QUALITY MANUAL
for Construction of Nuclear Power Plant Components

ASME B & PV Code Section III Div. 1
0.1 **Statement of Policy**

«Ansaldo Nucleare S.p.A. Corso F.M. Perrone, 25 Genoa 16125 Italy» (ANN) has established herein a Quality Assurance Program according to ASME B & PV Code Section III, Div.1 and the applicable requirements of 10 CFR 50 Appendix B for the following activity:

Construction of Section III, Division 1 Components for which overall responsibility is retained and for which fabrication and installation is subcontracted to appropriate Certificate of Authorization Holders. *This program also includes approval of Supplier of Services, Procurement of Materials from Quality System Certificate Holders with shipment of the materials to other parties for use in components to be certified by ANN.*

QLT Manager is hereby given the authority and responsibility for planning, establishing, releasing, implementing, updating, distributing and maintaining the Quality Assurance Program of Ansaldo Nucleare S.p.A. and to document it in this Quality Manual and to verify its effectiveness, adequacy and its correct implementation.

QLT Manager reports directly to the Ansaldo Nucleare S.p.A. Chief Executive Officer, thus assuring the required authority and organizational freedom are provided, including sufficient independence from other Units, cost and schedule considerations. *He has authority to stop work if deemed necessary by him.*

QLT Manager has the responsibility to identify quality problems, the authority and the organizational freedom to initiate, recommend and provide solution to quality problems and verify implementation of solution. He shall assure that further processing, delivery, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

All Managers and personnel involved in Code activities shall be required to comply with the requirements of this Quality Assurance Program and the Code. Conflicts between the QLT Manager and personnel involved in Code activities shall be submitted to the Ansaldo Nucleare S.p.A. Chief Executive Officer for resolution.

The resolution shall be in accordance with the Code and the Quality Manual.

The Chief Executive Officer
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# Acronym and Glossary

The terms used in this Quality Manual are referenced in current edition of ASME Code Section III, Division 1, Subsection NCA, Article 9000, and ASME NQA-1.

This section defines acronyms used in this Quality Manual.

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<td>ACO</td>
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<td>AEN</td>
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<td>ANN</td>
<td>Ansaldo Nucleare S.p.A.</td>
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<td>ANSI</td>
<td>American National Standards Institute</td>
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<td>ASME</td>
<td>American Society of Mechanical Engineers</td>
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<td>ASSM</td>
<td>Approved Supplier of Source Material</td>
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<td>ASSS</td>
<td>Approved Supplier of Subcontracted Services</td>
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<td>CAD</td>
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<td>Computer Aided Engineering</td>
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<td>Corrective Action Request</td>
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<td>Cost Control &amp; Planning Unit</td>
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<td>CEO</td>
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<td>CFD</td>
<td>Computational Fluid Dynamics</td>
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<td>CH</td>
<td>Certificate Holder</td>
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<td>Certified Material Test Report</td>
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<td>CoC</td>
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<td>Company’s Organization</td>
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<td>EMS</td>
<td>Environmental Management System</td>
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<td>ISF</td>
<td>Process and Fluid Systems Unit</td>
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<td>ISO</td>
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<td>Single Activity Manager</td>
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<td>Systems Applications Product</td>
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<td>Work Breakdown Structure</td>
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ANN Intranet Portal: Company Internal Web Site

Approved supplier: a supplier that has been evaluated and approved by a Material Organization or Certificate Holder in accordance with the requirements of NCA-3800 to supply qualified source material for conversion to material, or provision of services, to the party performing the evaluation and approval.

Authorized Nuclear Inspector: an Authorized Nuclear Inspector is an employee of an Authorized Inspection Agency who has qualifications for and has been properly
qualified for Division 1.

Certificate Holder: an organization holding a Certificate of Authorization, Certificate of Authorization (Corporate), or Quality Assurance Program Certificate issued by the Society. This does not include the holder of a Quality System Certificate or Owner's Certificate.

