

**Ministry of Environmental Protection and Nuclear Safety of Ukraine**

**State Enterprise**

**"State Quality Centre for Regulation of Supplies and Services"**

**CERTIFICATION BODY**

**PRODUCTION FOR NUCLEAR ENERGY UTILISATION**

**SERTATOM**

# REPORT

Number ER-11-01-24-157-98

**General Analysis of Certification Procedure to be  
applied for foreign equipment to nuclear facilities  
in Ukraine**

(Status at 01/09/98)

Kyiv city, 1998

## 1. Purpose.

This report was prepared in order to support the state regulatory bodies on nuclear and radiation safety (Nuclear Regulatory Administration, Ministry for Health Protection), state supervision bodies (Gosstandart, SQC of the Ministry of Interior, State Committee on Labour Protection) utilities, suppliers or organisations, that co-ordinate supplies in elaborating common approaches to the quality assurance of foreign supplies and procedures of conformity to meet the requirements (certification).

This report is presented as a final version on this issue which comprises comments given by the participants of the Working group on certification, in particular:

- letter of Ministry for Health ref. 7.09/272 dated 12/11/97
- letter of NRA Minekobežpeki (Ministry for Environmental Protection and Nuclear Safety of Ukraine) ref. 07/2-13/944 dated 11/11/97
- proposals of State Committee on Labour Protection as for the allowance of production to the nuclear facilities dated 10/11/97

As there were no comments and proposals to the first draft from Gosstandart, SQC of the Ministry of Interior, utilities, Energoatom it is considered that they agreed on the content of the report.

Description of the proposed certification and work procedures could help suppliers in making analysis and estimation of time, cost and possible "specific" requirements of Ukrainian legislation to the suppliers can have impact to the certification procedure.

### **1.1. When drawing up this report the following documents were used:**

- Law of Ukraine "On the Nuclear Energy Utilisation...", articles 27,28,34
- Law of Ukraine "On Entrepreneurs Activity" ", article 4.
- Law of Ukraine on ensuring sanitary and epidemiological well-being of population
- Decree of Cabinet of Ministers of Ukraine "On Standardisation and Certification".
- Enactment of Gosstandart of Ukraine dated 02.08.96â. 1 329 "Procedure of Works on Certification for Foreign Products on Schemes, including Inspection, Qualification and Certification of Their Quality Systems"
- Enactment of the Ministry for Health Protection of Ukraine # 190 dated 25/10/95 "On sanitary-hygienic expertise as for development of the manufacture, implementation of production that can have negative impact to the health of population".
- State Standard DSTU 1.3-93, DSTU 1.4-93
- State Standard DSTU 3417 "Procedure of Acknowledgement of certification results of imported products"
- Gosstandart normative document Ð 50-026-94
- Nuclear Regulatory Administration Normative Document
- Guidelines on Technical Specifications review and approval procedures approved on 03.04.97

## 2. Normative Basis.

There are three main statements applied in the quality assurance of supplies to nuclear facilities:

2.1. Certain types of activity, related to supplies, works and services can be undertaken only in case if there is a special permit (license) granted by the Regulatory Body.

- Law of Ukraine "On the Nuclear Energy Utilisation...", articles 27,28,34
- Law of Ukraine "On Entrepreneurs Activity" ", article 4.
- Law of Ukraine on ensuring sanitary and epidemiological well-being of population

Given that licensing issue is not the subject of this analysis it is not addressed in the present report

2.2. Technical specifications, which define requirements to production, are to be approved by Regulatory Bodies.

- Rules, state standard DSTU 1.03-93.
- Law of Ukraine on ensuring sanitary and epidemiological well-being of population

2.3. Safety related equipment is allowed for purchasing to nuclear facilities only if there is a certificate that conforms quality of supply

- Law of Ukraine "On the Nuclear Energy Utilisation...", articles 28
- Law of Ukraine on ensuring sanitary and epidemiological well-being of population
- Decree of the Cabinet of Ministers of Ukraine "On Standardisation and Certification".

## 3. Approval of Technical Specifications.

Technical Specifications is a mandatory document to begin works on certification. As a consequence of it the first step of certification from supplier and consumer side is development and approval by NRA of Technical Specifications for the equipment to be supplied.

Experience from contacts with suppliers, utilities that are going to purchase foreign production shows that mainly they have the following questions and concerns:

a) Which kinds of equipment to be supplied to NPP has to be regulated (i.e. technical specifications are to be approved and certification is mandatory)?

b) Can Technical Specifications submitted by foreign companies be used instead of those Ukrainian one?

c) Is there any procedure of approval technical specifications by the Regulatory Body?

d) Whether test results performed in the foreign company (or test made by authorised foreign body on certification) can be acknowledged as a kind of acceptance tests, which should be performed in accordance with existing Ukrainian procedure, that require participation of NRA representatives or delegated organisation (Guidelines requirements ..)

