GOVERNMENT OF THE RUSSIAN FEDERATION

DECREE

No. 612 of July 20, 2013

ON ACCREDITATION IN THE FIELD OF ATOMIC ENERGY USE

In accordance with the Federal Law "On Atomic Energy Use" the Government of the Russian Federation decrees the following:

1. To approve the Accreditation Rules for certification bodies and test laboratories (Centers) working on justification of compliance of products subject to requirements related to safety assurance in the field of atomic energy use, obligatory requirements, related to certification of accreditation experts in the field of atomic energy use, and engagement and recruiting of accreditation experts in the field of atomic energy use and technical experts to work on accreditation (hereinafter referred to as Accreditation Rules).

2. To establish that the State Atomic Energy Corporation "Rosatom" performs accreditation of certification bodies and test laboratories (centers) working on justification of compliance of products subject to requirements related to safety assurance in the field of atomic energy use (hereinafter referred to as accreditation), and to certification of accreditation experts (hereinafter referred to as certification).

3. To establish that accreditation activities related to the field of work of the federal executive authorities exercising state nuclear regulation and state regulation of the safe atomic energy use shall be exercised by the State Atomic Energy Corporation "Rosatom" in compliance with agreements on interaction with the said federal executive authorities on the issues of accreditation.

4. To establish that the State Atomic Energy Corporation "Rosatom" keeps the register of certification bodies and test laboratories (centers) working on justification of compliance of products subject to requirements related to safety assurance in the field of atomic energy use, obligatory requirements, and to keeping the register of accreditation

experts and the register of issued compliance certificates for products.

5. To establish that the accreditation documents issued before the given Decree has come into force are valid until their expiry date.

ConsultantPlus: Note.

Item 6 of the document is in force since July 29, 2013 (Item 9 of the document).

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6. State Atomic Energy Corporation "Rosatom" shall do the following during 9 months:

approve the procedure for keeping and the form of the register of certification bodies and test laboratories (centers) working on justification of compliance of products subject to requirements related to safety assurance in the field of atomic energy use, to obligatory requirements; the procedure for keeping and the form of the register of accreditation experts; the procedure for keeping and the form of the register of issued compliance certificates for products; as well as the procedure for provision of the data contained in the said registers;

approve the methodology for determining amount of payment for review of compliance of applicants' and certified individuals with the certification criteria defined by the certification bodies and test laboratories (centers), as well as requirements to them provided in the Annex to the Accreditation Rules;

approve the procedure for collecting payment for review of compliance of applicants' and certified individuals with the certification criteria defined by the certification bodies and test laboratories (centers), as well as requirements to them provided in the Annex to the Accreditation Rules;

create a certification commission to hold qualification examination for individuals pretending to the status of an accreditation expert and passing the procedure aimed at proving their competences;

approve the form of the accreditation certificate and the form of its annexes;

approve the form of the accreditation certificate for accreditation experts;

approve the form for the accreditation authority to decide on assessment of

compliance of an applicant with the accreditation criteria of the certification bodies and test laboratories (centers), and requirements to them which are provided in the Annex to the Accreditation Rules;

approve the forms of applications for accreditation, accreditation extension, reissuing of accreditation certificates, issuing a duplicate of the accreditation certificate; for reduction of the accreditation field; for cancellation of an accreditation certificate issued by the certification bodies and test laboratories (centers);

approve the forms of applications for certification of an accreditation expert, for reissuing qualification certificates of accreditation experts, for issuing a duplicate of a qualification certificate of an accreditation expert, for issuing a copy of a qualification certificate of an accreditation expert and for cancellation of a qualification certificate of an accreditation expert.

ConsultantPlus: Note.

Item 7 of the document is in force since July 29, 2013 (Item 9 of the document).

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7. State Atomic Energy Corporation "Rosatom" in interaction with the Federal Environmental, Industrial and Nuclear Supervision Service of Russia shall approve the following in the course of 9 months:

Provision for a certification commission to hold qualification examination for individuals pretending to the status of an accreditation expert and passing the procedure aimed at proving competences of an accreditation expert;

Provision for work of an expert commission;

Procedure of qualification examination for individuals pretending to the status of an accreditation expert and passing the procedure aimed at proving competences of an accreditation expert;

Methodology for accounting of factors influencing recruitment of accreditation and technical experts;

Procedure of forming of an appeal commission and its work on review of appeals against decisions or actions (inactions) of the accreditation authority.

8. Determine that the provisions of the given Decree are not applied in accreditation of authorities to perform works on approval of compliance with the requirements of products delivered to civil nuclear ships and other vessels with nuclear installations and radiation sources, and to ships transporting radioactive materials.

9. This Decree comes into force one day after its official publication, except for items 6 and 7 of the Decree, as they come into the force since official publication of the Decree.

Prime Minister
of the Russian Federation
D.Medvedev

Approved by
Resolution of the Government
of the Russian Federation
No. 612 of July 20, 2013

THE ACCREDITATION RULES FOR CERTIFICATION BODIES AND TEST LABORATORIES (CENTERS) WORKING ON COMPLIANCE APPROVAL FOR PRODUCTS SUBJECT TO REQUIREMENTS RELATED TO SAFETY ASSURANCE IN THE FIELD OF ATOMIC ENERGY USE, OBLIGATORY REQUIREMENTS, CERTIFICATION OF EXPERTS ON ACCREDITATION IN THE FIELD OF ATOMIC ENERGY USE, AND ENGAGEMENT AND RECRUITMENT OF ACCREDITATION EXPERTS IN THE FIELD OF ATOMIC ENERGY USE AND TECHNICAL EXPERTS TO PERFORM ACCREDITATION ACTIVITIES

I. General

1. These Rules establish procedure for accreditation of certification bodies and test laboratories (Centers) working on justification of compliance of products subject to requirements related to safety assurance in the field of atomic energy use (hereinafter referred to as products), obligatory requirements, related to certification of accreditation experts in the field of atomic energy use, and engagement and recruiting of accreditation experts in the field of atomic energy use and technical experts to work on accreditation.

Accreditation of certification bodies and test laboratories (centers) working on justification of compliance of products subject to obligatory requirements is performed by the State Atomic Energy Corporation "Rosatom" (hereinafter referred to as Accreditation Authority) in compliance with the given Rules and accreditation criteria for certification bodies and test laboratories (centers) and requirements to them as per the Annex

(hereinafter referred to as accreditation criteria).

2. The terms used in the Rules have the following meaning:

"accreditation": official acknowledgment by the accreditation authority of competence of a legal entity to perform works on approval of compliance of products with obligatory requirements;

"certified body": legal entity certified as a certification body, test laboratory (center) in compliance with the procedure defined by the given Rules;

"certification of accreditation experts": approval of compliance of an individual with the established requirements and acknowledgment of his/her competence to take part in accreditation activities;

"field review": assessment of compliance of an applicant or certified individual with accreditation criteria performed in the location (locations) of activities performed in the specified accreditation field;

"documentary review": the process of assessment of compliance of an applicant with the accreditation criteria by analyzing applicant's documents which prove its compliance with the accreditation criteria in the specified accreditation field;

"applicant": legal entity pretending to accreditation as a certification body, test laboratory (center);

"inspection control": procedure proving compliance of a certified body with the accreditation criteria;

"field of accreditation": field of activity of a legal entity regarding approval of compliance of products with obligatory requirements which has been applied for by the applicant and (or) for which an accreditation certificate has been provided;

"certification field": field of work of an accreditation expert who has got a qualification certificate of this accreditation expert;

"candidate": a physical person pretending to the status of an accreditation expert;

"certificate on qualification of an accreditation expert": a document proving certification of an individual as an accreditation expert in specific certification field;

"technical expert": a physical person with knowledge in specific accreditation field and engaged by the accreditation authority into works required for assessment of

compliance of applicants and certified individuals with the accreditation criteria;

"accreditation expert": a physical person who is certified by the accreditation authority and engaged by this authority into assessment of compliance of an applicant or certified body with the accreditation requirements in specific field of accreditation.

3. The accreditation authority performs the following within its accreditation activities and certification of accreditation experts:

a) review of documentation provided by applicants pretending to be certified;

b) decision making on accreditation (including extension or termination in the field of accreditation), denial in accreditation and suspension, renewal and termination of an accreditation certificate;

c) forming expert commissions and ensuring their work;

d) issuing and reissuing accreditation certificates and their duplicates;

e) forming certification commission and certification of accreditation experts;

f) decision making on reissue and termination of qualification certificate of an accreditation expert;

g) providing interested individuals with information on the accreditation procedure and certification of accreditation experts;

h) review of appeals of applicants, candidates, certified individuals and accreditation experts.

4. When conducting accreditation, the accreditation authority ensures protection of information with data classified as state secrete, trade secrete and other legally protected secret and data with restricted access in compliance with the legislation of the Russian Federation.

