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FRENCH REPUBLIC
MINISTRY OF INDUSTRY

DIRECTORATE FOR INDUSTRIAL
QUALITY AND SAFETY

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CENTRAL DEPARTMENT FOR THE
SAFETY OF NUCLEAR INSTALLATIONS
(SCSIN)

SIN n° Z/5613/81

BASIC SAFETY RULES
RULE n° V.2.a

PART V : General rules applicable to several systems, structures or components

Chapter 2 : Other general rules

RULE IDENTIFICATION WITHIN REFERENCED CHAPTER : a

SUBJECT : General rules applicable to Quality Assurance

SCOPE : Nuclear power plant units equipped with a pressurized-water reactor

PROVISIONAL DATE OF APPLICATION : 15th November 1981

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0. INTRODUCTION

RFS or "Règles Fondamentales de Sûreté" (Basic Safety Rules) applicable to certain types of nuclear facilities lay down requirements with which compliance, of the type of facilities within the scope of application covered by the RFS, is considered to be equivalent to compliance with technical French regulatory practice.

The object of RFS's is to take advantage of standardization in the field of safety, while allowing for technical progress in that field.

These RFS should make safety analysis easier and lead to better understanding between experts and individuals concerned with the problems of nuclear safety.

In no way do the RFS's limit the overall responsibility of the operating utility and in no way do they release it from its obligation to meet regulatory provisions in force.

For those nuclear facilities not yet granted a construction permit one year from the publication of a RSF, the operating utility which does not wish to apply this RFS must demonstrate that the safety objectives of the RFS are met by such alternative means as it shall propose, within the context of the regulatory procedures in force. Unless explicitly excluded, this time period may be extended by two years in the interests of standardization in the case of a facility regarded as identical to a facility which has already been granted a construction permit.

As far as other nuclear facilities are concerned, inasmuch as RFS's allow for technical updating while being based on information current at the time of publication, RFS publication does not, by itself, entail review of previous RFS's in the light of the new RFS, unless explicitly required by a decision applied retroactively and considered necessary irrespective of RFS publication.

Moreover, the SCSIN reserves the right to modify, when considered necessary, any RFS and specify if need be the terms under which a modification is deemed retroactive ; for other cases, the above-mentioned rules relating to the dates of applicability are to be applied under the same conditions as an original RFS when a RFS is revised.

In practice, therefore, the structure of RFS's, with respect to nuclear power plant units equipped with a pressurized water reactor, corresponds to the table of contents appended to this RFS in Appendix 1.

1. SCOPE OF THE RULE

Technical French regulatory practice with regard to nuclear safety requires the operating utility to ensure that safety-related structures, systems and components shall be designed, fabricated, erected and tested to quality standards commensurate with the importance of the safety functions to be performed. An efficient quality assurance program must be established to define the quality required, to achieve this quality, to control the quality achieved and to rectify any errors ; it must comprise the implementation of a series of planned and systematic actions, documented by written policies, procedures and instructions ; furthermore, it shall begin at the design phase, continue throughout plant construction, commissioning tests, plant operation and decommissioning.

The aim of this rule is to define a series of measures to meet these general regulatory requirements. By applying this rule, the quality assurance code of practice for nuclear power plant safety, established by the "Agence Internationale de l'Energie Atomique" (International Atomic Energy Agency), is considered to be observed. However, the rule comprises additional requirements not included in the I.A.E.A. code.

The standing committee on nuclear reactors was consulted in drawing up the rule.

2. TEXT OF THE RULE

In order to satisfy French regulatory practice as specified in 1 above, the provisions defined in 2.0. to 2.10. below are to be applied by the operating utility of a basic nuclear installation and by its suppliers :

2.0. General responsability of the operating utility

2.0.1. The operating utility is responsible for the safe operation of his plant. It is his responsibility to ensure that the provisions of this rule are applied and complied with by his personnel as well as by the various suppliers.

