) scope of application, sections mentioned in items 14 - 17, 19, 24, 25 of this Regulation;

2) requirements to specific QAPs for every life-cycle stage of the nuclear facility.

In case development of specific QAPs is not necessary, the content of the general QAP shall meet the requirements of all items of section IV of this Regulation.

11. The specific QAP shall have to the following content:

1) scope of application, sections mentioned in items 14 - 25 of this Regulation and developed in relation to the specific activities covered by the QAP and in accordance with the requirements of the general QAP (the specific QAP may omit the sections related to activities not performed by the organization provided that the reasons why the organization does not perform such activities are specified in these sections);

2) grounds for development of the specific QAP, as well as information on other QAPs, effective or planned to be developed, related to the QAP being developed (if such QAPs exist).

3) additional requirements to specific QAPs of the organizations performing works and rendering services to the operating organization (if such requirements exist).

12. The QAP shall set the procedure for its revision (at least once in 5 years) and for making necessary modifications and addenda.

13. In case the organization developing the QAP is governed by a quality management system or management system (hereinafter referred to as QMS), which had been developed in accordance with the national and/or international standards, such QAP shall have brief information on the QMS (including the QMS scope of application, information on the QMS compliance certificate, requirements set, validity period, references to QMS documented procedures used during development and fulfillment of the QAP).

IV. Requirements to Content of the Sections of QAPs

14. Quality Policy

The section shall present the quality policy of the organization developing the QAP specifying the following:

1) the priority to assure safety of the nuclear facility during performance of works in the field of atomic energy use;

2) main quality goals and methods to achieve them;

3) the duties of the management of the organization developing the QAP in the area of quality.

15. Organizational Activities

The section shall contain the following:

1) information on organizational structure of organization management as related to QAP fulfillment and description of the procedure for organizational modifications management;

2) brief information on the main functional duties, powers and responsibilities of the officials managing the development and realization of the QAP, as well as those who verify fulfillment and efficiency assessment of the QAP, including information on distribution of responsibility of officials (departments) performing works and verifying work quality;

3) main information on functions and interaction between organization departments participating in development of QAP;

4) main information on the procedure of interaction with the customer, superior organizations (if such exist), contractors, other organizations performing activities in the field of atomic energy, federal executive power authorities and authorized organizations engaged in state regulation of use of atomic energy and state regulations of safety during use or atomic energy.

16. Personnel Management

The section shall contain information on the management procedure of the personnel involved in performance and verification of works falling under the QAP, during the stages of selection, recruitment, training, qualification maintaining, advanced training and admission to unsupervised work.

A description shall be given of the procedures providing for the following:

1) determination of the demand in quantity of personnel, level of their training and qualification;

2) shaping and maintaining the organization's safety culture;

3) certification and/or examination of the knowledge and skills of the personnel performing works (rendering services) affecting safety of the nuclear facility;

4) development, fulfillment, analysis and correction of the programs for training, refresher training, advanced training and examination of knowledge and/or certification of personnel;

5) keeping documentation (records) on personnel management.

The section shall contain the requirement demanding that the job descriptions of the personnel and/or other documents of the organization shall contain requirements to duties, qualification, span of knowledge and skills of the personnel.

17. Documentation Management

The section shall contain the following:

1) description of effective procedures:

a) development, agreeing upon, approval, putting into force, identification, accounting, modifications, revisions, distribution, storage of documents, keeping their due quality, cancellation and destruction of revoked documents;

b) shaping and keeping records including determination of type of records, identification, registration, storage, protection, recovery and destruction of records;

2) list of regulatory and technical documents, used in the organization during performance of activities described in the QAP (or a reference to such list).

18. Design (engineering) Control

The section shall contain description of procedures for the following:

1) control of fulfillment in the design of the nuclear facility of the codes and regulations in the field of atomic energy, performance specification (or other document containing necessary and sufficient requirements to the design of an item), other documents;

2) quality assurance and quality control of a nuclear facility design, including control of input and output data, the process of design (elements design), examination of design and engineering documentation;

3) modification of design (elements design) documentation, as well as modification of building structures, nuclear facility constructions and systems (their elements) important for safety of the nuclear facility (including during repair, reconstruction, modernization and replacement of the mentioned items).

19. Management of Procurement of Equipment, Components, Materials, Semi-finished Products, Software Tools and Services

The section shall contain description of procedures for the following:

1) assessment and selection of organizations which perform activities and render services to the operating organization;

2) analysis of documentation related to quality and safety of the procured equipment, components, materials, semi-finished products, software tools, as well as rendered services, in order to provide for the fulfillment of the requirements set;

3) identification, ensuring use of the full scope of types of control and tests for the purchased equipment, components, materials, semi-finished products, and software tools;

4) storage, transportation, mothballing, packaging of equipment, components, materials and semi-finished products;

5) assessment of compliance of the equipment, components, materials, semi-finished products and software tools;

6) incoming inspection of the purchased equipment, components, semi-finished products and software tools;

7) acceptance of the works performed and services rendered.