II. Procedure and conditions of issue and reissue of accreditation certificates

5. To obtain an accreditation certificate, applicants submit to the accreditation authority their application on accreditation of certification bodies and test laboratories (centers) as per the form defined by the accreditation authority (hereinafter referred to as accreditation application). The following has to be indicated in accreditation applications:

a) full and short (if available) names of the applicant, its organizational and legal

form, address (location), telephone number and e-mail (if available);

b) addresses of locations where activities in the applied accreditation field are conducted;

c) taxpayer identification number;

d) applied accreditation field (list of products in relation to which the applicant plans to conduct work on approval of compliance of the products with the obligatory requirements; list of regulatory and legal acts and documents which establish requirements to the products indicated by the applicant in compliance with the legislation of the Russian Federation in the field of atomic energy use, technical regulation and uniformity of measurements; and a list of regulatory documents with requirements to techniques (methodologies) of tests (measurements) of each type of products indicated by the applicant).

6. Accreditation application is signed by the applicant's manager or his/her authorized representative.

7. The following documents are to be submitted within the accreditation application:

duly certified copies of constituent documents;

documents (copies) proving applicant's compliance with the accreditation criteria;

written consent of the applicant for inspection control in compliance with the Rules;

list of the attached documents.

In addition, the Applicant has the right to submit the following to the accreditation authority:

extract from the Unified State Register of Legal Entities;

a copy of a certificate of the state registration of the legal entity;

a copy of a certificate of registration at the tax authority.

8. Accreditation application and attached documents are submitted (provided) on hard copies by the applicant personally to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature via information and telecommunication network "Internet" (hereinafter referred to as Internet).

Documents in a foreign language are provided with their certified translation into Russian.

The accreditation authority requests data proving the fact of introduction of the applicant's information into the Unified State Register of Legal Entities from the federal executive authority which exercises state registration of legal entities and individual entrepreneurs. The accreditation authority also requests data proving the fact of registration of the applicant in the tax authority, i.e. the federal executive authority exercising functions of control and supervision over compliance with legislation of the Russian Federation in the field of taxes and duties, based on interdepartmental requests through the unified system of the interdepartmental digital interaction (in case the documents proving such information are not provided by the applicant within the documents submitted in the accreditation application).

In case data on the applicant are not in the Unified State Register of Legal Entities, in 20 days after registering the accreditation application the accreditation authority gives the Applicant a copy of the decree on accreditation denial, the accreditation application with attached documents or sends them in a registered letter with a return receipt or in the form of a digital document with a digital signature.

The accreditation authority does not have the right to require the applicant to provide documents which are not stipulated by Items 5 and 7 of the given Rules.

9. Accreditation application with attachments are accepted according to a list and the accreditation authority registers them on the date of receipt. A copy of the list with the date when the accreditation application and attachments were received, is given to the applicant or sent in a registered letter with a return receipt or in the form of a digital document with a digital signature.

10. The accreditation authority examines completeness of the documents submitted by the applicant in the course of 5 days.

If the applicant did not provide the documents in the full scope and (or) the accreditation application was not properly developed, in 7 days after registration the accreditation authority provides the applicant with its notification on elimination of non-conformities and (or) provision of missing documents in 10-day term.

The notification is sent in a registered letter with a return receipt or in the form of a digital document with a digital signature.

11. If the applicant does not provide in due term properly developed accreditation application and (or) full set of documents identified in Item 7 of the given Rules, the accreditation authority gives the applicant a copy of decision on accreditation denial, the accreditation application with its attachments, or it sends them in a a registered letter with a return receipt or in the form of a digital document with a digital signature.

12. Decision on accreditation or its denial is made by the accreditation authority on the basis of assessment of applicant's compliance with the accreditation criteria. The decision is made within 90 days since the applicant has provided properly developed accreditation application and a full set of required documents.

13. An expert commission performs assessment of the applicant's compliance with the accreditation criteria based on the decision made by the accreditation authority regarding such an assessment in the form of a documentary review and a field review.

The accreditation authority approves the form of its decision on conducting assessment of applicant's compliance with the accreditation criteria.

The composition of such a commission is decided by the accreditation authority in its decree on assessment of the applicant's compliance with the accreditation criteria. The expert commission is guided by the Provisions approved by the accreditation authority in agreement with the Federal Environmental, Industrial and Nuclear Supervision Service of Russia.

The expert commission consists of accreditation experts and, if necessary, technical experts. The expert commission is headed by its chairperson who is appointed by the accreditation authority from among the accreditation experts included into the commission.

Expert commission is composed in compliance with the accounting methodology of factors (hereinafter referred to as factors accounting methodology) which influence the process of recruitment of accreditation experts and technical experts in the field of atomic energy use. The methodology is approved by the accreditation authority with the approval by the Federal Environmental, Industrial and Nuclear Supervision Service of Russia.

Information on the composition of the expert commission is sent by the accreditation authority to the applicant in a registered letter with a return receipt or in the form of a

digital document with a digital signature. In 3-day term after receiving such information, the applicant has the right to provide the accreditation authority with information on non-conformance of an accreditation expert or technical expert included into the expert commission with the provisions envisaged in items 89 - 90 of the given Rules.

In case the fact of an accreditation expert or technical expert not meeting the said provisions is proved, the accreditation authority makes a decision on replacement or exclusion of such accreditation and technical experts from the commission in the course of 3 days after the non-compliance fact is proved.

Having been made a decision by the accreditation authority, appropriate information is sent to the applicant in 3-day term in a registered letter with a return receipt or in the form of a digital document with a digital signature.

14. Documentary review is performed by the expert commission in the course 40 days after the applicant has submitted the accreditation application with attachments. Results of review of applicant's documentation are provided in the expert conclusion which is signed by all the members of the expert commission who took part in the review, they are also approved by the chairperson of the commission in the course of 2 work days after completion of the review.

The expert conclusion is provided in 2 copies and contains the following information:

- date, time and place of drawing up of the conclusion;

data and number of the decision made by the accreditation authority on conducting assessment of compliance of the applicant with the accreditation criteria which is used as a basis for the documentary review;

family names, names and patronymic names of accreditation and technical experts, and name of the chairperson of the expert commission;

name of the reviewed applicant;

list of reviewed documents which prove applicant's compliance with the accreditation criteria;

information on the results of the documentary review, including assessment of compliance of the provided documents which prove applicant's compliance with the accreditation criteria in the applied field of accreditation;

conclusion on compliance (non-conformity) of the applicant with the accreditation criteria based on the results of the documentary review; there are to be given such criteria and basis for appropriate conclusions.

One copy of the expert conclusion is given to the head of the applicant (or representative) against signed receipt or it is sent by post with the delivery notification.

In two-day term upon receiving the expert conclusion, the applicant submits it to the accreditation authority in person or sends it by post with the delivery notification.

15. Based on the documentary review, the accreditation authority makes one of the following decisions:

a) denial in accreditation: in case the applicant does not meet the accreditation criteria;

b) on assessment of compliance of the applicant with the accreditation criteria by the location (locations) of implementation of activities in the field applied for accreditation (hereinafter referred to as field review).

16. In case denial is decided, in 3-work-day term after it has been made the accreditation authority gives the applicant a copy of the order on denial in accreditation with the reasons of denial and its reference details; the accreditation application with attached documents or sends them in a registered letter with a return receipt or in the form of a digital document with a digital signature.

17. Field review is performed by the expert commission and officials of the accreditation authority in compliance with the program of the field review which is approved by the accreditation authority and is an attachment to decision made by the accreditation authority regarding assessment of compliance of the applicant with the accreditation criteria (hereinafter referred to as assessment program).

The assessment program and notification on the period of the field review shall be sent to the applicant by the accreditation authority in a registered letter with a return receipt or in the form of a digital document with a digital signature within 3 days before the start of the review.

18. The assessment program contains the following:

a) list of works to be held during field review;

b) list of exams which are performed by the officials of the accreditation authority and are aimed at proving reliability of data provided in the act of the field review.

19. Maximum term of field review shall not exceed 20 work days.

Based on the results of the field review, a field review act is prepared in two copies, the following is to be indicated there:

- date, time and place of drawing up of the act;

data and number of the decision made by the accreditation authority on conducting assessment of compliance of the applicant with the accreditation criteria which is used as a basis for the field review;

family names, names and patronymic names of accreditation and technical experts;

name of the reviewed applicant;

family name, name, patronymic name, position of the applicant's representative who attended the field review;

date, time and location (locations) where the field review was held;

data on the results of the field review, conclusion on compliance (non-conformance) of the applicant with the accreditation criteria; provision of those criteria and reasons for appropriate conclusions;

information about applicant's representatives and individuals participating in the field inspection familiarization or denial in familiarization with the act.

The act of the field review is signed by the members of the expert commission and it is approved by its chairperson during 2 work days after completion of the field review.

One copy of the act of the field review is given to the head of the applicant (or representative) against signed receipt or it is sent by post with the delivery notification.

In two-day term upon receiving the field review act, the applicant submits it to the accreditation authority in person or sends it by post with the delivery notification.

The field review act is attached to the expert conclusion developed in compliance with item 14 of the given Rules.

20. The documentary and field reviews, except for the field review held within an ad hoc inspection in compliance with item 38 of the given Rules, are held on a paid basis. The amount of payment and payment procedure are defined in compliance with the

methodology of determination of payment amount for assessment of compliance of applicants and certified individuals with the accreditation criteria and payment procedure for their compliance assessment which are approved by the accreditation authority.