As a rule the mentioned matters can be solved by suppliers under condition of fulfilment the following recommendations:

- 1. At the stage of development of technical requirements Customer - utility, general designer have to give preliminary classification of equipment to be supplied according to its safety classes in compliance with OPB-88. With this in further steps (development or submission of technical specifications, application for certification and other documents attached to equipment) the safety class (taking into account possible corrections) should be mentioned in correspondent documents. Moreover, at this stage it is necessary to define whether sanitary-hygienic expertise is needed in order to take into account hygienic certification (or submission of information) in the schedule.*
2. In order to avoid discrepancy with regulations, rules and standards on nuclear and radiation safety it is reasonable to involve regulatory bodies or their expert organisations at the sage of TS preparations for preliminary assessment of compliance of technical requirements to the planned supply.

*Such recommendations enable to define equipment for which procedures of TS approval and certification procedures shall be fulfilled and to ensure favourable conditions at the stage of their approval.*

Possibility to acknowledge Technical specifications as a document that can replace technical specifications required in Ukraine is defined by the Nuclear Regulatory Administration in case if supplier provides them with comprehensive information on a certain production, which allows to identify that requirements to the content, format and approval of technical specifications meet the requirements of DSTU1.3-93, DSTU 1.5 - 93, and that requirements to the content and format meet requirements of KND 50-009-93 normative document. The procedure of acknowledgement and approval itself is practically identical to those one, defined by the Guidelines for Ukrainian developers and suppliers on Technical Specifications Review and Approval procedures approved on 03.04.97

In more formal terms, when approving technical specifications the procedure described above foresees the following steps:

### **3.1. Step 1 Submitting of Technical Specifications to the Nuclear Regulatory Administration for Review**

While making preliminary review of the documents the NRA defines:

1. **necessity** of approval of technical specifications as an element related to safety according to safety classification
2. completeness of the documents submitted
3. **necessity to perform expertise of technical documents** in order to check their compliance with radiation and safety regulations

**Safety class of equipment (according to OPB-88 classification) has to be defined by the general designer (p.2.9 of OPB-88) and it should be mentioned in the submitted documents (2.11 of OPB-88).**

Content of the documents should be complete enough to identify compliance with following requirements:

1. technical requirements
2. regulatory requirements on nuclear and radiation safety
3. acceptance rules
4. control, test, analysis and measuring methods
5. provisions for transporting and storing
6. operation instructions

### **3.2. Step 2 Acceptance (Qualification) Tests**

Acceptance tests are organised in the following order:

1. **Setting up of acceptance committee** and defining of power of the Administration representative or representative of organisation delegated to take part in tests
2. Review, **approval** of programmes with Administration or delegated organisation

**Requirements to the tests are defined in Main Safety Provisions (OPB-88, p. 4.1.9)**

### **3. Tests, completing of results.**

**Tests should be undertaken using methods, at stand benches and in conditions maximally approached to the operational conditions (direct methods) and in scope sufficient for receiving true results on quality of the tested products.**

#### 4. Submission of the test report to the Administration

It should be noted that results of the tests which were performed without participation of representative from the Administration can be fully or partially acknowledged if there is a document conforming that an authorised organisation, independent from the manufacture and consumer (qualified certification body or independent test laboratory, centre) participated in the tests or after review of the documents, containing test results performed by Administration.

##### 3.3. Step 3.

#### **Approval of Technical Specifications is the final step of the procedures between Supplier and NRA.**

TS can be approved on the basis of the following:

1. Positive expert conclusion on the content of the submitted documents
2. Signature of NRA or delegated organisation representative in the documents (report, act, protocol) drawn up on the results of the tests.

Approval of the TS by NRA can be done by means of approval letter or by Director signature at TS title sheet.

- **NRA approval of TS does not replace mandatory approval by other State Bodies.**

##### **3.4. Step 4. For the case if "Hygienic statement" of the Ministry for Health Protection of Ukraine**

1. Hygienic certificate of a manufacturing country (original and translation) which confirms safety of production and safety conditions of its use
2. A copy of the contract with specification for equipment supply.
3. Technical description of production including all the parameters, that can have an impact to the working conditions, population health, conditions of environmental elements (atmospheric air, water, soil), materials used when manufacturing production. Technical specifications can be submitted as a technical description if its content is fully reflects the mentioned above.
4. In case if a hygienic certificate is not available studies are needed in accordance with enactment # 190 of Ministry for Health of Ukraine dated 25/10/97.

Sanitary-hygienic expertise of the documents and correspondent studies are performed by organisations, institutions authorised by the Ministry for Health Protection to perform this activity.

This work shall be done by organisations on the contractual basis.

