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| Title : | REGULATIONS ON THE DEDICATION OF COMMERCIAL GRADE ITEMS AND CERTIFICATION OF DEDICATION AGENCY  |
| Date : | 2008.10.23 |
| Legislative : | 1. 中華民國九十二年十二月三日行政院原子能委員會會核字第 092003268 1 號令訂定發布全文 12 條；並自發布日施行 2. 中華民國九十五年十二月十二日行政院原子能委員會會核字第 0950034 131 號令修正發布名稱及全文 13 條；並自發布日施行（原名稱：核能同級品檢證作業及檢證機構認可管理辦法） 3. 中華民國九十七年十月二十三日行政院原子能委員會會核字第 0970017 212 號令修正發布第 2、4 條條文；並增訂第 5-1、6-1、12-1 條條文 |
| Content : | <p>REGULATIONS ON THE DEDICATION OF COMMERCIAL GRADE ITEMS AND CERTIFICATION OF DEDICATION AGENCY</p> <p>Promulgated by Decree Hueih-Her-Tze No. 0920032681 on December 3, 2003 Revised and promulgated by Decree Hueih-Her-Tze No. 0950034132 on December 12, 2006 Revised and promulgated by Decree Hueih-Her-Tze No. 0970017212 on October 23, 2008</p> <p>Article 1 These Regulations are enacted pursuant to Article 16 of the Nuclear Reactor Facilities Regulation Act.</p> <p>Article 2 The terminology used in these Regulations shall be respectively defined as follows:</p> <p>1. Critical Characteristics: Essential characteristics such as design, materials, functions of the Nuclear Grade Item which can be demonstrated through inspections, tests and/or analysis, etc. to provide reasonable assurance that the item can indeed perform its intended safety functions.</p> <p>2. Commercial Grade Item: An item not designed nor fabricated in accordance with the Nuclear Grade Item' s unique specifications.</p> <p>3. Dedicated Commercial Grade Item: A Commercial Grade Item demonstrated through specific dedication procedures whose characteristics are equivalent to the Critical Characteristics of the corresponding Nuclear Grade Item.</p> <p>4. Technical Evaluation: The evaluation process for establishing the Critical Characteristics and Acceptance Criteria in accordance with the item' s functional requirements and for confirming that all relevant requirements are specified in detail in the item' s procurement document.</p> <p>5. Dedication: The operation through the Technical Evaluation and the Acceptance Procedure to verify that the Commercial Grade Item' s characteristics are equivalent to the Critical Characteristics of the corresponding Nuclear Grade Item.</p> <p>6. Acceptance: The approach of the provision of reasonable assurance based on objective evidence that the Commercial Grade Item received is indeed the corresponding Dedicated Commercial Grade Item.</p> <p>7. Acceptance Criteria: Acceptance standard for an Item' s dedication results, established in accordance</p> |

with the intended functional requirements for the Nuclear Grade Item.
8. Environmental Qualification Test: A test performed to dedicate the characteristics of the randomly selected items from the same manufacturing batch, and under the simulated actual environmental conditions. The test results must assure that the same batch of items will be suitable for the actual environmental conditions. The main actual environmental conditions to be simulated shall include temperature, pressure, humidity, radiation and chemical effect, etc.
9. Failure Modes and Effects Analysis: The evaluation of an item's failure mechanism and its effect on the intended safety functions.

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10. Safety Functions: Those functions, as listed in the following, of a system, structure, or component of a nuclear reactor facility during normal service conditions, anticipated abnormal events, design basis accidents, external events, and natural phenomena must be assured.
(1) The integrity of the reactor coolant pressure boundary,
(2) The capability to shut down the reactor and to maintain its safe shutdown conditions, and
(3) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite radiation exposures exceeding the prescribed specific limits.
11. International Nuclear Procurement Quality Assurance Organization: A non-profit international organization represented by international nuclear utilities operating nuclear power plants to conduct joint audits on dedicated commercial grade item suppliers or dedication agencies in accordance with Quality Assurance Criteria and Quality Assurance Program for nuclear power plants.
12. Approved Suppliers List: A list established by the licensee after the licensee has reviewed the dedicated commercial grade item suppliers or dedication agencies that are qualified through joint audits by International Nuclear Procurement Quality Assurance Organization.
13. Safety Hazard: Degradation of the safety functions to the structures, systems, and components of a nuclear facility that has caused significant reduction of protection to public health and safety.

Article 3

The Licensee is subject to the inspections by the Regulatory Authority for the regulation of the

Commercial Grade Item dedication, and is responsible for the following:

1. Establishing plan(s) and procedure(s) for the dedication of Commercial Grade Items,
2. Conducting technical evaluation and establishing acceptance criteria,
3. Checking and confirming the suitability of the dedication procedures whether the dedication is conducted by the Licensee or by the Licensee's certified dedication agency.