21. The accreditation authority performs examinations foreseen under the assessment program to prove reliability of data indicated in the act of the field review.

Based on the results of the said examination, the accreditation authority makes a decision on accreditation of the applicant or denial in accreditation with indication of reasons for appropriate conclusions.

22. In case it is decided positively on accreditation, the accreditation certificate is issued with the accreditation order. The form of the accreditation certificate and its appendices is defined by the accreditation authority.

The accreditation certificate is valid for 5 years.

23. In 5-day-term after deciding on accreditation, the accreditation authority gives the accreditation certificate to the applicant (authorized representative) or sends it by post with the delivery notification.

24. The basis for denial in accreditation includes the following:

a) the applicant does not meet the accreditation criteria;

b) unreliable information in the accreditation application and its attachments;

c) deviation from the established form of the accreditation application, failure to implement requirements envisaged for it and its applications;

d) failure to provide documents proving the fact of payment for assessment of compliance of the applicant with the accreditation criteria.

25. In case denial is decided, in 3-work-day term after it has been made the accreditation authority gives the head of the applicant (or authorized representative) a copy of the order on denial in accreditation with the basis for denial and its reference details; the accreditation application with attached documents or sends them in a registered letter with a return receipt or in the form of a digital document with a digital signature.

26. In case of loss (damage) of the accreditation certificate in the period of its validity, the applicant receives its duplicate upon request for an accreditation certificate duplicate written in the form approved by the accreditation authority.

A hard copy of the accreditation duplicate application is submitted (provided) to the accreditation authority by the applicant in person, or in a registered letter with a return receipt or in the form of a digital document with digital signature.

A duplicate of the accreditation certificate is issued for the term not exceeding the validity period of the lost (damaged) accreditation certificate.

In the 5-work-day term after registration, a duplicate of the accreditation certificate is given to the certified individual by the accreditation authority or sent by post with the delivery notification.

27. The accreditation certificate is to be reissued in the following cases:

a) reorganization of the certified body in the form of transformation;

b) changing of the name of the certified body;

c) changes in allocation of the certification body;

d) changes in location (locations) where the test laboratory (center) performs its activities;

e) extension of the accreditation field in compliance with item 33 of the Rules;

f) reduction of the accreditation field in compliance with item 54 of the Rules;

28. To reissue the accreditation certificate in cases envisaged by sub-items "a" - "c" of item 27 of the Rules, the certified body or its legal successor submit the following documents to the accreditation authority in the course of 15 days after introduction of changes into the Unified State Register of Legal Entities:

application on reissue of the accreditation certificate made in the form approved by the accreditation authority;

a copy of the valid accreditation certificate.

Application for reissue of the accreditation certificate and attached documents are submitted (provided) on hard copies by the applicant in person to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature via information and telecommunication network "Internet" (hereinafter referred to as Internet).

The application for reissue of the accreditation certificate shall contain new data on the certified body or its legal successor, as envisaged by item 5 of the Rules.

29. In cases envisaged by sub-items "a" - "c" of item 27 of the Rules, the accreditation authority revises reliability of new data provided in the application for reissue of the accreditation certificate in 10-day-term upon receiving the application; it makes decision on reissuing the accreditation certificate or on denial.

The accreditation authority requests information on the applicant contained in the Unified State Register of Legal Entities from the federal executive authority which exercises state registration of legal entities and individual entrepreneurs. The accreditation authority also requests data on registration of the applicant in the tax authority, i.e. the federal executive authority exercising functions of control and supervision over compliance with legislation of the Russian Federation in the field of taxes and duties, based on interdepartmental requests through the unified system of the interdepartmental digital interaction.

30. Availability of unreliable information is a basis for denial in reissuing the accreditation certificate in cases envisaged by sub-items "a" - "c" of item 27 of the Rules.

In case it is decided on denial in reissuing the accreditation certificate, in 3-day-term after the accreditation authority gives the certified body or its legal successor a copy of the order on denial in reissuing the accreditation certificate with reasons of such denial or sends it by post in a registered letter with a return receipt or in the form of a digital document with a digital signature.

According to the established procedure, the accreditation certificate is suspended for the period of its reissue in the following cases:

the certified body has not submitted to the accreditation authority its documents envisaged by item 28 of the Rules in 15 work days since introduction of appropriate changes into the Unified State Register of Legal Entities;

the accreditation authority decides to deny reissue of the accreditation certificate in the case envisaged by the first paragraph of this item.

The certified body does not have the right to work under the suspended accreditation certificate before it is reissued in compliance with the procedure defined by these Rules.

31. In case envisaged by sub-item "d" of item 27 of the given Rules, reissuing of an accreditation certificate is based on an application for reissuing such a certificate in

compliance with the procedure defined by items 5 - 25 of the given Rules, without documentary review.

32. Reissued accreditation certificate is sent (given) to the certified body or its legal successor (head or official representative) in person or sent by post with the delivery notification in 3-day term after the accreditation authority decided to reissue the accreditation certificate.

The certified body shall submit (send) the original of its previous accreditation certificate to the accreditation authority in 3 work days upon receiving the reissued accreditation certificate.

33. The accreditation authority may extend the field of accreditation for a certified body on the basis of an application from such a certified body to extend the field of accreditation of certification bodies and test laboratories (centers) which is to be prepared in compliance with the form established by the accreditation authority and with the procedure envisaged by items 5 - 25 of the given Rules.

Application for extension of the field of the accreditation certificate for certification bodies and test laboratories (centers) and attached documents are submitted (provided) on hard copies by the certified body in person to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature.

Extension of the field of accreditation for a certified body is performed by the accreditation authority without conducting any field review in case the assessment of the documents provided by the applicant showed that work by the certified body in the extended field of accreditation meets the accreditation criteria upon which the certification body or test laboratory (center) were certified earlier.

34. Accreditation for a new period is conducted in compliance with the procedure envisaged by items 5 - 25 of the given Rules.

Accreditation for a new period (in case extension of the field of accreditation is not envisaged) is performed without any field review if in one-year period before applying for the new term of accreditation there were no identified non-conformities of the certified body with the accreditation criteria, as well as in case there were no facts of suspension of the accreditation certificate, non-fulfillment of prescriptions for elimination of violations

revealed in the course of inspection control.

III. Approval of compliance of the certified entities with the accreditation criteria

35. Approval of compliance of the certified entities with the accreditation criteria is conducted in the form of scheduled and ad hoc inspections.

36. Scheduled inspections are conducted based upon annual plans which are approved in the orders by the accreditation authority. Annual inspection plan is published on the official Internet-site of the accreditation authority before December 15 of the year preceding the inspection control.

37. There are the following grounds for introduction of a certified body into the annual inspection plan:

a) decision by the accreditation authority on accreditation (first inspection is held one year after accreditation);

b) two years after the previous inspection of the certified body.

38. There are the following grounds for ad hoc inspections:

a) expiration of the term for implementation by the certified body of the prescription to eliminate revealed non-conformity of the entity with the accreditation criteria;

b) information which is provided to the accreditation authority by the state control (supervision) authorities and which states on non-conformance of the certified body with the established requirements to the certified products and on non-conformance of the certified body with the accreditation criteria;

c) applications (requests) to the accreditation authority from legal entities purchasing (using) products on non-conformance of the products certified by the authority with the established criteria;

d) an order by the head of the accreditation authority issued to implement the instructions of the President of the Russian Federation, the Government of the Russian Federation, or based on a prosecutor's request to conduct an ad hoc inspection within the framework of supervision over compliance with the laws in response to information and

notices received from legal entities - purchasers (users) of the products.

39. Requests and applications which do not allow to determine the individual who applied to the accreditation authority, and request and applications without information on non-conformance of the products certified by the accreditation authority with the established requirements cannot be used as grounds for ad hoc inspections.

40. Scheduled and ad hoc inspections are performed as field reviews conducted by an expert group. During inspection the expert group has the right to request from the inspected certified body any reporting documents and other data required for inspection control.

41. The composition of expert groups is approved by orders (decrees) of the accreditation authority and it is attached to annual instruction plans.

42. The expert group consists of accreditation experts and, if necessary, technical experts.

The accreditation authority appoints head of the expert group from among the accreditation experts included into the group.

43. An expert conclusion is prepared based on the results of scheduled and ad hoc inspections in two copies; the following is to be indicated there:

a) date, time and place of drawing up of the statement;

b) family names, names and patronymic names of accreditation and technical experts;

c) name of the inspected legal entity, family name, name, patronymic name and position of its representative who is present at the field review;

d) date, time and location (locations) where the field review was held;

e) data on the results of the field review, including information on compliance (non-conformance) of the certified body with the accreditation criteria; provision of those criteria and reasons for appropriate conclusions;

f) information about legal entity's representatives and individuals participating in the field inspection familiarization or denial in familiarization with the conclusion.

44. The expert conclusion is to be signed by the members of the expert group and it is approved by its chairperson during 2 work days after completion of the field review.

45. One copy of the expert conclusion is given to the head of the legal entity (or

representative) against signed receipt or it is sent by post with the delivery notification.