The term of the expertise and issuance of the "hygienic statement of the Ministry of Health of Ukraine" is, as a rule, 1 month if all necessary documents are available.

In case if special studies and laboratory investigations (tests) are needed terms of certification can be extended to 2 or more months.

List of organisations, institutions that perform necessary studies (tests) shall be updated after preliminary review of the submitted documents by the Department on Medical Issues related to Chernobyl accident and Radiation Protection of the Ministry for Health Protection of Ukraine.

#### **4. Certification**

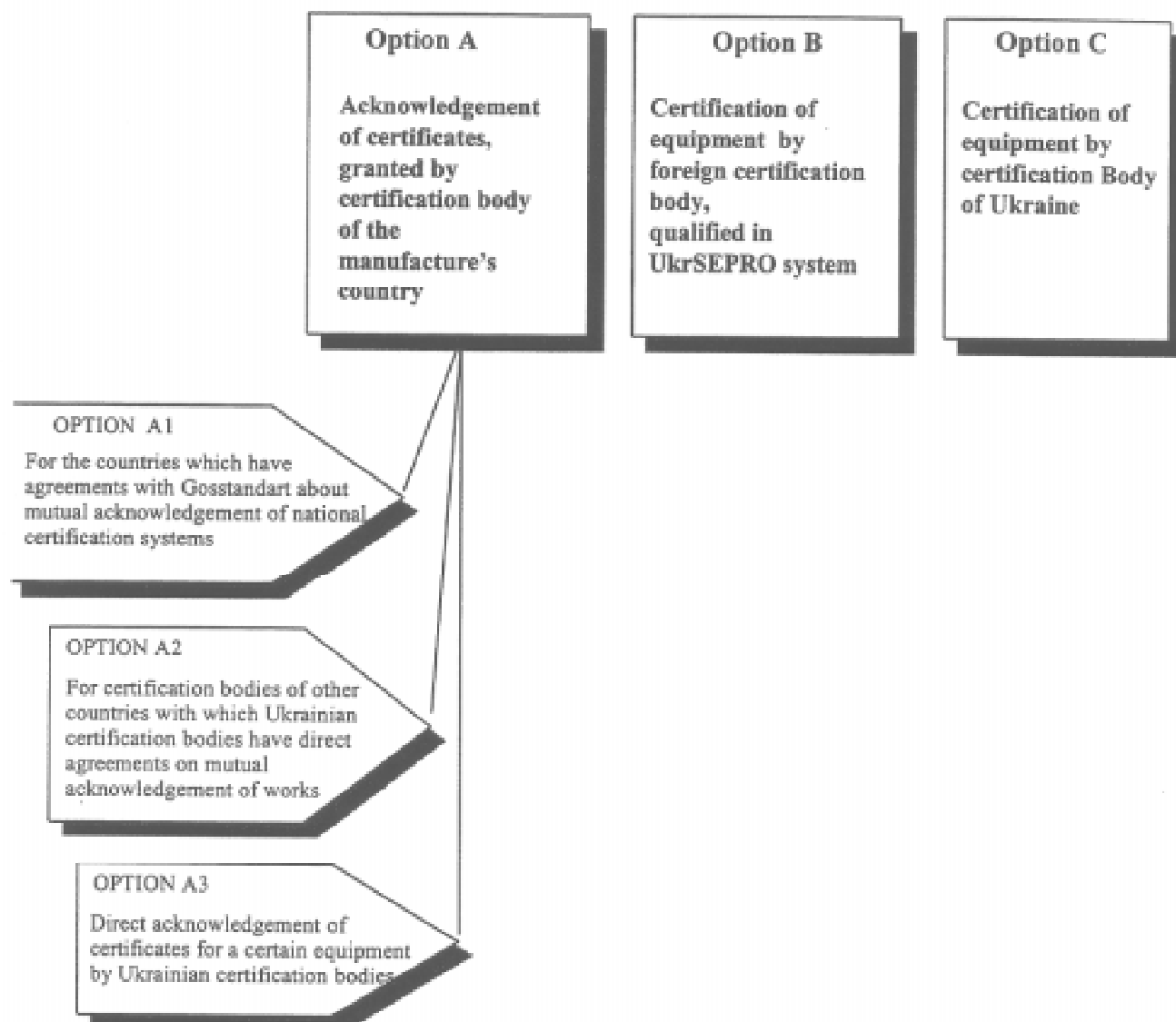
Mandatory certification of equipment to be supplied to nuclear facilities follows the requirements of article 23 Law of Ukraine "On Nuclear Energy Utilisation and Radiation Safety".