The Licensee shall check and confirm the reliability and safety of the Dedicated

Commercial Grade Item used in nuclear safety-related applications, and

4. The documentation control of the Dedicated Commercial Grade Item.

Article 4

The licensee can directly procure Dedicated Commercial Grade Items or dedication services from

suppliers in the Approved Suppliers List but the licensee shall be responsible for executing the following

subject to inspection by the Regulatory Authority:

1. Conforming that the Commercial Grade Item procured from a supplier in

the Approved Suppliers List
has Critical Characteristics equivalent to, and can be used the same as,
the corresponding Nuclear
Grade Item.

2. Conforming that the dedication implemented by the Commercial Grade Item
Dedication Agency in
Approved Suppliers List is in accordance with the dedication procedure(s).

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3. Reviewing and updating the Approved Suppliers List every year and
keeping the related
documentations until the nuclear reactor facility is decommissioned.

Article 5

The Commercial Grade Item Dedication Agency (hereinafter as Dedication
Agency) is responsible for
the following:

1. Establishing Commercial Grade Item dedication procedure(s) and quality
assurance program, and
accepting inspection or auditing from the Licensee and the Regulatory
Authority.

2. Accepting a Licensee' s order to provide technical evaluation and
acceptance criteria.

3. Accepting order from and being responsible to a Licensee or Commercial
Grade Item supplier to
conduct dedication in accordance with the procurement document concurred by
the Licensee.

4. Effective control of the Commercial Grade Item' s dedication
documentation.

Article 5-1

Dedicated commercial grade items shall not apply to fuel assemblies,
control rod assemblies, and reactor
coolant pressure boundary components.

Article 6

Both the Dedication Agency and the Licensee shall be responsible to file
Attachment I to report the
abnormality of the Dedicated Commercial Grade Item to the Regulatory
Authority within one month
when defect or unsuitable condition has been found on a Dedicated
Commercial Grade Item.

Article 6-1

If a deviation or nonconformance is discovered or informed by a qualified
supplier, the licensee shall
notify the Regulatory Authority within 24 hours and submit a report within
30 days to describe whether
the deviation or nonconformance may cause safety hazards.

Article 7

Technical Evaluation of the Dedicated Commercial Grade Item shall include
the following:

1. Confirming that the proper specifications and safety grade which are
used for the nuclear grade items
in the reactor facilities.

2. Analyzing the failure modes and failure effects of the Commercial Grade
Items to the safety function
of systems and components / parts of the nuclear grade items.

3. Establishing the Critical Characteristics and test plan for the nuclear
grade items based on the failure
modes and effects analysis, and evaluating its effects to the monitoring of
the structures,
systems, and components (SSC) and the in-service inspection and testing
program.

4. Establishing the requirements for the procurement specification and
acceptance criteria
conforming the procurement requirements, based on the results of the
technical evaluation.

5. Evaluating the relevance to include seismic qualification and the
environmental

qualification to the dedication program.

Article 8

Based on the acceptance criteria to establishing the acceptance program, the following acceptance methods shall be selected on the specific Critical Characteristics of the nuclear grade items.

1. Special Tests and Inspections

Special Tests and Inspections shall be conducted in accordance with the established acceptance criteria and procedures, and shall verify that the Dedicated Commercial Grade Item does have the Critical Characteristics required to carry out its safety functions.

2. Survey or Audit of Supplier

The supplier shall have a qualified Quality Assurance (QA) program and operating procedures. These requirements shall be extended as needed to include the parts of the Commercial Grade Items and/or the material manufacturer. Supplier survey or audit shall include not only QA specialist but also technical personnel in order to ensure that the supplier, the parts and/or the material manufacturer do have an appropriate and effectively implemented QA program.

3. Source Verification

For those Critical Characteristics or Acceptance Criteria that can not be assured by special tests and inspections, Source Verification, through on-the-scene inspections of the procedures and documentation of the Commercial Grade Item's material fabrication process, shall be conducted to ensure that the item has been fabricated in accordance with a specified process. The requirements for Source Verification shall be stated in the procurement document.

4. Acceptable Supplier/Item Performance Record

Acceptable Supplier/Item Performance Record means acceptable supplier/item performance record based on the dedication requirements.

Method 2 and method 4 shall not be used alone. They shall be used together with other method(s).

Article 9

The Dedication of Commercial Grade Items shall be in compliance with the ROC national codes and standards, and other codes and standards recognized by the Regulatory Authority.