The expert conclusion is submitted (given) by the head of the expert group which performed the field inspection to the accreditation authority in 5-day term after completion of the field inspection.

IV. Procedure for suspension and termination of the accreditation certificate, reduction of the field of accreditation

46. The accreditation authority may decide on complete or partial suspension of the accreditation certificate on the basis of review of the expert conclusion prepared in compliance with item 43 of the Rules. Such a decision is made in case of acknowledgment of non-conformity of the certified body with the accreditation criteria before such a non-conformity is eliminated.

Decision on complete or partial suspension of the accreditation certificate in some field of accreditation is made by the accreditation authority in the form of order in 5 work days after registration of the expert conclusion which was the basis for the accreditation authority to decide on non-conformance of the certified body with the accreditation criteria.

A prescription on elimination of revealed non-conformities of the certified body with the accreditation criteria is attached to the said decision with indication of the term for their elimination. The term of complete or partial suspension of the accreditation certificate in some field of accreditation shall not exceed 3 months since such a decision.

In two work days after decision has been made, a copy of the order on complete or partial suspension of the accreditation certificate in some field of accreditation shall be given to the head of the certified body (its representative) against signed receipt or is sent by post with delivery notification.

The certified body does not have the right to perform its activities within the accreditation certificate or in suspended field of accreditation since the date it has received the notification on complete or partial suspension of the accreditation certificate in some field of accreditation in compliance with the established procedure, and upon the date

when the certificate will be renewed.

47. During some specified term of complete or suspension of the accreditation certificate in some field of accreditation, the certified body has the right to send (submit) to the accreditation authority its application for extension of the term given to implement the prescription on elimination of the revealed non-conformities of the certified body with the accreditation criteria. Such an application is submitted (provided) to the accreditation authority by the applicant in person, or in a registered letter with a return receipt or in the form of a digital document with digital signature.

Elimination of revealed non-conformance of the certified body with the accreditation criteria shall be implemented upon a request from the accreditation authority within 3 months since decision on complete or suspension of the accreditation certificate was made.

48. Decision on complete or partial renewal of the accreditation certificate in specific field of accreditation is made by the accreditation authority in the form of an order based on the results of an ad hoc inspection which is to be held in compliance with sub-item "a" of item 38 of the given Rules.

In five work days after decision, a copy of the order on complete or partial renewal of the accreditation certificate in some accreditation field shall be given to the certified body in a registered letter with a return receipt or in the form of a digital document with a digital signature.

49. In case an ad hoc inspection control to be held based upon sub-item "a" of item 38 of the given Rules revealed that the certified body did not fulfill timely the prescription on elimination of earlier detected non-conformities with the accreditation criteria, the accreditation authority makes one of the following decisions:

a) to suspend the accreditation certificate;

b) reduction of the accreditation field for the certified entity.

50. The validity of the accreditation certificate is terminated by decision of the accreditation authority made for the following cases:

a) early termination of the accreditation certificated based upon a request made upon the accreditation authority's established form by the certified entity on termination of the accreditation certificate's validity;

b) liquidation of a legal entity;

c) reorganization of a legal entity, except for reorganization of a legal entity made in the form of transformation;

d) failure of the certified authority to fulfill in due time prescriptions made by the accreditation authority regarding elimination of revealed non-conformity of the certified entity with the accreditation criteria;

e) detection of non-conformity of the certified entity with the accreditation criteria if the accreditation certificate was suspended twice during its validity period;

f) denial or deviation of the certified entity fro proving its compliance with the accreditation criteria in accordance with Section III of the Rules.

51. In case validity of the accreditation certificate is terminated by decision of the accreditation authority, all the activities of the legal entity aimed at proving compliance of its products with the obligatory requirements within the accreditation certificate are to be ceased since the entity is notified in compliance with the established procedure.

52. According to item 50 of the Rules, the accreditation authority decides on termination of the accreditation certificate's validity in the form of an order in 10-work-day period since:

a) receiving of the application of the certified entity on early termination of validity of the accreditation certificate;

b) receiving of documents proving the data indicated in sub-items "b" and "c" of item 50 of the Rules;

c) registration of expert conclusions proving the facts indicated in sub-items "d" and "e" of item 50 of the Rules;

d) receiving of data proving the facts indicated in sub-item "f" of item 50 of the Rules.

53. The accreditation certificate is terminated since the date when the accreditation authority signs its order on termination of the accreditation certificate's validity.

A copy of appropriate order on termination of the accreditation certificate's validity is sent in 3-work-day period by the accreditation authority to the legal entity, whose accreditation certificate has been terminated, in a registered letter with a return receipt or

in the form of a digital document with a digital signature.

54. The accreditation authority decides on reduction of the accreditation field:

a) in the case envisaged by sub-item "b" of item 49 of the Rules;

b) in case the certified entity applied for reduction of the field of accreditation to the certification bodies and test laboratories (centers) in the form established by the accreditation authority.

55. Application for extension of the field of the accreditation certificate for certification bodies and test laboratories (centers) and attached documents are submitted (provided) on hard copies by the certified body in person to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature.

56. Decision made by the accreditation authority on reduction of the accreditation field is registered in an order at the same tame when the accreditation certificate is reissued.

The accreditation authority gives to the certified entity its reissued accreditation certificate in 3-work-day period since decision was made on reduction of the accreditation field, or sends it by post with the delivery notification.

The field of accreditation is reduced since the date when the accreditation authority signs its order on reduction of the field of accreditation.

V. The procedure of certification of accreditation experts, and procedure for engagement and recruitment of accreditation and technical experts to perform works in the field of accreditation

57. The accreditation authority engages accreditation and technical expert into accreditation activities.

58. Accreditation experts are individuals meeting qualification requirements envisaged by item 59 of the Rules and certified by the accreditation authority.

59. An accreditation expert shall satisfy the qualification requirements:

a) higher education in the field of training (speciality) appropriate for the specialization field in accreditation;

b) at least 5 year work experience in one of the following fields:

quality management of nuclear facilities;

production of equipment or products for nuclear facilities;

design of nuclear facilities, construction, production, testing of equipment and products for those facilities;

ensuring of state supervision and control of nuclear facilities;

c) practical experience in accreditation (participation as an expert or a trainee in accreditation process for at least 3 times and in two field inspections of certified bodies in 3 years before applying for certification);

d) knowledge of the Russian regulatory legal acts in the field of atomic energy use, recommendations of the International Atomic Energy Agency, regulatory, technical, methodological, guiding documents regulating accreditation issues, establishment of requirements to products in the field of atomic energy use, applied gauges, testing equipment, standard specimen, assessment of compliance of products in the applied field of certification, and systems for quality assurance of activities performed by the certification bodies and test laboratories (centers);

e) the following skills (with the account of the certification field):

tasking for assessment of compliance of the applicant with the established accreditation criteria in the form of documentary and field reviews;

detection of violation by the certified body of the accreditation criteria;

preparation of expert conclusions, acts of field reviews based on results of documentary and field reviews;

f) knowledge of safety assurance at nuclear facilities;

60. The qualification certificate of the accreditation expert is issued according to the form established by the accreditation authority. Accreditation experts are certified by the accreditation authority in specific accreditation fields.

61. To obtain the qualification certificate of the accreditation expert, applicants shall submit to the accreditation authority the following documents:

a) an application for certification of an accreditation expert made in compliance with the form established by the accreditation authority; the application form shall contain family name, name and patronymic name (if available) of an individual, his/her place of residence, identification document data, telephone number and e-mail (if available), and the applied field of certification;

b) copies of documents proving higher education and work experience in the applied field of certification;

c) copies of documents proving training in the applied accreditation field;

d) a copy of the document proving that the applicant passed the certification (or other form of proving his/her competences) as an accreditation expert in one of the certification systems in the field of atomic energy use (if available).

62. The accreditation authority does not have the right to require the applicant to provide documents which are not stipulated by items 61 of the given Rules.

63. The application for certification of an accreditation expert may optionally include a request to provide information on the certification issues in the digital form.

64. The application for certification of an accreditation expert and attached documents may be submitted (provided) on hard copies by the individual in person to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature.

The application for certification of an accreditation expert and attachments are accepted by the accreditation authority according to a list and registered on the date of receiving. A copy of the list with the date when the said application and attachments were received is given to the applicant or sent in a registered letter with a return receipt or in the form of a digital document with a digital signature.

65. Assessment of compliance of the applicant with the qualification criteria is held in the form of assessment of provided documents and qualification examination in 60 days since registration of the application for the qualification certificate of the accreditation expert.

66. Assessment of the applicant's documents is performed by the accreditation authority in the period of up to 10 days since registration of the application for the

qualification certificate of the accreditation expert.

67. The accreditation authority makes one of the following decisions upon the results of assessment of the documents submitted by the applicant:

a) denial in certification of the accreditation expert in case his accreditation application was prepared with violation of the established requirements and (or) documents listed in item 61 of the Rules, are incomplete and (or) assessment of the documents provided by the applicant revealed non-compliance of the applicant with the qualification requirements envisaged by item 59 of the Rules;

b) admission of the applicant to the qualification examination;

c) certification of the applicant as an accreditation expert without organizing the qualification examination for him/her in case the results of assessment of the provided documents and data show that the applicant had passed certification (or other form of proving his/her competence) as an accreditation expert in one of the system of voluntary certification in the field of atomic energy use (in case a document proving such certification is available, and the applicant complies with the qualification requirements established by item 59 of the Rules).