This work should be done in accordance with Rules and procedures of national standardisation system UkrSEPRO, defined by GOSSTANDART of Ukraine:

In this context (certification of foreign equipment) in the frames of national certification system UkrSEPRO DSTU 3417 "Procedure of Acknowledgement of certifications results for imported products "is valid. With this UkrSEPRO system has the right to acknowledge certification results with regards to its compliance to the regulatory requirements

##### **4.1. *Analysis of options. Conventional classification used for analysis.***

Certification of production according to documents valid in Ukraine can be undertaken according to the following options:



#### **4.2. Assessment of option applicability.**

##### **4.2.1. Option A-1. Acceptable.**

Agreements on acknowledgement of certification of equipment are concluded where:

- there is a national certification system of the importer state that has administrative and methodological documents, duly qualified equipment certification bodies, testing laboratories (centres) conforming with the requirements of ISO/IEC regarding certification and with the series of standards ISO 9000, EN 45000, EN 29000;
- there are equipment certification bodies and testing laboratories qualified in accordance with the international systems of certification for a certain type of equipment, founded jointly with the states that are parties to the agreement.



- there are certification bodies, test laboratories, qualified in the international certification systems for a certain type of equipment, organised jointly with states-members of agreement.

Rules and procedures for mutual acknowledgement of national certification systems shall be established on the basis of bilateral or multilateral agreements.

Certifications of equipment on the basis of an agreement are issued by the body in charge of certification of this piece of equipment with a certificate (mark) of acknowledgement in UkrSEPRO in accordance with DSTU 3413. While the agreement is valid, complete acknowledgement of certificates (marks) of equipment is possible. In such case, a warrant of acknowledgement is issued according to the established form in accordance with DSTU 3498.

At present, the following foreign certificates are being recognized within the UkrSEPRO system:

1. Those issued within the national certification systems of CIS countries, parties to the International Agreement on Standards, Metrology and Certification, with which bilateral agreements were signed.

These countries are: Armenia (05.17.1993), Georgia (05.26.1993), Russia (04.12.1994), Belarus (06.16.1994), Uzbekistan (04.26.1995), Moldova (07.07.1995), Kirghizia (06.19.1996).

2. Those issued within the framework of international certification systems to which Ukraine acceded:
  - the Electronic Components Certification System (IECQ);
  - the system of electric equipment certification according to safety standards (IECEE), scheme CB

Note: Certificates of conformance of national certification systems (with which bilateral agreements were signed) issued for equipment of third countries are not acknowledged in the System.

Practical application of this option requires Gosstandart clarification of procedures and terms. Particular certification bodies qualified in the national certification systems, time and cost of works are not known. Therefore, this option can be applied only conventionally and only for the supplies made from Armenia, Georgia, Russia, Belarus, Uzbekistan, Moldova, Kirghizia (06.19.1996).

#### 4.2.2. Option A-2.

SQC does not have any data concerning actual agreements of Ukrainian certification bodies with certification bodies of other countries or terms of any such agreements. No practical experience of application of such option is available.

#### 4.2.3. Option A-3. The Basic Option.

Certificate is issued by the equipment certification body qualified to the UkrSEPRO in accordance with the requirements of DSTU 3417-96.

The results of certification of foreign equipment not covered by the agreement, including the certificates (marks) of equipment, may be acknowledged in the UkrSEPRO on the basis of decision about acknowledgement of:

- without further certification procedures (full acknowledgement);
- with the application of additional certification procedures (partial acknowledgement);
- on the basis of positive results of equipment certification in the UkrSEPRO

**Full acknowledgement of certificates** (marks) of equipment not covered by the agreement and of equipment testing results is possible in the case of conformance with the following set of requirements:

- identity of fundamental criteria underlying rules for certification of a piece of equipment in the UkrSEPRO system and in the importer-country
- suing of procedures, similar to those of UkrSEPRO system (first of all regarding the choice of certification model-scheme and samples)
- undertaking of certification tests in the testing centres (laboratories) that have confirmed their technical competence and independence by certificate of qualification granted by the national certification system
- similarity of supervision procedures applied for certified products, quality systems or qualified manufacture

In this case, the certification body issues a warrant of acknowledgement in line with DSTU 3498.

**Partial acknowledgement of certification results** and other functional elements of certification systems of the country of manufacturing which is not a party of the agreement, is possible where an agreement is reached between parties, where insignificant discrepancy emerges during the evaluation of documents pertaining to the characteristics of equipment subject to mandatory certification. In such case, the certification body of a piece of equipment issues a recommendation that additional procedures for certification of equipment regarding those characteristics be applied in testing laboratories of the UkrSEPRO System.

In case of significant divergence emerging during the evaluation of documents pertaining to the characteristics of equipment subject to mandatory certification, the certification body issues a recommendation that full-scale testing of equipment should be undertaken by testing laboratories of the UkrSEPRO or other laboratories in accordance with the UkrSEPRO. The certification body shall upon completion of certification in the UkrSEPRO, issue a certificate of conformance in accordance with DSTU 3413.