The operating utility is bound by contract to exercise this responsibility in the following manner :

- the operating utility shall inform suppliers of the provisions in the rule, whereupon the suppliers shall apply them in their operations and, if necessary, in further operations which they are required to undertake according to these provisions,

- the operating utility or the suppliers shall implement an appropriate supervision program including, where necessary, a definition of phases and operations for which representatives sent by the operating utility, possibly from its own staff, must be present or at least notified. In such cases the operating utility shall define the functions, responsibilities and powers of the representatives ; for cases where the provisions are not respected, it shall implement an appropriate penalty system which, for example in a manufacturing context, could involve a refusal of purchased equipment.

The operating utility shall perform audits and shall draw any relevant conclusions.

Furthermore, the operating utility shall ensure that wherever suppliers themselves deal with other suppliers, the provisions specified in the rule shall be applied under the same conditions.

2.0.2. The operating utility is required to include in its preliminary safety analysis report a succinct description of the measures taken or envisaged by both the operating utility and its suppliers for applying the rule to plant design, construction and, where necessary, tests prior to fuel loading.

The preliminary safety analysis report (PSAR), or in some cases to the general operating rules, shall include a description of the measures envisaged for applying the rule to the following activities : commissioning tests, maintenance, supervision, repairs, modifications and plant operation ; the PSAR shall also include a report summarizing the efficiency of the measures envisaged and the lessons drawn therefrom with respect to design, construction and preliminary testing.

In the final safety analysis report (PSAR) the operating utility is required to include a report summarizing the efficiency of the measures taken and the lessons learned, particularly during commissioning tests ; the final safety analysis report shall also include any modifications suggested to be made to the original measures.

2.1. General organisation

2.1.1. The provisions defined below are applicable to all activities affecting safety-related functions of structures, systems and components in the nuclear installation involved.

These activities deal with designing, constructing, commissioning, testing, plant operation, decommissioning and concern studies, purchase, process, fabrication, handling, shipping, storage, cleaning, erection, installation, tests, in service inspection, maintenance, repair, refuelling and modifications.

2.1.2. The operating utility shall ensure, within the framework of his overall responsibilities as specified in 2.0., that the provisions defined in 2.1. to 2.10. shall be applied in all the above activities ; they may be accomplished by the operating utility or its suppliers, and the suppliers may supply equipment or provide services.

A supplier is defined as the holder of contract for supplying equipment or providing services concluded with the operating utility or another company which itself provides services.

However, where the operating utility or one of its suppliers deals with a company supplying only personnel or equipment, the company may not be bound by the provisions of the rule, provided that the operating utility or supplier dealing with the company subjects the personnel or equipment to their own internal requirements.

2.1.3. For nuclear plant safety-related activities which commence before a construction permit has been granted, the provisions specified in this RFS shall be implemented at the beginning of each activity. The future operating utility shall submit a declaration to the Central Department for the Safety of Nuclear Installations (Service Central de Sûreté des Installations Nucléaires, S.C.S.I.N.), in connection with its construction permit request and the required preliminary safety analysis report : the declaration shall concern the commencement of these activities and the steps it has taken to ensure that this RFS is applied. This declaration shall enable the SCSIN to perform any surveillance visits it deems necessary during these activities.

For pre-construction activities, the provisions of this rule may however be adapted or not totally applied in as much as no irreversible provision may result from them.

2.1.4. Having declared that it will implement the provisions of this RFS, the operating utility may however depart from the rule and authorize its suppliers to do so with respect to certain activities where applying the rule is impossible or creates requirements out of all proportion with safety objectives ; on condition that the alternative measures chosen provide the same guarantees that the activities shall be accomplished with proper regard for safety. The operating utility must be able to provide justification in this respect.

2.1.3. For nuclear plant safety-related activities which commence before a construction permit has been granted, the provisions specified in this RFS shall be implemented at the beginning of each activity. The future operating utility shall submit a declaration to the Central Department for the Safety of Nuclear Installations (Service Central de Sûreté des Installations Nucléaires, S.C.S.I.N.), in connection with its construction permit request and the required preliminary safety analysis report : the declaration shall concern the commencement of these activities and the steps it has taken to ensure that this RFS is applied. This declaration shall enable the SCSIN to perform any surveillance visits it deems necessary during these activities.