Certificate of Authorization: a document issued by the Society that authorizes the use of an ASME Certification Mark and appropriate designator for a specified scope of activity.

Certificate of Compliance: a written statement attesting that the materials are in accordance with specified requirements.

Certificate of Conformance: a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Certification: the act of verifying and attesting in writing that documents, processes, procedures, items, or the qualifications of personnel are in accordance with specified requirements.

Certification Mark: an ASME symbol identifying a product as meeting Code requirements.

Certification Mark Stamp: a metallic stamp issued by the Society for use in impressing the Certification Mark.

Certified Material Test Report (CMTR): a document attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, tests, and examinations.

Component: a vessel, concrete containment, pump, pressure relief valve, line valve, storage tank, piping system, or core support structure that is designed, constructed, and stamped in accordance with the rules of this Section.

Construction (as used in Division 1): an all-inclusive term comprising of materials, design, fabrication, examination, testing, inspection, and certification required in the manufacture and installation of an item.

Corrective action: measures taken to rectify conditions adverse to quality, and, where necessary, to preclude repetition.

Customer: Owner or Owner's Agent

Data Report: a document that certifies that an item was constructed in accordance with the requirements of this Section.
Design output documents: documents defining technical requirements for Section III items such as Certified Design Reports, drawings, calculations, Load Capacity Data Sheets, Certified Design Report Summaries, and Construction Specifications.

Design Report: the design document that shows that the allowable limits stated in this Section are not exceeded for the loadings specified in the Design Specification.

Design Specification (Division 1): a document prepared by the Owner or Owner’s designee that provides a complete basis for construction in accordance with this Section.

Fabrication: those actions required to manufacture components, parts, and appurtenances. These actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification. Fabrication does not include design.

Hold point: a designated stopping place during or following a specific activity at which inspection or examination is required before further work can be performed.

Item: a product constructed under a Certificate of Authorization or NS Certificate of Authorization (supports) (NCA-3120), or material (NCA-1220).

Material: for Section III, Division 1, metallic materials manufactured to an SA, SB, SFA, or any other material specification permitted in Section III and that are manufactured, identified, and certified in accordance with the requirements of Section III.

Material Organization (Metallic), Certified: an organization certified by holding a Quality System Certificate issued by the Society to provide materials or services in accordance with the requirements of Section III, NCA-3800.

Material Organization (Metallic), Qualified: an organization surveyed and qualified to provide materials or services in accordance with the requirements of Section III and NCA-3800 to the certified Material Organization or Certificate Holder that performed the qualification.

Material specification: a document that establishes the requirements for a material.

Owner: the organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.
Qualified source material: metallic products produced by an approved supplier, Material Organization, or Certificate Holder in accordance with the requirements of NCA-3800 or the output of the qualification process requirements of NCA-3855.5.

Quality assurance: as used in this Section, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that all items designed and constructed are in accordance with the rules of this Section.

Quality Assurance Program: a controlled system of planned and systematic actions required to provide adequate confidence that items designed and constructed are in accordance with the rules of the Code.

Quality System Certificate: a Certificate issued by the Society that permits an organization to perform specified Material Manufacturer or Material Supplier activities in accordance with Code requirements.

Repair: the process of physically restoring a nonconformance to a condition such that an item complies with Code requirements.

Source material: metallic products used by a Material Organization or Certificate Holder in a product form conversion process in the manufacture of material [NCA-3851.2(a)(l)] or in a qualification process based on test and examination to the requirements of the material specification [NCA-3855.5(a)(2) and NCA-3855.5(a)(3)]. Source material may be qualified or unqualified.

Supplier: any individual or organization that furnishes materials or services in accordance with a procurement document.

Survey: a documented evaluation of an organization's ability to perform Code activities as verified by a determination of the adequacy of the organization's quality program and by a review of the implementation of that program at the location of the work.