Provisionally marked with **A-3** code mark in the Procurement Plan.

#### **4.2.4. Option B. Unapplicable.**

SQC does not have any data concerning foreign certification bodies qualified with the UkrSEPRO. No practical experience of application of such option is available.

#### **4.2.5. Option C. Fully applicable under condition of approval of procedure of certification of serial imported products with Gosstandart**

The "Procedure of Works on Certification for Foreign Products on Schemes, including Inspection, Qualification and Certification of Their Quality Systems", approved by Decree of Gosstandart of Ukraine dated 02/08/97 # 329 defines general administrative requirements on certification, including inspection, qualification of foreign manufactures and certification of their quality systems. According to Gosstandart the provisions of the document are used for serial products or large batches of industrial cycle (more than 1 year).

On our opinion the main shortcoming of the procedure proposed by Gosstandart is its complication because of necessity to approve a number of working procedures with Gosstandart.

The Procedure of certification of foreign equipment proposed in the document contains the following stages:

Stage	Stage description	Organisation Responsible
1.	Application and review of application for certification	Certification Body
2.	Decision making on the application	Gosstandart
3.	Setting up of a Committee to undertake works on certification	Gosstandart
4.	Development of working programme	Gosstandart
5.	Inspection, qualification of foreign manufacture	Committee
6.	Selection, identification of samples	Committee
7.	Tests	Laboratory
8.	Analysis of results received and conclusions	Certification Body
9.	Development of technical supervision Programme	Certification Body
10.	Formalising and registration of compliance certificates	Certification Body
11.	Technical supervision of certified products	Certification Body

At the stages 8,9,10 approval of documents by Gosstandart is mandatory.

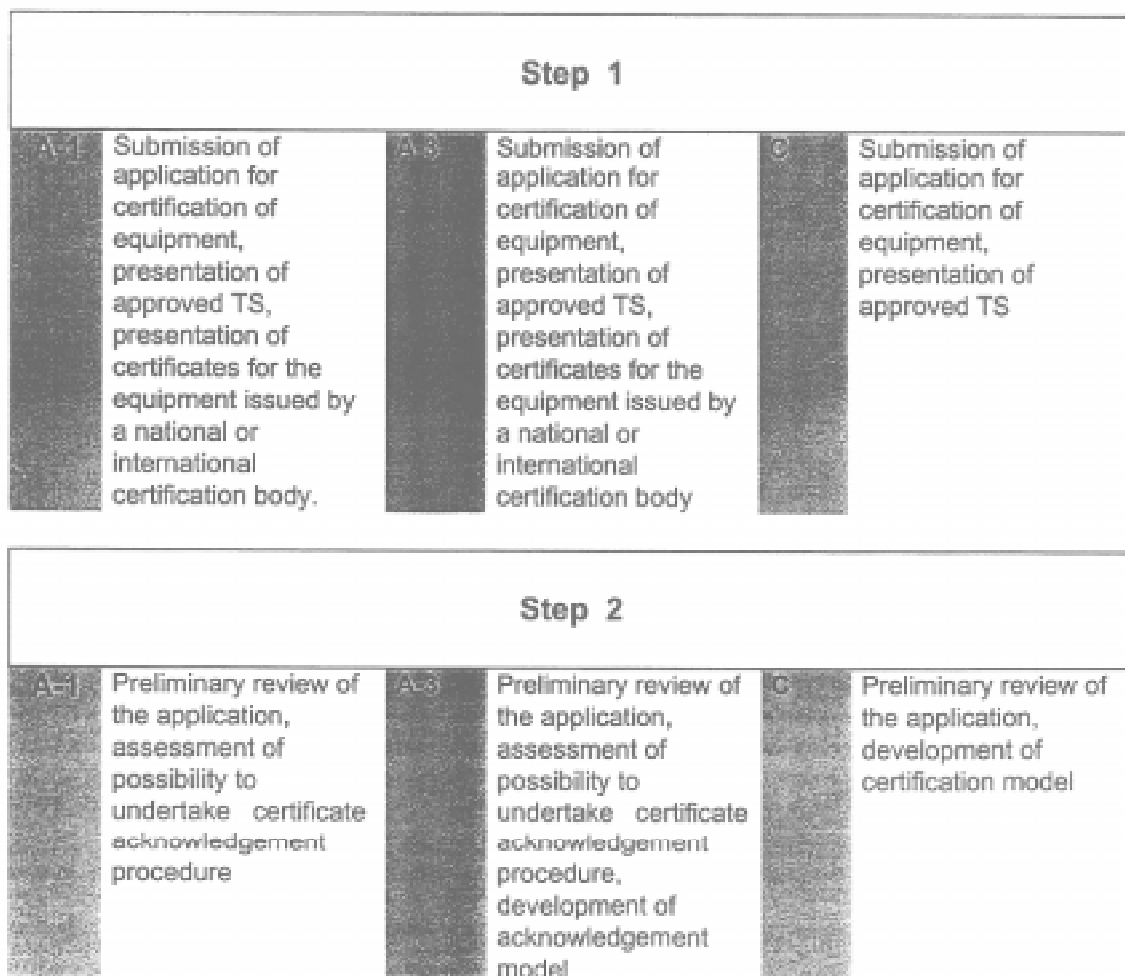
Therefore necessity to receive numerous approvals while undertaking certification procedures complicates work which can lead to increasing of cost and time.