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2.2. Principles

2.2.1. The operating utility shall identify safety-related activities and define the requirements for each activity with regard to safety and regulations in force.

2.2.2. The operating utility shall ensure that the human and technical resources and the implementation program for each activity are adapted to the requirements as defined. Quality Assurance objectives shall be achieved by those personnel responsible for executing the Quality Assurance program.

2.2.3. The operating utility shall establish an efficient system to provide control over each activity. This system shall also ensure that corrective actions are taken to rectify any non-conformances and faults.

2.2.4. The operating utility shall ensure that measures are taken to establish that the system adopted as per 2.2.1., 2.2.2. and 2.2.3. shall function efficiently under suitably controlled conditions. Persons and organizations performing quality assurance functions shall be directly answerable to the appropriate management level for the activity concerned and report regularly on their activities and the information gained from them, and propose measures they consider necessary.

2.2.5. The Quality System is defined as the collective measures taken to meet the above requirements. The measures taken to meet the above requirements for a specific activity or group of activities constitute the Quality Assurance program for the activity or group of activities concerned. Where the term "quality assurance program" is used in this RFS, the measures envisaged covers both cases of a specific activity or of a group of activities.

2.2.6. These quality assurance programs may be revised. Where changes are made, interim provisions adopted for each activity shall be precisely defined.

2.3. Documents

The operating utility shall ensure that the following documents concerning safety-related activities are established and up dated :

2.3.1. A document or set of documents designated the "quality assurance manual", which describes the appropriate quality assurance program before each activity is begun. The manual may cover several activities.

2.3.2. Procedures, describing a priori the way in which each safety related activity shall be accomplished, particularly in accordance with the principles in 2.2., the way it shall be controlled and any non-conformances rectified, in accordance with the principles in 2.2.3. Documents concerning a particular activity may be included in the quality assurance manual.

2.3.3. A surveillance program, to be established in accordance with the principles in 2.2.4., aiming to verify that the system established as per 2.2.1., 2.2.2. and 2.2.3. is correctly implemented.

2.3.4. Documents, prepared in accordance with those documents specified in 2.3.1. and 2.3.2. which report the progress of each activity and the trend of main parameters which make it possible to identify and caracterize the conditions under which each activity is accomplished and controlled, and to evaluate its results. These documents shall certify a posteriori that the principles specified in 2.2.2. an 2.2.3. have been conformed with.

2.3.5. Reports, prepared in accordance with the documents specified in 2.3.3., certifying that the checks envisaged in pursuance of the principles of 2.2.4. have been implemented and indicating their results.

2.3.6. In compliance with the provisions of 2.0.2., a summary based on information contained in the documents specified in 2.3.4. and 2.3.5. evaluating the efficiency of the quality assurance program and its adequacy to fulfill quality objectives.

2.4. Document retention

The operating utility shall ensure that the documents specified in 2.3. are kept for the appropriate retention period and under suitably controlled conditions ; they shall be easily accessible and kept up to date.

Retention arrangements shall be explained in a written description to be kept up to date. Document retention principles shall be submitted to the appropriate management level and any modifications thereto must be presented to the management in a written declaration.

2.5. Human resources

The operating utility shall ensure that persons performing safety-related activities are suitable, and that only those persons with the appropriate qualifications may accomplish such activities. It must define those activities requiring prior certification of personnel, taking into account the provisions in force and the extent to which the activity is important to safety. It shall ensure that the conditions under which personnel are certified or re-certified are suited to the activities to be performed by the personnel concerned and correspond to the importance of each activity.

The operating utility shall define those activities whose nature and importance justify the fact that the measures taken for qualifying and certifying personnel assigned thereto are included in the quality assurance program and described in the documents specified in 2.3.

The operating utility must be able to report to the appropriate administrative level on the definition and application of these measures and provide the required justifications.

Certification of personnel shall be performed by the employer in accordance with clearly defined procedures under management control ; the aim is to qualify one person for performing specific activities.

2.6. Technical resources

The technical resources for a given activity are the equipment and processes used and the conditions under which an activity is accomplished.