68. In the course of 15 days since registration of the application for certification of an accreditation expert, the accreditation authority sends to the applicant who was admitted for the qualification exam based upon assessment of the provided documents, its notification on admission to the qualification examination (indicating the date and place of the exam). The notification is sent in a registered letter with a return receipt or in the form of a digital document with a digital signature.

69. Qualification exam is held in compliance with the procedure established by the accreditation authority with approval of the Federal Environmental, Industrial and Nuclear Supervision Service of Russia, the certification commission founded by the accreditation authority and working pursuant to the provisions approved by the accreditation authority with approval of the Federal, Environmental, Industrial and Nuclear Supervision Service of Russia.

The certification commission includes representatives of scientific and expert organizations.

70. In due time the applicant shall come to the qualification examination with his/her identification document.

71. Results of the qualification exams and decision based upon their results are prepared in the form of the minutes of the certification commission.

72. The accreditation authority makes one of the following decisions upon the results of the qualification examination:

a) certification of an accreditation expert in the form of an order, if based upon the results of the qualification exam it was decided that the applicant complied with the qualification requirements;

b) denial in certification of the applicant, if based upon the results of the qualification exam it was decided that he/she did not meet the qualification requirements to the accreditation expert.

73. There are the following grounds for denial in certification as an accreditation expert:

a) impleteness of the submitted documents or unreliable information in those documents;

b) applicant's non-compliance with the qualification requirements envisaged by item 59 of the Rules which was detected in the course of assessment of the documents and data provided by the applicant or based upon the results of the qualification examination;

c) absence of the applicant at the qualification examination.

74. In case the accreditation authority decides to certify the accreditation expert, simultaneously with such an order the qualification certificate of the accreditation expert is prepared in compliance with the form established by the accreditation authority. In 3 work days since registration, the qualification certificate is given to the individual qualified as an accreditation expert in person or sent by post with the delivery notification.

75. In case of denial in certification of the accreditation expert, in 3 work days since it was decided to deny in certification of the accreditation expert, the accreditation authority gives the applicant its order on denial in certification, the application on certification of the accreditation expert with the set of provided documents, or it sends them in a registered letter with a return receipt or in the form of a digital document with a digital signature.

76. The qualification certificate of the accreditation expert is open-ended.

77. Once in five years accreditation experts are subject to the procedure of confirmation of their competence in the form of a qualification exam which is held in compliance with the procedure established by the accreditation authority.

78. In case of loss of the original of the qualification certificate of the accreditation expert, the accreditation expert has the right to get a duplicate at the accreditation authority. The duplicate is also signed by the accreditation authority.

To get a signed copy or duplicate of the qualification certificate of the accreditation expert, the expert provides (sends) to the accreditation authority its application for a copy or duplicate of the qualification certificate of the accreditation expert prepared in compliance with the form established by the accreditation authority.

The application for a copy or duplicate of the qualification certificate of the accreditation expert is submitted (provided) on hard copies by the accreditation expert personally to the accreditation authority, in a registered letter with a return receipt or in the form of a digital document with digital signature.

A copy of the qualification certificate of the accreditation expert or its duplicate is given by the accreditation authority personally or sent in a registered letter with a return receipt in three work days after the accreditation expert applied for a copy or duplicate of the qualification certificate of the accreditation expert.

79. In case an expert changes his/her family name, name and patronymic name, his/her qualification certificate of the accreditation expert is subject to reissue. The accreditation expert submits to the accreditation authority an application for reissue of his/her qualification certificate of the accreditation expert in compliance with the form established by the accreditation authority. Such an application shall contain information about the accreditation expert and details of the document confirming the fact of introduction of changes into the identification document.

A hard copy of the accreditation reissue application is submitted (provided) to the accreditation authority by the applicant in person, or in a registered letter with a return receipt or in the form of a digital document with digital signature.

80. An application for reissue of the qualification certificate of the accreditation

expert is submitted to the accreditation authority in the period of 15 work days since appropriate changes have been introduced.

81. Reissue of the qualification certificate of the accreditation expert is performed in 3 work days since the accreditation authority has received an application for its reissue from the accreditation expert.

82. Decision on termination of validity of the qualification certificate is made by the accreditation authority in the period of 3 work days since the following events:

a) the accreditation authority has received a properly prepared application from the accreditation expert for termination of validity of the qualification certificate of the accreditation expert, submitted in the form determined by the accreditation authority;

b) the accreditation authority has confirmed the fact of violation of the requirements applied to accreditation experts and envisaged by items 89 - 90 of the Rules;

c) the accreditation authority has confirmed the fact of unreliability or bias of the results of work of the accreditation expert;

d) the expert has not passed the process of qualification examination in due time which is envisaged by item 77 of the Rules;

e) it has been identified that in the period of 1 year the accreditation expert repeatedly denied to hold documentary reviews, field reviews or to participate in an inspection without providing by the accreditation expert of any documents confirming reasons for such a denial.

83. Decision on termination of the qualification certificate of the accreditation expert is registered in an order by the accreditation authority. In 3 work days after its approval, the individual is notified in a registered letter with a return receipt or in the form of a digital document with a digital signature.

84. If it was decided to terminate the qualification certificate of the accreditation expert of an individual, the latter may again apply for certification as an accreditation expert in 1 year after his qualification certificate of the accreditation expert was expired.

The accreditation authority does not examine applications for qualification as accreditation experts from individuals in respect of which it was decided to terminate their qualification certificates of the accreditation experts due to confirmation of the fact of

unreliability or bias results of their activities.

85. The accreditation authority engages accreditation experts into the following activities:

a) development of the program for assessment of compliance of applicants and qualified individuals with the established accreditation criteria;

b) documentary review;

c) field review;

d) inspection.

86. The accreditation authority engages accreditation and technical experts into works in the field of accreditation, including them into the expert commissions and groups which assess compliance of applicants and qualified individuals with the accreditation criteria, and perform inspections.

87. Recruitment of accreditation experts is random choice from the register of the accreditation experts. It is done with the help of automated information system pursuant to the methodology of factors accounting.

88. The accreditation authority choses technical experts pursuant to the methodology of factors accounting. Experts are recruited from among those recommended by the state authorities regulating the atomic energy use and state nuclear safety regulatory authorities by request from the accreditation authority. In recruitment, educational background is taken into account as well as work experience in the field of confirmation of compliance of products and metrological provision of activities by test laboratories (centers) on confirmation of compliance of products with obligatory requirements.

89. Accreditation and technical experts shall be independent from any commercial, financial or administrative influence which impacts or may impact decisions made by the accreditation authority while certifying and assessing a certified individual.

90. Accreditation experts cannot combine their work in the field of accreditation with assessment of compliance of products with obligatory requirements if the latter corresponds to this field of accreditation.

91. Accreditation and technical experts ensure confidentiality of information which they received in the course of accreditation and which is the state, commercial or other

secret protected by the law, as well as information with restricted access in compliance with the legislation of the Russian Federation. And the experts use such information only for applied purposes.

92. Accreditation and technical experts do not have the right to consult applicants and certified individuals in the course of accreditation and inspections. The said experts notify the accreditation authority on existing or earlier existed relationship with the applicant or certified individual whose compliance with the accreditation criteria is reviewed.

VI. Accreditation Registers

93. The accreditation authority

a) keeps the register of certification bodies and test laboratories (centers) which work on confirmation of compliance of products subject to requirements to safety assurance in the field of atomic energy use, obligatory requirements (hereinafter referred to as the Register of Certified Individuals); the register of accreditation experts in the field of atomic energy use (hereinafter referred to as the Register of Accreditation Experts), the register of products compliance certificates issued earlier;

b) provides information from the Register of Certified Individuals, Register of Accreditation Experts, and Register of Products Compliance Certificates to interested parties and publishes the said Registers on its official web-site on the Internet.

94. The certification body approves the procedure of maintenance and the form of the Registers of Certified Individuals, Accreditation Experts and Products Compliance Certificates, as well as procedure for providing information contained there.

95. The accreditation authority introduces data into the Registers of Certified Individuals and Accreditation Experts in the period of 3 work days since decision has been made to do the following:

a) to issue a qualification certificate, to reissue a qualification certificate, to suspend, to renew or to terminate a qualification certificate;

b) on issue, reissue and termination of qualification certificate of the accreditation expert;

96. In 3 days after receiving information on issuing products compliance certificates, its suspension, renewal, extension or termination by the certification body, the accreditation authority introduces the data into the Register of Products Compliance Certificates.

97. Information on issued products compliance certificates is given by the certification body to the accreditation authority in person, or in a registered letter with a return receipt or in the form of a digital document with digital signature in the following terms:

a) in 3 work days after it has been decided to issue a product compliance certificate;

b) in 1 work day after it has been decided to suspend, renew, extend or terminate an issued product compliance certificate.