Unqualified source material: source material not produced by a Certificate Holder, Material Organization, or approved supplier in accordance with the requirements of Section III, NCA-3800.

Use-as-is: a disposition assigned an item previously identified as nonconforming after reconciling design output documents with the item's as-built condition and verifying that applicable requirements of this Section have been met.

Verification: a review to ensure that activities have been performed and documented in accordance with applicable requirements.
1. ORGANIZATION

1.1 GENERAL

Ansaldo Nuclere S.p.A, operates through its own organization with activities specified in Chapter 1.2,
ANN S.p.A. is under the complete control of Ansaldo Energia S.p.A. (AEN).
ANN, control 100% of Ansaldo Nuclear Engineering Services (ANES), a Company operating in three workshops in UK, involved in decommissioning programs and other sectors of nuclear activities. The agreement with ANES allows ANN to improve its skills in the areas of decommissioning of nuclear installations, as well as its manufacturing capacity and commissioning of special class components.
Ansaldo Nuclere S.p.A operates within the field of Nuclear components construction according to ASME B & PV Code, Section III Div. 1, applicable portions of 10CFR50 App. B and Customer's requirements.
The functions and responsibilities of the Managers involved are shown in the Exhibits 1.1 and 1.2.

1.2 ANSALDO NUCLEAR S.P.A. (ANN)

Ansaldo Nuclere S.p.A. (ANN in the following) has the following responsibilities:
(a) Management and control of all the activities related to the construction of nuclear plants or whatever kind of intervention on them, including passive preservation and decommissioning; concerning that, ANN develops both promotional and commercial activities, as well as the following management tasks, including engineering, design and on-site servicing;
(b) Concerning development of new technologies and related nuclear products, ANN is the owner of the technical knowhow related to the nuclear technologies, caring for their maintenance and development aimed to the engineering of new products for which the added value of these technologies is relevant,
(c) Concerning development, promotion and marketing of products related to the nuclear fuel handling and conditioned radioactive waste, transportation and storage, ANN performs both the activities aimed to implement and develop technologies and products, and the necessary commercial and management activities.

ANN for Code activities, is organized as shown in Exhibits 1.1 and 1.2

Responsibilities for activities according to the scope of the Quality Assurance Program (QAP) are described below.

Activities may be delegated by the responsible manager to a qualified delegate, but he maintains the responsibility for all activities.
1.3 **Chief Executive Officer (CEO)**

He directs and manages the Company in compliance with the Board of Directors’ decisions.

Concerning the Quality Assurance Program (QAP):

1. he approves the present Quality Manual (QM);
2. he signs the statement of Policy in QM;
3. he is fully responsible for the implementation of the QAP;
4. he reviews and approves the Quality Status Report;
5. he approves the Organization, Communications and Procedures;
6. He maintains the Inspection Service Agreement with an Authorized Inspection Agency (AIA) accredited by ASME;
7. He appoints the Lead Auditor for the performance of Audits of QLT Unit.

The following functions directly refer to the CEO: Quality and Environmental Unit (QLT), Nuclear Markets & Strategies Unit (NMS), Nuclear Science Development Unit (NSD), Cost Control & Planning Unit (CCP), Design and Realization Unit (PRZ), Project Management Unit (PWR) while the Human Resources Unit (HRS) reports to him at an operational level.

1.4 **QLT Manager**

The QLT Manager, within the limits of the authority granted to him, provides for the following activities related to the QAP:

1. Quality Manual verification and issue;
2. Identification of the documentation associated to the Quality Manual for describing the QAP processes;
3. Definition of the operating methods concerning the Quality Policy guidelines;
1.5 **Nuclear Markets & Strategies (NMS)**

The NMS Unit organizes the business policies of ANN and ANES, by ensuring the continuous monitoring of market development, identifying business development areas, realizing strategies for commercial alliances, taking care of the promotion and development of new products. The NMS Manager reports to ANN Management CEO and interfaces with ANES Managing Director to identify opportunities and provide his full support.