The operating utility shall ensure that the technical resources are suitable for each safety-related activity.

Taking into account the provisions in force and the extent to which the activity is important to safety, the operating utility shall define the activities for which technical resources are qualified and stipulate the corresponding resources and qualification conditions.

Measures relating to the quality and qualification of the technical resources employed for a given activity shall be all included in the quality assurance program for this activity ; the documents specified in 2.3. shall contain a description of these measures and indicate the way in which they are applied. The operating utility must be able to report to the appropriate administrative level on the definition and application of these measures and provide the required justification.

2.7. Organization

2.7.1. The operating utility shall ensure that :

a) Each activity affecting safety-related functions is accomplished with the appropriate technical and human resources ; this may comprise examination, verification and inspection of work by those who perform it.

b) Each activity is efficiently accomplished and its results are satisfactory and that correction of any non-conformances is systematically controlled. These control measures may be implemented by the personnel performing the activity in question. However, they must be implemented by qualified persons familiar with quality problems and using the appropriate technical resources. A report on these control measures shall be submitted to those persons with sufficient authority over the personnel who perform the activity in question ; the persons in authority may at any time modify or suspend the activity or reject some of its products.

c) The measures specified in a) and b) above are properly established and efficiently controlled by persons independent of those performing the activity specified in a). These persons shall be clearly identified and their duties precisely defined ; they shall have all appropriate human and technical resources at their disposal. They shall report to the management level having general authority over the activity in question.

The operating utility shall ensure that a comprehensive system of audits is performed to verify the implementation and efficiency of the quality assurance program for each safety-related activity. The audits shall be performed by persons not directly responsible for the activity to be audited. Audit reports shall be submitted directly to the appropriate management level as defined in 2.2.4. The number and extent of the audits to be performed depends upon the importance of the safety-related activity in question ; the audit schedule shall be established according to the actual progress of these activities.

d) According to 2.0.1. above, activities which are the subject of a contract between an operating utility and supplier shall be supervised, in order to ascertain that the supplier applies the provisions of this RFS and that a quality assurance program and organization exist, of the type described in a), b) and c), provided that the provisions specified in 2.1.4. are conformed with. The documents described in 2.3. shall be made available to the persons performing the supervision.

2.7.2. The operating utility shall ensure that all special precautions are taken with regard to site cleanliness, identification of stocks and materials, calibration of equipment, or definition and surveillance of certain construction or inspection parameters.

2.7.3. Where an activity or group of activities involves several operating utility shops or offices, or one or several suppliers, the responsibilities of each and their interfaces shall be clearly defined and the coordination between these organizations assured by the appropriate measures. The content and distribution of documents describing the links between these organizations shall be specified on the basis of their importance for safety.

2.7.4. The measures established in compliance with paragraph 2.7.1. shall be included in the quality assurance program for the activity in question and shall be described in the various documents specified in 2.3.

The operating utility shall report to the appropriate level of the administration on the definition and application of these measures and provide the required justifications.

2.8. Non-conformances and incidents

Any deviation from an important safety requirement shall be considered as a non-conformance or fault, along with any situation justifying corrective action from the safety point of view. Non-conformances and faults shall be considered as significant inasmuch as they affect safety.

Provisions 2.8.1., 2.8.2. and 2.8.3. deal exclusively with safety-related non-conformances and faults ; provisions 2.8.4., 2.8.5. and 2.8.6. deal with overall non-conformances and faults.

2.8.1. The operating utility shall ensure that all safety-related non-conformances and faults are recorded in a written statement and forwarded to the appropriate administration level as soon as possible. The statement shall be accompanied by a description of the preliminary measures taken to limit the non-conformance or fault in question and, if need be, to limit the consequences. Where the installation is in operation, the statement shall specify the measures taken or envisaged for recommencing operation under sufficiently safe conditions.

2.8.2. Taking into account where possible previously established criteria, a procedure shall make it possible to determine for each activity those non-conformances or faults considered to be significant from the safety point of view. It shall specify those persons responsible for determining the above.