The Dedication Agency shall have a QA program in compliance with the ROC national codes, standards or other codes and standards recognized by the Regulatory Authority.

Article 10

The organization of the Dedication Agency shall have the following functional units in order to conduct the dedication:

1. Technical Unit for Dedication

The Technical Unit shall have engineering specialists in various fields to conduct the Dedication of

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Commercial Grade Items. These engineering specialists shall have at least 3 years of relevant nuclear experience.

2. Dedication Facility

The Dedication Facility shall have a laboratory or equipment to conduct electrical, electronics, mechanical, chemistry, nuclear, material, structural, and radiation functional tests and analysis of the Critical Characteristics as required for the scope of the dedication.

3. Quality Assurance Unit

The QA unit shall possess a dedication relevant QA program, QA procedures, and QA engineer(s).

4. Document Control Center

The Document Control Center shall have a document storage room and a document control system.

The center shall have capability to store documents for 40 years.

If needed, the Dedication Agency may entrust local or foreign qualified laboratory(ies) or qualified professional institute(s) to conduct the dedication, but the Dedication Agency shall be responsible for the results of dedication.

The qualified laboratory or qualified professional institute referred to in the preceding paragraph shall denote the laboratory or professional institute which has been evaluated by the Dedication Agency or has been recognized by prestigious independent institute for verification.

Article 11

For Certification, the Dedication Agency shall state and submit to the Regulatory Authority the application as per Attachment II. A Certificate of Dedication Agency will be issued once the application has been reviewed and approved.

The valid period of the Certificate of Dedication Agency referred to in the preceding paragraph

shall be three (3) years, and an application enclosing the documents set forth in Attachment II

may be re-submitted to the Regulatory Authority for renewal during the six (6)-month period prior to the expiration.

Article 12

During the validity of the Certificate of the Dedication Agency, the Regulatory Authority may

order the Dedication Agency to improve the situation within the specified period, if any of the following circumstances occurs:

1. The inspection or audit by the Regulatory Authority has been declined thereby.

2. During the operation of dedication executed by the Dedication Agency, there is a gross ineffectiveness in respect of quality or dedication, which has resulted in a nuclear incident or equipment damage(s).

3. Failure to report abnormality of the Dedicated Commercial Grade Items in accordance with the prescriptions.

4. Serious violation of prescriptions under these Articles hereto.

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Article 12-1

The Licensee shall submit a status report, on the use of the Dedicated Commercial Grade Items in previous year, to the Regulatory Authority before the end of February every year.

Article 13

These Regulations shall become effective as of the date of promulgation.

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ATTACHMENT I

Abnormality Report of Dedicated Commercial Grade Item

I. Basic Information

Date of Finding: _____ Date of Submission: _____ No.:

Reporting Unit: Reporter: Tel:

Entrusted Unit of Dedication Agency:

Appellation of Item: _____ Supplier:

Installation Location/System: _____

Type No: Specification: Quantity:

II. Description of abnormality

III. The condition of hazard which has or shall have caused to nuclear reactor facilities

IV. The evaluation of conditions in this country and in countries abroad

V. The corrective action which has been completed, underway, or to be adopted

VI. Suggestion(s)

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ATTACHMENT II

Application for Certification of Dedication Agency for Commercial Grade Items

I. Basic Information

1. Responsible Person for the Agency: _____

Date of Application: _____

2. Full Name of the Agency: _____

3. Address for Correspondence: _____

4. Telephone: __ __

Facsimile: _____

II.

Materials to be enclosed herewith

1. The scope of dedication applied for and the description on the competency of the dedication laboratory. (Applicable to application for certification)

2. The quality assurance manual of the dedication agency. (Applicable to application for certification)

3. The procedures for dedication of the commercial grade items. (Applicable to application for certification)

4. The Letter of Certification stating that the applicant is willing to accept the audit and the inspection of ROCAEC. (Applicable to foreign agency)

5. The record on dedication for the past three (3) years. (Applicable to foreign agency and/or application for renewal)

6. The written proof that during the past three (3) years, the inspection held by the national Regulatory Authority in charge of nuclear safety of the country/state where the dedication agency is located. (Applicable to foreign agency and/or application for renewal)

7. The summary of major amendment(s) on the quality assurance system. (Applicable to application for renewal)

8. Description on the change in personnel that may have significant effects on the dedication. (Applicable to application for renewal)

III. The applicant does hereby warrant that the contents of this application and the materials enclosed herewith are true, and shall be subject to the punishment decided by ROCAEC

according to the statutory regulations, if there is any false.

Signature of Responsible Person for Dedication Agency: _____

Attachments : 附件一核能同級品零組件異常提報表.DOC
附件二核能同級品零組件檢證機構認可申請書.DOC