1. In order to make the commercial policies as efficient as possible, the NMS Manager is also supported by a Strategic Committee, comprised of the top management of both companies, who will meet periodically to evaluate the analyses prepared and examine the proposed initiatives.

2. NMS is also in charge of the implementation of commercial activities in Italy and other countries except for the United Kingdom, where it is performed by ANES through its UK Business Development Unit, which will functionally interface with NMS through the team of Product Managers.

In order to undertake the above described activities NMS is organized in two different Units:

a) **Product Management (PRM)**

The PRM Unit is composed of a single integrated team of Product Managers, common to ANN and ANES, which is in charge of:

- Analyzing, for each type of product in the ANN and ANES product range, the requirements and trends of the market, identifying the commercial priorities to be followed;
- Preparing and keeping updated the integrated chart of available expertise for each type of product, in each company;
- Identifying new products required as a result of market development and potentially accessible markets, based on the expertise available;
- Preparing Development Plans for single products, aimed at improving their competitiveness in terms of time, cost and quality, also by taking advantage of the synergy of expertise between the two companies, acquisition of licenses, R&D and training of personnel;
- Monitoring Product Development Plans and ensuring the Time-Schedule;
- Supporting the Sales Units, in both companies, also as Technical Responsible of a bid, in the preparation of relevant bids for product development, collecting and integrating the contribution of the technical Units involved;
- Ensuring the promotion of the lessons learned, both by participating in design reviews and by performing critical analyses for bid failure.
b) Customers and Sales (CSL)
CSL performs the following main functions:

- Control target customers and countries, by identifying the opportunities for ANN in the national and international nuclear market, preparing marketing plans and strategies by a continuous analysis of the status and potentiality.
- To prepare the budget of the acquisitions, in the field of the businesses established by the Company Management, and take the responsibility for its implementation;
- For the business opportunities to be pursued, CSL promote the constitution of the Bid Team and ensure its coordination through a representative; the description of the Bid Team is included in the procedure N-P-ANN-B001 “Bid Process”;
- Prepare the bids, with the help of the Technical Units and Proposal Managers of the PRZ Unit, and elaborate the price to be submitted to the CEO within the bid deadline;
- Prepare proposals for financing, where necessary, with the collaboration of the Business Units of AEN;
- Manage the commercial negotiations with the customers and partners up to the completion of orders and agreements;
- Organize the Final Bid Review, involving the company Units according to their responsibilities;
- Look after the ANN image, with the collaboration of External Relations Units of AEN, by preparing the technical/economical information to be used in the Company communication.

1.6 Cost Control & Planning (CCP)

The CCP Unit is responsible for the following activities:

- Monitoring the timing and costs of the projects in the execution phase, checking that they are in line with the proposals and highlighting any gaps/differences; elaborates the relative reports
- Controlling the other company costs, supporting the management in the realisation of efficiency programs.
- Ensuring the activities relative to the Company Budget construction and processing and the medium to long-term strategies.
- Monitoring the main management & commercial performance indicators with the support of the Services & Administration Unit of AEN.
- Supporting the PRZ Unit in the elaboration of the initial Full Life Operating Budget (POVI) in the finalizing offer phase and subsequently the PM to update the POVI during the contract execution.
- Elaborating the Planning Schedules of the project and its relative revisions.
1.7 **Quality and Environmental Unit (QLT)**

Based on the politics established by the CEO, QLT is responsible for the activities of Quality, Environmental, Health and Safety Management for which it defines the operating documents (Manual and Project Quality Plan) and for activities of Quality Control to verify the agreement between project specifications and products by through site and Suppliers’ workshop checks.