2.8.3. For each non-conformance or fault, the operating utility shall ensure that a "dossier" is gradually prepared for the following purposes :

- To analyse the origin of the non-conformance or fault and evaluate the lesson they provide, if need be, for other activities for which the operating utility is responsible ;

- To evaluate the extent to which the non-conformance or fault may be adverse to safety ;

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- To define or justify any measures required with regard to extra checks, repairs or modification of operating conditions ;

- To define or justify the extra checks which may be required for in-service inspection of the installations concerned ;

- To analyse the way in which the quality assurance program operates for a given non-conformance or fault and the lesson they provide ; if need be, to re-examine the qualification of the human and technical resources concerned.

This "dossier" shall be prepared according to a schedule consistent with the design, construction and operation program of the installations concerned. A preliminary evaluation of the schedule along with the first documents available shall be submitted to the appropriate administration's level, apart from a few justified exceptions, approximately one month after the non-conformance or fault has been declared. The schedule shall also specify the locations where surveillance visits may be performed, to ensure that the above-mentioned documents are duely prepared and substantiated and that the relevant actions are efficiently accomplished.

2.8.4. More generally, appropriate measures shall be established to notice and emphasize the existence of non-conformances and faults and, depending on the case, to prevent the use or installation of the items involved or the inadvertent execution of the activity affected. Wherever possible, these non-conforming items shall be identified by marking, tagging and segregating by physical separation so that such actions are not repeated and the use of equipment affected is forbidden.

The appropriate administration's level must be informed in cases where the non-conformance or fault, whether significant or not, is likely to affect safety and has caused a deviation from the rule stipulated in the safety analysis reports or in their appendices.

2.8.5. In compliance with the principles specified in 2.2.3., wherever non-conformances or faults are detected, the non-conforming items or actions shall be reviewed to define the activities concerning them and the information to be gained from them for the whole of the activity. Persons responsible for the review and authorized to correct non-conformances and faults shall be identified. The operating utility shall be informed where non-conformances are accepted by one of its suppliers.

2.8.6. The measures established in compliance with paragraphs 2.8.1. to 2.8.5. shall be included in the quality assurance program for the activity concerned ; the documents specified in 2.3. shall contain a description of these measures and the way in which they are applied.

The operating utility shall report to the appropriate level of administration on the definition and application of these measures and provide the required justifications.

2.9. Provisions relating to specific safety-related activities

Without prejudice to the general provisions of this RFS, certain safety-related activities shall be subject to the special provisions below, except where paragraph 2.1.4. is applicable. These provisions shall be included in the quality assurance program for each activity ; the documents specified in 2.3. shall contain a description of these provisions and as well as of the actual way in which they are applied.

2.9.1. Design

The design area covers the various studies dealing with design, construction and operation, and in particular the measures established to guarantee that safety regulations are complied with and that preparatory documents for the different activities are prepared.

a) Specific procedures

The quality assurance program for activities related to the design of systems, structures and components and the preparation of safety-related test, operating, maintenance, surveillance, repair and modification rules shall include procedures to identify those persons involved in each design activity, to ensure that design documents are properly distributed and allocated, that the observations made are taken fully into account, and that successive revisions are provided based on the appropriate procedures.

The procedures shall also ensure that the various persons or organizations involved in design are aware of other design material and documents such as design bases, codes, standards or regulatory requirements applicable to design activities. Where related design activities are performed by different persons or organizations, appropriate procedures shall ensure that design interfaces are coherent.

b) Special design control provisions

In pursuance of 2.7.1.b) or 2.7.1.c) and except in justifiable cases, all safety-related design activities shall be verified, to an extent commensurate with their importance to safety, by means of checks performed by persons other than those who achieved the original design and in accordance with a quality assurance program.

These verifications shall comprise control measures with respect, in particular to the validity of basic documents used, to verify conformance to regulatory requirements and adequacy of the study. For verifying calculations, different or simplified methods may be used. The verification may also be based on appropriate tests. Exceptional cases where alternative methods may only be partially used are :

- Where experience gained elsewhere (nuclear power plant operating experience, rules of the art) has made it possible to validate the processes and codes used ; in this case, the validity of the assumptions made shall be systematically checked by different methods.