98. Information in the Register of Certified Individuals, Register of Accreditation Experts and Register of Products Compliance Certificates is open for familiarization for the governmental authorities, local government bodies, legal entities and individuals, except for the data with restricted access pursuant to the Russian legislation. Access to data kept in the Registers of Certified Individuals, Accreditation Experts and Products Compliance Certificates is ensured in the following way:

a) publication of data kept in the the Registers of Certified Individuals, Accreditation Experts and Products Compliance Certificates on official Internet-site of the accreditation authority;

b) provision of hard copies of data kept in the the Registers of Certified Individuals, Accreditation Experts and Products Compliance Certificates upon requests from interested parties;

c) provision of digital copies of data kept in the the Registers of Certified Individuals, Accreditation Experts and Products Compliance Certificates upon requests from interested parties;

VII. Appeal

99. Appeals against decisions, actions (inactions) of the accreditation authority

submitted by applicants, aspirants, certified individuals and accreditation experts are sent to the accreditation authority and studied by the Appeal Commission. The procedure of founding and work of such a commission is approved by the accreditation authority in agreement with the Federal Federal Environmental, Industrial and Nuclear Supervision Service of Russia.

The accreditation authority establishes the procedure to examine appeals.

Attachment
to Accreditation Rules
for Certification Bodies
and Test Laboratories (Centers)
Working on Confirmation of
Compliance of Products
Subject to
Requirements Related to
Safety Assurance
in the Field of Atomic Energy Use,
Obligatory Requirements,
Certification of Accreditation Experts
in the Field
of Atomic Energy Use,
and Procedure for Engagement and Recruitment
of Accreditation Experts
in the Field of Atomic Energy Use,
and Technical Experts
for Accreditation Activities

CRITERIA
FOR ACCREDITATION OF CERTIFICATION BODIES AND TEST LABORATORIES (CENTERS) AND REQUIREMENTS THEREOF

I. General Provisions

1. The document is developed with account of provisions of international standards.

II. Accreditation Criteria for Certification Bodies

2. The following are accreditation criteria for certification bodies:

a) availability of quality management system at applicant's and (or) entity certified as a certification body; compliance of the certification body with certification requirements of the quality management system provided in the quality manual of the certification body. Quality manual of a certification body is developed with account of the requirements of Article 13 of the Convention on Nuclear Safety. Quality manual of a certification body establishes priority of safety assurance prevailing any other priorities in the work of the certification body and it is aimed at creation of safety culture among all the individuals participating in confirmation of products compliance with obligatory requirements;

b) possessing by an applicant and (or) individual qualified as a certification body of an Internet-site with information on activities performed by the certification body pursuant to requirements of the quality management system envisaged in the quality manual;

c) possessing by an applicant and (or) individual qualified as a certification body of regulatory legal acts, including the set of federal regulations and guides in atomic energy use, regulatory documents of the state atomic energy use regulatory authorities and state nuclear safety regulatory authorities, documents in the field of standardization and others related to the field of accreditation applied for and (or) in the qualification certificate which establish requirements to products and (or) procedures of confirmation of products compliance with the obligatory requirements;

d) possessing by an applicant and (or) individual qualified as a certification body of employees at the principal work place who take part in activities related to confirmation of products compliance with obligatory requirements and working in each of the fields applied for accreditation, but at least 3 employees in total with the following qualities:

higher, secondary professional education or additional professional education with specialization in the field corresponding to that one of accreditation;

at least 3 years of work experience in confirmation of products compliance with the obligatory requirements in the applied field of accreditation or in the accreditation certificate;

e) ownership or other legal possessing by an applicant and (or) individual qualified as a certification body of premises, equipment, technical means and other material resources

(in the area of work in the accreditation field and in the area of temporary works) to implement work on confirmation of products compliance with the obligatory requirements pursuant to the requirements of the regulatory legal acts, standardization documents and other regulations related to the applied accreditation field or accreditation certificate;

f) possessing by an applicant and (or) individual qualified as a certification body of documents confirming that its personnel know regulatory and organizational and methodological documents in the field of safety assurance of atomic energy use, including federal standards and regulations related to the accreditation field. Managers and specialists shall hold examination of knowledge by the personnel of regulations, standards and instructions on safe conduct of works in the field of atomic energy. It shall be performed in compliance with the procedure of examination determined by the state atomic energy use regulatory authorities and state nuclear safety regulatory authorities.

3. Additional criterion (taking into consideration the accreditation field) may be possessing by an applicant and (or) individual qualified as a certification body, or by the personnel of the said organizations of required authorizing documents which allow to hold activities related to the use of data of the State Secret level and (or) classified as restricted distribution information.

4. Certification body shall comply with requirements envisaged by Section IV of the document.

III. Accreditation Criteria for Test Laboratories (Centers)

5. There are the following criteria for test laboratories (centers):

a) availability of quality management system at applicant's and (or) entity certified as a test laboratory (center); compliance of the test laboratory (center) with certification requirements of the quality management system provided in the quality manual of the test laboratory (center). Quality manual of a test laboratory (center) is developed with account of the requirements of Article 13 of the Convention on Nuclear Safety. Quality manual of a test laboratory (center) establishes priority of safety assurance prevailing any other

priorities in the work of the test laboratory (center) and it is aimed at creation of safety culture among all the individuals participating tests aimed at confirmation of products compliance with obligatory requirements;

a) availability of the following documents at applicant's and (or) individual certified as a test laboratory (center) on the condition of compliance with the requirements of these documents in its activity:

regulatory legal acts, regulatory documents in the field of standardization, codes and properly certified methodologies (techniques) for tests and measurements as well as sampling codes and other regulatory documents related to the applied accreditation field or to the field defined by the accreditation certificate which are used as a basis for tests aimed at confirming of products compliance with obligatory requirements;

documents related to maintenance of appropriate condition of testing equipment and measurement instruments (schedules for examination (calibration) of the applied measuring instruments and for certification of test equipment, their passports, techniques of certification of test equipment and of calibration of measuring instruments, operation documentation for the applied measuring instruments and test equipment);

documents defining information storage systems and test results (minutes, working registers, reports, documents on arrangement of document turnover and information protection);

c) possessing of the following qualities by employees of the applicant and (or) individual qualified as a test laboratory (center) who directly work on confirmation of products compliance with obligatory requirements in the applied field of accreditation or accreditation certificate:

higher, secondary professional education or additional professional education with specialization in the field corresponding to that one of accreditation;

at least 3 years of work experience in confirmation of products compliance with the applied field of accreditation or in the accreditation certificate;

d) ownership or other legal possessing by an applicant and (or) individual qualified as a test laboratory (center) of premises, test equipment, measuring instruments and standard samples complying with the appropriate Russian legislation on ensuring the uniformity of

measurements, and other technical means and other material resources (in the area of work in the accreditation field and in the area of temporary works) to implement work on confirmation of products compliance with the requirements of the regulatory legal acts, standardization documents, regulations and methodologies (techniques) for tests and measurements, as well as sampling codes and other regulatory documents related to the field of accreditation specified in the application or the accreditation certificate;

d) additional accreditation criteria for test laboratories (centers) where tests or test conditions in the applied field of accreditation are related to ownership (use) of nuclear facilities or with possibility of a nuclear and (or) radiation hazard, including the following:

availability of documents of the state atomic energy use regulatory authorities, state nuclear safety regulatory authorities, state customers (or access to them) which establish obligatory requirements related to activities in appropriate field of accreditation;

availability of qualified and specially trained and certified personnel pursuant to the requirements of the federal regulations and guides in the field of atomic energy use;

possessing by the employees of permits granting them the right to work in the field of atomic energy use;

availability of test equipment and measuring instruments complying with the requirements of the Federal Law "On Ensuring the Uniformity of Measurements";

availability of control and supervised areas, protective clothing and individual protection means for personnel and visitors at test laboratories (centers) categorized as nuclear facilities;

availability of documented procedures for admission of individuals who are not the staff;

physical protection ensuring for test laboratories (centers) categorized as nuclear facilities;

availability of documented procedures for accounting (control) of samples at test laboratories (centers) which test samples with nuclear materials and (or) radioactive substances;

availability of documented procedures for accounting information on transfer, return, decommissioning and writing-off of samples with nuclear materials and (or) radioactive

substances, as well as permit documentation for their transportation in compliance with the Russian legislation, federal regulations and guides in atomic energy use and regulations for transportation of dangerous goods;

availability of specific places (facilities) arranged in compliance with the Russian legislation and the requirements of the federal safety regulations and guides in atomic energy use and aimed at storage of radioactive waste generated due to activities at test laboratories (centers).

6. A test laboratory (center) shall comply with the requirements envisaged by Section V of the document.

IV. Requirements to Certification Bodies

7. A certification body shall have a quality manual for a certification body with requirements of the quality management system. Such a manual shall be prepared in the form of a single document or a set of documents, it is signed by the head of a legal entity or authorized representative. Such a manual is to be certified by the seal of the legal entity.