20. Production Activity

The section shall contain the description of procedures for planning, performance and control of the main production processes carried out during performance of activities covered by the QAP.

The section shall contain inter alia:

1) description of effective procedures:

a) for production preparation;

b) fulfillment and control of the production activities (including processes where it is difficult or economically unpractical to verify the compliance of the finished items);

c) technical control (including non-destructive examination);

d) designer supervision and maintenance;

2) description of procedures:

a) for technical witnessing, maintenance, repair, reconstruction, modernization of systems (their elements);

b) prolongation of service life of the systems (their elements) important for safety of the nuclear facility (applies to the operating organization);

c) ensuring the necessary control (including operational control of metals), diagnostics, testing and examination of systems (elements) important for safety and performance of the mentioned activities according to the set criteria and schedules;

d) qualification of the welding procedure, methods for equipment control and diagnostics;

e) assessment of compliance of equipment, components, semi-finished products and materials (applies to the manufacturing organizations);

f) ensuring emergency preparedness of the nuclear facility (applies to the operating organization).

21. Metrological Support

The section shall contain description of procedures for the following:

1) keeping the measuring tools in working condition;

2) examination (calibration) of the measuring tools;

3) accounting and qualification of the measuring equipment;

4) accounting and qualification of measurement methods;

5) metrological expert review of the documentation developed within the organization;

6) performance of metrological supervision over the condition and application of the measuring tools, standard specimen, methods of measurement, observance of schedules for examination (calibration) of measuring tools.

22. Quality Assurance of Software Tools and Calculation Techniques

The section shall contain the following:

1) list (or a reference to it) of effective calculation techniques and qualified software tools applied during assessment and (or) ensuring safety of a nuclear facility, as well as during assessment of system (element) parameters including their strength, durability and reliability;

2) description of effective quality assurance procedures for software tools and calculation techniques, including their qualification and verification.

23. Reliability Assurance

The section shall contain description of procedures for the following:

1) assurance of reliability and control of compliance with the requirements to reliability indicators of systems (elements) important for safety and other systems (elements) taken into consideration during performance of the probabilistic safety analysis, during the whole period of operation (including extended period of operation);

2) collection, registration, processing, accumulation, storage, analysis and distribution of information on reliability of systems (elements) important for safety of the nuclear facility

to the interested organizations performing works and/or rendering services to the operating organization.

24. Non-conformance Management

The section shall contain description of procedures for the following:

1) identification and recording of non-conformities;

2) determination and analysis of causes of non-conformances identified (taking into account the impact of non-conformities on safety of the nuclear facility);

3) ensuring that non-conforming products, works and services are never used;

4) notification of the management about non-conformities identified;

5) capturing tendencies of changing causes and nature of violations based on the results of non-conformity analysis;

6) development, implementation, control of implementation of corrective and preventive actions, analysis of efficiency of such measures.

25. Audits (Inspections)

The section shall contain the procedure for performance of audits (inspections) aimed at verification of implementation of the QAP, as well as of QAPs of contractors and subcontractors, providing for the following:

1) planning of audits (inspections) regarding QAP implementation;

2) establishing committee comprised of competent and independent specialists;

3) development of criteria to assess QAP effectiveness;

4) assessment of QAP implementation effectiveness in accordance with the criteria set;

5) documenting the results of audits (inspections) regarding QAP implementation;

6) review of the results of audits and assessment of QAP effectiveness as implemented by the management of the organization and, if necessary, development, implementation and control of implementation of plans of corrective and preventive actions.

Appendix
to the Requirements to Quality Assurance Programs
of Nuclear Facilities
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TERMS AND DEFINITIONS

The following terms and their definitions are used in the present document.

1. Nuclear Facility lifetime - (depending on the category of the facility) - siting, designing (including survey), engineering, production, building or construction (including installation, pre-commissioning, commissioning), operation, reconstruction, overhaul, decommissioning (closure), transportation (transfer), handling, storage and disposal of nuclear facilities;

2. Quality Assurance is a part of a coordinated work on quality management aimed at building confidence that quality requirements are met.

3. Quality Policy - general intentions and directions of quality-related activity formally defined by the top management.

4. Quality assurance program (QAP) - a document which defines the set of organizational and technical arrangements for safety assurance affecting safety of a nuclear facility.