- Where plant commissioning tests may confirm the results obtained, and where it shall be possible to make any necessary modifications under favourable conditions ; the number of cases within this category must remain sufficiently limited so that there are few modifications required at an advanced stage of construction.

- Studies for which there are no verification methods independent of those already used and to be presented in a list with all useful justifications in the safety analysis reports.

In these three cases, studies follow-up procedures shall indicate with all the required justifications the extent to which different methods are used.

Furthermore, controls may comprise overall reviews at the project level or of its sub-assemblies.

Finally, procedures are adapted for studies which aim to achieve a more accurate estimation of safety margins or to define extreme accident sequences (particularly for preparing emergency plans) for which it is by definition impossible to establish the existence of margins ; in this case, simplified calculations are no longer required for confirmation purposes, but are to be used wherever possible.

2.9.2. Use of suppliers for a safety related activity

a) Specific procedures

Quality assurance program measures shall ensure that regulatory requirements, design bases, standards, specifications, test and inspection requirements provisions regarding access to installations and factory documents for inspection, audit and control purposes, and quality requirements are properly recorded in the appropriate procurement documents and that they are respected by the supplier with the guarantees provided by the provisions of this RFS.

b) Special design control provisions

Suppliers shall be chosen on the basis of an evaluation of their ability to provide equipment and services which will satisfy the requirements of the procurement documents and the provisions of this RFS.

The evaluation is based on the supplier's quality assurance program as described in its quality assurance manual, and the following may also be taken into account :

a) Quality data obtained in the past from similar procurement operations,

b) Supplier's quality assurance report files, supported by documents containing quantitative and qualitative data which could be objectively appraised,

c) Evaluation of the supplier's technical abilities,

d) Evaluation of selected product samples.

Furthermore, equipment and services must be checked to verify their conformance with procurement documents. This check shall comprise the following measures : objective proof of quality provided by the contractors, inspection and audit by the supplier and inspection of equipment upon delivery. Hold points during fabrication may be envisaged to enable inspectors commissioned by the customer to perform special controls on the supplier.

Samples of materials such as those specified shall, where necessary, be kept in a suitable place for a certain time so that further controls can be performed.

2.9.3.

a) Identification and control of materials, parts and components

Measures shall be established for the identification and control of items, including partially fabricated assemblies, as required throughout fabrication, erection, installation and use of the item. These measures shall ensure that identification of the item is maintained by lot number, part number, serial number or other appropriate means, either on the item or on documents traceable to the item, as required throughout fabrication, erection, installation and use of the item. The documents required must be made available for the materials, parts and components as they are incorporated into the construction process.

Identification on the item itself is used as far as possible. Where this means of identification is impractical or unsatisfactory, physical segregation, control by procedures or other appropriate methods are used so that identification is maintained. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts and components.

Where identification by marking is used, the marks shall be clear, accurate and indelible, and shall not interfere with the normal operation of the item. They must not be concealed by any form of surface treatment or coating unless an alternative means of identification have previously been assigned to the item.

b) Handling, storage and shipping

Measures shall be established to control the handling, storage and shipping. These shall include cleaning, packing and preservation of material and equipment in conformance with established instructions, procedures or drawings to prevent damage, deterioration or loss. When necessary for particular items, special coverings, special handling equipment and special protective environments shall be specified and provided and their existence verified.

2.9.4. Special processes

The operating utility shall specify the special activities and processes for which he decides that the sampling fractions, criteria and methods outlined in 2.7.1.b) and c), the certifications in 2.5. and the technical resources qualifications in 2.6. shall be carefully defined and subjected to his prior approval. The operating utility shall provide full justification for his choice for the relevant administration's level.

The operating utility shall possess documents indicating the measures for applying the samp ng fractions, criteria and methods relevant to certifications and technical resources qualifications checking.

2.10. Retroactivity

Within the context of the modes of application specified in 0. Introduction, a decision deemed retroactive shall be made for applying this RFS to all nuclear power plant units equipped with a pressurized water reactor within two years.

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