8. The quality manual of the certification body shall envisage the following requirements of the quality management system:

a) determination of the scope of application for the quality management system which shall cover all the work places under the field of accreditation, as well as places for temporary work.

b) availability of a quality policy statement in relation to the certification body; the statement shall define the following:

quality objectives and tasks in relation to work performed by the certification body;

obligation of the certification body to comply with the accreditation criteria and requirements to certified individuals;

the requirement to employees of the certification body who take part in certification of products, to familiarize with the quality manual and apply quality policy in their activities in relation to the work done by the certification body;

provisions on observance by the certification body of safety priority against any other

priorities and on formation of safety culture among all the individuals participating in confirmation of products compliance with the obligatory requirements;

c) availability of requirements to arrangement of internal work of the certification body, envisaging the following:

rights and duties of a structural division within a legal entity (its employees) which works on certification of products in interaction with the executive division of the legal entity and its other structural divisions (their employees) to exclude the conflict of interests;

allocation of rights, duties, and responsibilities among the employees of the certification body;

necessity of job descriptions (instructions) signed by the employees;

direct subordination of a structural division of the legal entity which works on certification of products, to the executive body of the legal entity or deputy of the sole executive body to exclude any conflict of interests of the structural division of the legal entity working on certification of its products and employees with the interests of other structural divisions of the legal entity and their personnel;

availability of a manager (quality manager) who ensures introduction of the quality management system and its functioning, who occupies the position of the head of the certification body or his/her deputy, or other official authorized for the said functions by the executive body of the legal entity;

d) availability of a system ensuring independence and impartiality of the certification body in its activities, and introduction of requirements envisaging the following:

development and implementation of measures aimed at prevention and solving of a conflict of interests;

guarantees of independence of the certification body from any commercial, financial, administrative and other impact which could influence the quality of certification work done by the certification body;

duty to ensure impartiality of decision making by the certification body in its products certification activity;

disclosure of information on persons affiliated with the certified legal entity in

compliance with the antimonopoly legislation of the Russian Federation;

e) availability of rules ensuring confidentiality of information including that from third parties;

f) availability of documentation control system (document turnover) at the certification body; the system shall include the following:

the rules for approval and registration of documents, including complaints;

the rules for accounting and documenting results of products certification activities;

the rules for familiarization of the personnel of the certification body with documentation;

the rules of documentation backup and recovery;

the rules for ensuring actuality of the applied version of documents;

rules ensuring availability of the required documents in the places where they are used by personnel of the certification authority;

date of introduction of changes into documents;

the rules envisaging registration within the documentation control system of the date when appropriate changes were introduced into the documents and the name of the employee who introduced them;

the system for storage and archiving documentation, and the rules of storage and archiving;

the rules for systematization and maintenance of the documentation archive, including the conditions for issuing documents from the archive, terms for keeping documents in the archive (groups of documents), the rules for registration of documents coming to the archive, storage conditions for documents;

maintenance of the register of data on the workers of the certification authority who take part in products certification;

g) availability of the rules for publishing and update of the following data on the Internet-site of the certification body:

name of the certification body, its address (location), telephone number and e-mail;

composition of the board of the certification body, including family name, name and patronymic name (if available) of the head of the certification body;

description of the products certification schemes;

the rules for consideration of complaints about decisions made by the certification body;

the list of the documents used in the work on confirmation of products compliance with the obligatory requirements and defining requirements to such activities;

approximate price of works performed by the certification body in relation to specific types of products and in compliance with the applied schemes of compliance confirmation;

the list of test laboratories (centers) with which the certification body cooperates to perform tests and measurements;

h) availability of requirements to legal entities engaged by the certification body into specific works on confirmation of products compliance with the obligatory requirements; availability of rules for keeping records on compliance of the work they perform with the obligatory requirements;

i) availability of rules for certification of products, including the following:

description of the products certification schemes;

the rules for consideration of applications for products certification, including those regarding the procedure of choice of the scheme for products certification;

the rules for preparation of action plans for products certification;

the rules for auditing of the quality management system of the applicant (in case it is envisaged by the products certification scheme);

the rules for providing the applicant with the results of work on confirmation of products compliance with the obligatory requirements;

the rules for inspection control (in case inspection control is envisaged in the products certification scheme);

the rules for consideration of complaints abut decisions made by the certification body, as well as for the procedure of answering upon the results of consideration of complaints;

j) availability of a mechanism for internal control of compliance with the quality management requirements which would envisage the following:

establishment of requirements for control of compliance with the requirements of the

quality (hereinafter referred to as internal audit) conducted by the certification body; the rules shall include periodicity of internal audits, a program for internal audits as well as rules for preparation of a documentary report with the results of the internal audit, including information on measures taken due to detection of works on confirmation of products compliance with the obligatory requirements which were conducted with violation of the established requirements (hereinafter referred to as corrective measures);

establishment of rules for quality management system analysis arranged by the head of the certification body or his/her deputy, including the following:

analysis technique;

periodicity of analysis;

the procedure for preparation of a documentary report with analysis results and information on corrective measures;

k) availability of the application form which the applicant submits to the certification body to get a compliance certificate;

l) availability of rules for corrective measures which would establish the following:

the system for analysis of reasons explaining violation of the established requirements while conducting confirmation of products compliance with the obligatory requirements;

procedures for selection of corrective measures for elimination of the revealed problems;

the rules for assessment of objectives achievement by the corrective measures;

9. The certification body shall ensure availability of hard and (or) digital copies (if necessary, applying digital legal reference systems) of regulatory legal acts, documents in the field of standardization and other documents related to the accreditation field indicated in the accreditation application or certificate, which establish requirements to products and (or) procedures for confirmation of products compliance with the obligatory requirements, and compliance by the certification body with the document requirements.

10. The certification body shall have document confirming its compliance with the provisions of sub-item "g" of item 2 of the given document, including labour or civil law contracts, personnel's documents on higher education, secondary or additional professional education, employment record books.

11. The certification body shall ensure competence of the personnel whereto requirements are envisaged by sub-item "g" of item 2 of the given document; and of other employees who take part in confirmation of product compliance with the obligatory requirements. The certification body shall also ensure that the employees are skilled enough to work on confirmation of products compliance with the obligatory requirements in the accreditation field specified in the application or accreditation certificate.

12. the certification body shall have documents (their copies) justifying their ownership or other legal possessing of premises, equipment, technical means and other material resources to to implement work on confirmation of products compliance with the obligatory requirements pursuant to the requirements of the regulatory legal acts, standardization documents and other regulations related to the applied accreditation field or accreditation certificate.

13. The certification body shall have documents (licenses) proving its permit to work in the field of products certification in compliance with the accreditation field specified in the application or accreditation certificate and activities related to the use of data classified as state secret.

V. Requirements to Test Laboratories (centers)

14. A test laboratory (center) shall have a quality manual for a certification laboratory (center) with requirements of the quality management system. Such a manual shall be prepared in the form of a single document or a set of documents, it is signed by the head of a legal entity or authorized representative. Such a manual is to be certified by the seal of the legal entity.

15. The quality manual of the test laboratory (center) shall envisage the following requirements of the quality management system:

a) determination of the scope of application for the quality management system which covers all the work places under the field of accreditation, as well as places for temporary work.

b) availability of a quality policy statement in relation to the test laboratory (center);

the statement shall define the following:

quality objectives and tasks in relation to work performed by the test laboratory (center);

obligation of the test laboratory (center) to comply with the accreditation criteria and requirements to certified individuals;

the requirement to employees of the test laboratory (center) participating in testing and measurement to familiarize with the quality manual and apply quality policy in their activities in relation to the work done by the test laboratory (center);

provisions on observance by the test laboratory (center) of safety priority against any other priorities and on formation of safety culture among all the individuals participating in tests aimed at confirmation of products compliance with the obligatory requirements;

c) availability of requirements to arrangement of internal work of the test laboratory (center), envisaging the following:

rights and duties of a structural division of the test laboratory (center) which works on test and measurement in interaction with the executive division of the legal entity and its other structural divisions (their employees) to exclude the conflict of interests;

allocation of rights, duties, and responsibilities among the employees of the test laboratory (center);

necessity of job descriptions (instructions) signed by the employees;

direct subordination of a structural division of the test laboratory (center) performing tests and measurements to the executive body of the legal entity or deputy of sole executive body of the legal entity to avoid conflict of interests of the structural units of the legal entity performing tests and measurements with the interests of other structural divisions of the legal entity (their personnel), in particular, working on design, product, construction, installation, adjustment, operation, storage, transport, sale and decommissioning of products;

availability of a manager (quality manager) who ensures introduction of the quality management system and its functioning, who occupies the position of the head of the test laboratory (center) or his/her deputy, or other official authorized for the said functions by the executive body of the legal entity;

d) availability of a system ensuring independence and impartiality of the test laboratory (center) in its activities, and introduction of requirements envisaging the following:

measures for prevention and solving of conflict of interests;

guarantees of independence of the test laboratory (center) from any commercial, financial, administrative and other impacts which could influence the quality of work done by the test laboratory (center) (in case the latter participates as a third party in activities on confirmation of products compliance with the obligatory requirements);

obligation of the test laboratory (center) not to participate in activities which could undermine confidence in its impartiality;

e) identification of policy and procedures for detection of need in additional professional training and training of personnel working at the test laboratory (center), and the procedure for such training;