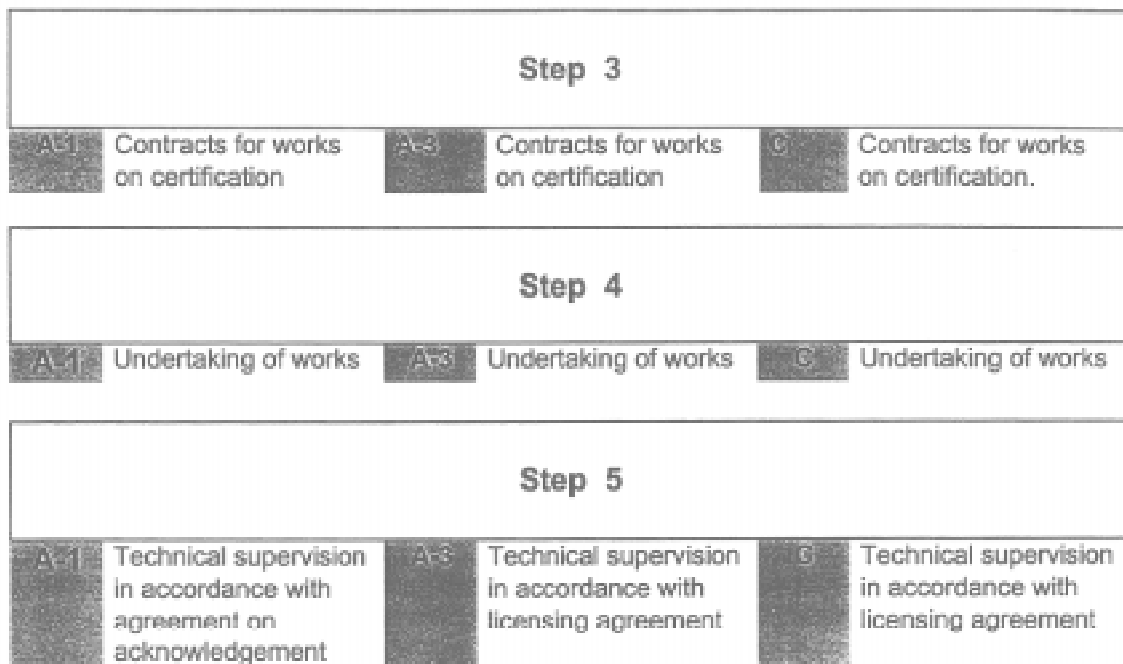
It should be noted, that certification of single products or batch of products, undertaken by certification body in accordance with DSTU 3417 "Procedure of Acknowledgement of certification results of imported products" and with DSTU 3413 does not have such shortcomings.

That is why for foreign supplies made in the frames of assessment programmes it is reasonable to develop and approve with Gosstandart mutually acceptable certification procedures, based on DSTU valid in UkrSEPRO system.

#### . General Description of Certification Procedures

##### 4.2.6. A) General procedures typical for any options (A-1, A-3, C).





**4.2.7. b). Specific procedures.**

**For A-1.**

To receive a **warrant of acknowledgement**, an Applicant has to submit

- an application
- foreign certificate of compliance;
- standard (technical requirements) for equipment (if required by Certification Body)
- certificate on qualification in the national system of certification body and in a test laboratory

**For A-3.**

To receive a **warrant of acknowledgement**, an Applicant has to submit:

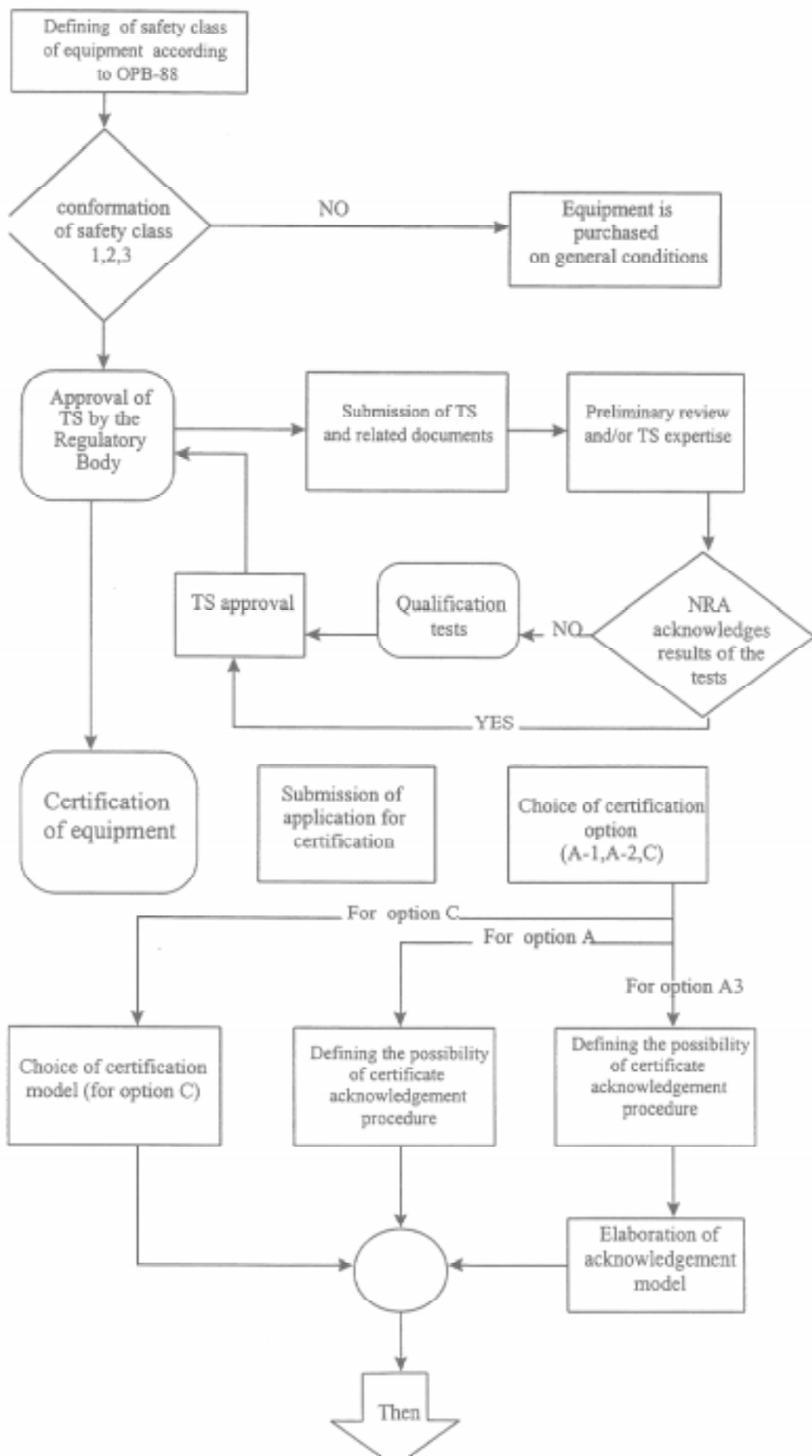
- an application
- foreign certificate of compliance;
- standard (technical requirements) for equipment (if required by Certification Body)
- certificate on qualification in the national system of certification body and in a test laboratory