In particular, QLT is responsible for:

- Preparation/Revision and Distribution of the Quality Manual (MQ) and Environment, Health and Safety Manual (MSGI)
- Development of the Quality, Environment, Health and Safety Management System, processing and managing the Documents that define it
- Check the implementation and efficiency of the QMS and SGI through internal audit highlighting eventual deficiencies and collaborating with the other Units in the definition of the quality requirements.
- Approving supply documents relevant to manufacturing & site assembly checks
- Check that the orders and relevant technical documents conform to the quality requirements established, proposing corrections.
- Processing of procedures, with the support of the Units involved.
- Leading the Supplier evaluation activities and approve their Quality Plans.
- Undertake the checking and control activities during the manufacturing, assembly and start-up activities, acceptance tests and site installation; in particular guarantee the correct resolution of the non-conformities.
- Take care of the education and training of personnel on the relevant quality management issues.
- Look after, where necessary, the qualification and certification of personnel that undertake the activities that have an impact on quality.
- Maintain contacts with clients and Control Authorities relating to quality aspects.
- Take care of the graphic and typographic aspects of presentation and didactic support material, ensuring homogeneity, quality and traceability of issues.
- Management of technical database
- Management of the ANN library.

Quality Manager assigns a Quality Engineer to each project. He operates within QLT Unit and is assigned to Project teams, described in the PWR section of the Manual, through appropriate Service Communications and he is assisted by Quality Inspectors. Site Quality Assurance and Control report directly to QLT.
1.8 Human Resources and Systems (HRS)

The Human Resources and Systems activities are performed by the corresponding structure of Ansaldo Energia S.p.A. through a dedicated representative who reports to the ANN CEO.

Concerning the present QAP the HRS Manager is in charge to interact, also, with the other functions centralized in Ansaldo Energia, by providing the necessary support for coordinating the Informative systems activities.

1.9 Nuclear Science Development (NSD)

The NSD Unit Manager is responsible for the continuous monitoring of the ANN specialist capabilities (their maintenance and development), consistent with the indications received from the Chief Executive Officer regarding the strategy the Company intends to follow and to assure the development of specific knowledge of the Centres of Excellence. He is also responsible for looking after the connection with the world of research and Universities together with promoting the participation of Ansaldo Nucleare in international projects of high technological value.

1.10 Design and Realization (PRZ)

The following activities - proposal, design, realisation and start-up of systems, part of systems or components supplied by ANN are undertaken by the PRZ Unit that is organised by discipline in the following Technical Units:

a) Process and Fluid Systems (ISF)

b) Electrical and Automation Systems (IEA)

c) Plant Integration (INI)

d) Civil Structure Engineering (ISC)

e) Field Operations (FOP)

f) Centres of Excellence:
   - Reactors and Safety (RSC)
   - Decommissioning and Waste Management (TDW)
   - Special Components and Structural Analyses (CSA)
These Units are generally responsible for:

- The preservation of the product quality, in compliance with the efficiency goals established for each specific Project;
- The preparation, for the respective discipline, of technical documentation and technical estimates for bids;
- The performance, for the respective discipline, of the design activities;
- The implementation and development of the technical knowhow, including the computer aided design methods;
- The preparation of the purchase technical documents and the technical follow-up of the purchase orders;
- The erection and start up supervision activities for systems and components.

Within the Technical Units some resources may be appointed as Advisors. Their functions are defined in specific service communications.

For multi-disciplinary projects or projects with significant economic value, the PRZ Manager, upon request of the relevant Business Leader identifies and appoints, for the duration of the project, a **Project Engineer (PE)** charged with the technical coordination of the activities related to the job. The PE is in particular responsible for:

- Freezing the conceptual design elaborated in the offer phase
- Defining the engineering operating schedules and estimates, and subsequent updating and changes, agreeing with the Managers of the Technical Units and Centers of Excellence the applicable efficiency standards;
- Supplying and/or controlling the design inputs, the management of internal technical interfaces and the selection of the technical options in agreement with the Managers of the Technical Units and Centers of Excellence;
- The best coordination of the activities related to the job aimed to reach the technical-management goals (effectiveness/efficiency), checking the conformity of the technical documentation to the needs of the project;
- Supporting the Project Manager in the technical interface with the Customer and, when necessary, with the Safety Authorities.