f) availability of rules ensuring confidentiality of information including that from third parties;

g) availability of documentation control system (document turnover) at the test laboratory (center); the system shall include the following:

the rules for documents approval and registration;

the rules for accounting and documenting of test and measurement results, and the rules of development and introduction of changes into minutes, requirements to the contents of such minutes. Registration of test results shall ensure registration of initial measurements, calculations and other data, individuals who received the sample, prepared it for tests and held tests and measurements; exclusion of subjectivity when registering measurement results (if possible, parameters are registered automatically), and observance of the established requirements to documenting at all the stages of registration and issuing testing results (except for corrections, identification of signatures, availability of seals, dates and other document turnover requirements);

the rules for familiarization of the personnel of the test laboratory (center) with documentation;

the rules of documentation backup and recovery;

the rules for ensuring actuality of the applied version of documents;

rules ensuring availability of the required documents in the places where they are used by personnel of the test laboratory (center);

the rules for revision of documents and introduction of changes;

the rules envisaging registration within the documentation control system of the date when appropriate changes were introduced into the documents and the name of the employee who introduced them;

the system of storage and archiving of documents, including the rules for storage and archiving of documents related to methodologies (techniques) of tests and measurements, analyses and technical reports on tests and reports on examinations, test minutes, documentation on maintenance and repair of equipment and measuring instruments, documents with all the registered information on tests. Scope and contents of the registered information on tests subject to storage shall provide for comparison of test results in case of their repetition;

the rules for systematization and maintenance of the documentation archive, including the conditions for issuing documents from the archive, terms for keeping documents in the archive (groups of documents), the rules for registration of documents coming to the archive, storage conditions for documents. Storage conditions for documents shall ensure their safety during the period established in the legislation of the Russian Federation, confidentiality of information and state secret observance;

keeping the register of data on the workers of the test laboratory (center) who are directly involved into tests and measurements;

h) availability of requirements to legal entities engaged by the test laboratory (center) for specific activities in the field of confirmation of products compliance with the obligatory requirements, and the rules for keeping records on compliance of the work done with the established requirements which also envisage the rules of purchasing and examination of reagents and other consumables for tests and measurements for compliance with the established requirements, and availability of documentation for the consumables;

i) availability of rules for equipment application for tests and measurements which envisage the following:

identification of each unit of equipment and software (including the name of manufacturer, identification of type and serial number or other unique identification);

identification of equipment allocation (if necessary);

availability of equipment user guides and operating manuals;

provision of data on tests, established obligatory metrological requirements to tests, including accuracy values, and on approval of measurement instrument type;

indication of dates, results and copies of all the certificates of examination and (or) calibration certificates;

availability of a maintenance plan (if necessary) and results of conducted maintenance of equipment;

description of all the damages, malfunctions, modifications or repair of equipment;

availability of documents confirming exclusion of any possibility that the test results obtained with the digital data processing system were mispresented. The system of digital data processing shall be able to detect malfunctions of computer equipment during calculations to take appropriate measures. Systematic examination of calculations and data transmission shall be arranged.

j) availability of a mechanism for internal control of compliance with the quality management requirements which would envisage the following:

establishment of the rules for internal audit by the test laboratory (center) which would include the following:

periodicity of internal audit with indication of experts responsible for internal audits;

the program of internal audits with the procedure, facilities, participants of the internal audit;

the rules for development of a documentary report on the results of the internal audit with data on corrective measures;

establishment of rules for quality management system analysis arranged by the head of the test laboratory (center) or his/her deputy, including the following:

availability of an analysis technique;

periodicity of analysis;

the procedure for preparation of a documentary report with analysis results and

information on corrective measures;

the system for control of work done by the employees of the test laboratory (center) by persons meeting the provisions envisaged by sub-item "c" of item 5 of the given document;

k) availability of the rules for internal quality control of tests and measurements;

l) availability of rules for assurance and control of appropriate external conditions required for the test laboratory (center) to conduct its work (temperature, air humidity, luminosity, noise level, radiation level and other external conditions which influence quality of the results of the tests and measurements in respect of appropriate technical work depending on the field of accreditation), including the following:

data on required indicators of external conditions as well as admissible deviations, and on technical requirements to the premises;

the rules for periodic documenting and control of indicators of external conditions, including the rules for prevention of external impact conditions which do not meet the established requirements, on the results of specific studies (tests), measurements and other works conducted by the test laboratory (center);

m) availability of the rules for safe management, transport, storage, use and scheduled maintenance of standard samples, measurement instruments and testing equipment to ensure their adequate functioning and prevention of contamination or damage;

n) availability of the rules for selection and use of methodologies (techniques) for tests and measurements appropriate for the field of activity of the test laboratory (center) which would envisage the following:

the rules for documenting of data on the applied methodologies (techniques) of tests and measurements, and providing workers of the test laboratory (center) with methodologies (techniques) of tests and measurements;

the rules for documenting of data on registered by tests (measurements) deviations from the requirements established by the methodologies of tests and measurements; the rules for technical justification of the said deviations, and their approval by the customer of the tests (measurements);

o) availability of the rules for development, acceptability appraisal and use by the test

laboratory (center) of unstandardized techniques developed by the test laboratory (center), of standard techniques applied beyond their assigned field, and extensions and modifications of the standard techniques (if the said techniques are used or planned to be used);

p) availability of the rules for the situation when there are works performed with violation of the established requirements envisaging the following:

duties of the employees of the test laboratory (center) in case of works performed with violation of the established requirements (including the situation with suspension of works, suspension of issue of test and measurement minutes);

necessity of assessment of the impact on results of tests and measurements by works performed with violation of the established requirements;

the duty of conducting corrective measures;

the rules for notification of the customer on works performed with violation of the established requirements;

responsibility measures in relation to the employees of the test laboratory (center) who made an unjustified decision on renewal of the works;

the rules for description of the works performed with violation of the established requirements;

q) availability of rules for corrective measures which would establish the following:

the system for analysis of the reasons why it was decided to conduct works which were held with violation of the established requirements;

the rules for selection of corrective measures;

the rules for assessment of objectives achievement by the corrective measures;

the rules for description of results of the corrective measures;

r) availability of the rules for implementation of arrangements aimed at prevention of works with violation of the established requirements, envisaging the following:

identification of potential reasons of occurrence of works which were held with violation of the established requirements;

the rules for initiation of arrangements aimed at prevention of works held with violation of the established requirements and at prevention of re-occurrence of works

performed with violation of the established requirements;

the rules for planning of arrangements aimed at prevention of works performed with violation of the established requirements and description (registration) of their results;

s) availability of the rules for sampling for tests and measurements if this activity is conducted or planned) which would envisage the following:

the rules for selection, retrieval and preparation of a sample for tests and measurements, and the sampling plan;

the rules for selection, retrieval and preparation of a sample for tests and measurements, and the plan for sampling in the places of sampling;

the rules for documenting of data on operations related to sampling, including for situations with deviation of the sampling procedure from the standard one; the rules with the applied sampling procedure, sampling specialist assignment, external sampling conditions (if required) and materials for identification of the sampling area;

t) availability of the rules for management with items subject to tests and measurements envisaging the following:

the rules for transport, acceptance, use, protection, storage, safety assurance and (or) removal of the tests and measurements items which exclude deterioration of characteristics, loss or damage of the tests and measurements items;

the identification system for tests and measurements items;

the rules for documenting of works with tests and measurements items, including the cases of deviation of the test and measurement results from the normal or desired conditions;

u) availability of the rules for examination and (or) calibration of measurement instruments which ensure traceability to the state primary standard of a relevant measurement unit or in case of their absence to the national unit standards of other states; such rules should envisage the following:

measures ensuring compliance with the requirements to examination and (or) calibration of measurement instruments;

the rules for management with the standards while calibrating measurement instruments.

16. The test laboratory (center) shall ensure availability of hard and (or) digital copies of regulatory legal acts, standardization documents, rules and methodologies of tests and measurements, including sampling rules and other documents related to the applied field of accreditation (including the use of digital legal reference systems) .

17. The test laboratory (center) shall have documents confirming compliance with the provisions of sub-item "e" of item 5 of the given document, including the following:

a) labour or civil law contracts, documents on higher, secondary professional or additional professional education of the workers, employment record books;

b) appropriate permits (licenses) granting the right to perform works in the field of atomic energy use which are subject to licensing in compliance with the legislation of the Russian Federation.

18. The test laboratory (center) shall ensure competence of its workers who take part in confirmation of products compliance with the obligatory requirements, and their skills in activities on confirmation of products compliance with the accreditation field specified in the application or accreditation certificate.

19. The test laboratory (center) shall have documents (their copies) which confirm its ownership or other legal possessing of premises, test equipment, measuring instruments and standard value samples, standard samples and other technical means and other material resources (in the area of work in the accreditation field and in the area of temporary works) to implement work on confirmation of products compliance with the requirements of the regulatory legal acts, standardization documents, regulations and methodologies (techniques) for tests and measurements, as well as sampling codes and other documents related to the field of accreditation specified in the application or the accreditation certificate;

20. The test laboratory (center) shall have certificates on examination and (or) certificates of calibration for its measurement instruments.