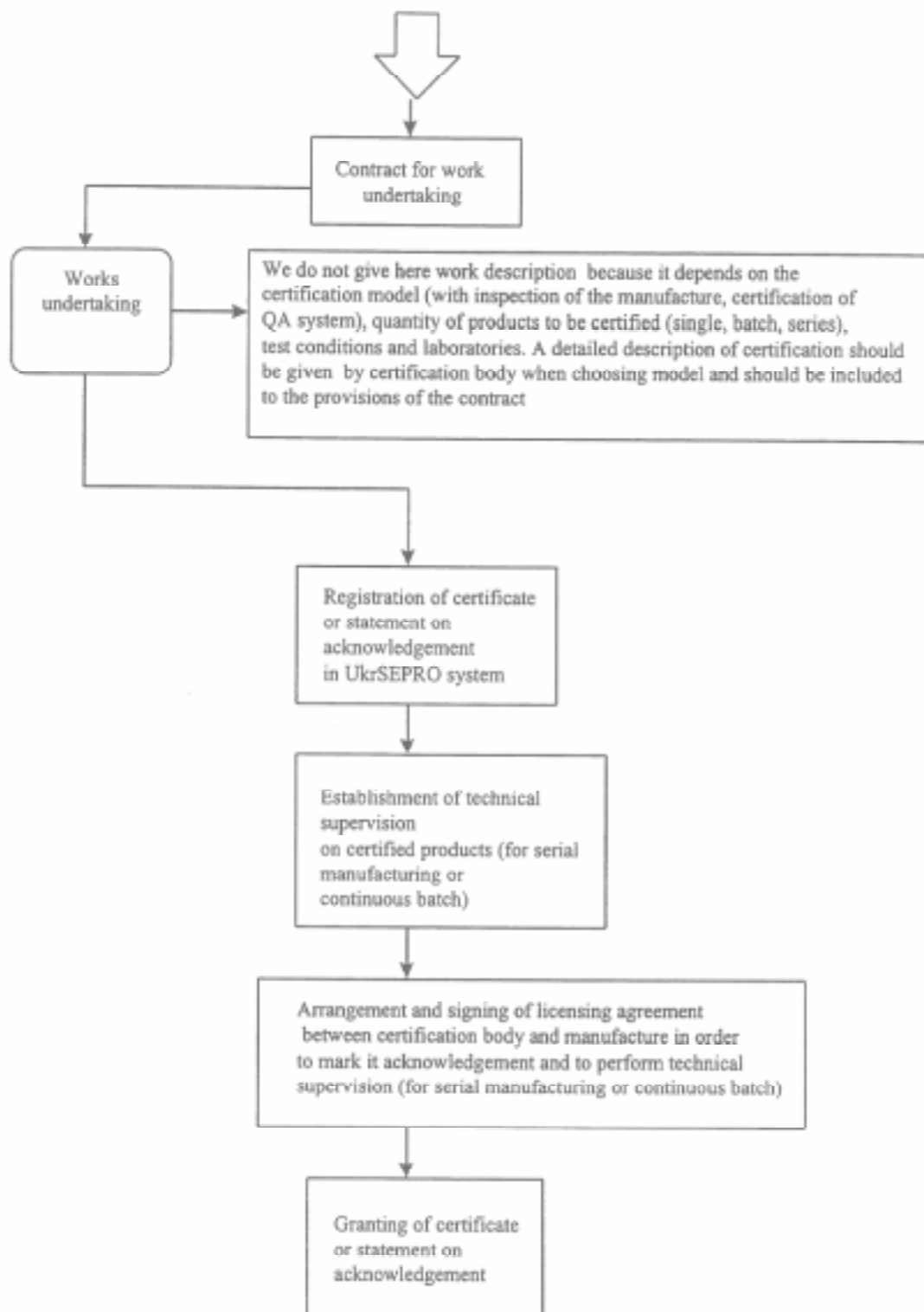
- Protocol of tests
- Manufacture or QA system (if any) certificate

Certification Body can require any additional information to be submitted by an applicant

### **Conclusion**

On the basis of the analysis proposed above the sequence of action is the following:







## 5. (for information) Cost and Time of Certification

For Ukrainian manufactures the Rules on cost estimation of certification work are defined by Appendix K-to DSTU 3413-96.

### 5.1. Time Input

Time needed for obtaining the certificate, varies depending on the kind of equipment subject to certification. As a rule, time needed for completion of certification is three to eight months, **complete with tests**.

In case if time needed for testing of equipment or its components in qualified UkrSEPRO testing laboratories is not taken into account, the tentative normative labour input for certification works, from the moment when application is submitted, taking into account experience of SERTATOM Certification Department is from 18 to 42 man-days.

The indicated labour input depends on complexity groups of a manufacture and equipment, as well as on the necessity of a certification body to participate in the certification tests.

## 6. Conclusions.

Analysis of national UkrSEPRO system shows possibility its application for R4/Kh2 completion project and as well for direct supplies to Ukrainian NPPs

- for supplies made by Ukrainian companies in full according to **option C**
- for enterprises of seven CIS countries: Russia, Belarus, Georgia, Moldova, Uzbekistan, Armenia and Kirghizstan, that signed the agreement on acknowledgement of national certification systems at the level of member states' Gosstandarts: in full, ***on condition of certain coordination work between the certification bodies according to option A-1***;
- for supplies from EC countries **according to option A-3 or C**.

While undertaking work by SQC experts, the following comments and recommendations were made:

- 1 Safety classification proposed by KIEP has to be approved by NRA according to the classification accepted in OPB-88 since only safety-related equipment is to be certification.
- 2 Under any selected option (**A-1, A-3, C**) for foreign producers it is reasonable to apply for certification in Ukraine depending on the selected option beforehand

- 3 To facilitate acknowledgement (A-1, A-3, C) (time and labour input) Ukrainian auditors, whose participation would not affect the time needed to undertake certification of foreign equipment and products should be involved for the job.

The present document contains a preliminary analysis for developing general issues or decisions by participants of the procedures (first of all, Nuclear Regulatory Administration, MINENERGO, utilities, certification bodies and Gosstandart) and can not be used as a normative or methodological document

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*Director*