For these functions, the PE is the only interface between the Technical Units and the Project Manager, with whom he operates in close cooperation as part of the Project Team.

The above functions are directly performed by the Project Manager in case of Projects which a PE is not needed.
Besides that the PRZ Manager acts as the Responsible Officer in the frame of the requirements of 10 CFR PART 21.

The PRZ Unit is also in charge, through Proposal Unit (PRP), of the following activities:

- During the Bid Process, ensure the coordination of the resources and contributions provided by the Technical Units for developing the reference solution identified by NMS, considering the defined target price
- Issue the Bid Technical File and develop the internal and external costs estimation and prepare the support documentation as the Economic Value Added Analysis (VAE) and the risk analysis.
- Ensure the analysis of contractual conditions of active orders and define the agreements between the partners identified by NMS Unit
- Issue the Administrative/Certification Dossier, including possible bid bond, with the support of the Central Services of the Leader Ansaldo Energia
- Provide for the storage of the bids, active contracts and company’s agreements.

a) Process and Fluid Systems (ISF)

The ISF Unit is responsible for the following activities:

- definition of the functional requirements and design criteria to be used for the plants design, considering the safety aspects and also the Customer’s needs; preparation of the related Design Guides;
- conceptual and detailed design of the fluid systems, up to the definition of the functional requirements for each component;
- performance of integrated design reviews for the process systems aspects;
- issue of the purchase orders technical documentation, technical evaluation of related suppliers proposals, follow up of the components supplies for fluid systems or functional packages.

b) Electrical and Automation Systems (IEA)

The IEA Unit is responsible for the following subjects:

- conceptual and detailed design of electrical systems, up to the definition of the functional requirements of the single components;
- definition of the general plant automation architecture, identification of the general criteria for the protection and control systems and preparation of the related specifications on the basis of the functional requirements coming from the plant integrated analysis;
• analysis of the man-machine interface problems, functional design of control room, conceptual design of the supervision and operator’s aid system;
• perform of integrated design reviews;
• issue of the purchase order technical documentation, technical evaluation of proposals, follow up of the supplies of components for electrical systems, instrumentation, control systems and functional package systems;

c) Plant Integration (INI)
The INI Unit is responsible for the following activities:

• Integrated management of space and the definition of arrangement of components, equipment and structures;
• Routing of piping, raceway (power and instrumentation) ventilation and location of supports;
• Support Design of piping, raceway (power and instrumentation) ventilation and definition of material lists;
• Development of computer aided plant design methods (CAD/CAE) integrating the layout;
• Piping stress analysis, including fatigue analysis and failure analysis for nuclear and conventional plants;
• Construction design, issue of technical purchase specifications, technical evaluation of proposals, follow up of supplies related to piping, supports, line components;
• Participation in integrated design reviews.

d) Structural Civil Engineering (ISC)
The ISC Unit is responsible for the following activities:

• Basic and detailed design of concrete and steel structures of nuclear and conventional facilities;
• Development of computer aided methods for structural design (CAD/CAE)
• Design of attachment, embedment and anchoring systems;
• Construction design, construction bidding, issue of technical specifications for erection of concrete and steel (civil works) structures and the relevant documentation for subcontracting;
• Participation in integrated design reviews.
e) Field Operations (FOP)

The Field Operations Unit is responsible for the following activities:

- Operational Assistance for existing plants, including maintenance plans and in service inspections;
- Checking of the status of plants, with an engineering evaluation of the aging of systems and components;
- Plant life extension studies for plants in operation;
- Development of technical specifications for mechanical and electroinstrumental assembly and relevant documentation for subcontracting;
- Construction Installation supervision;
- Development of start-up procedures;
- Commissioning of systems and components;
- Preparation of operating manuals for systems and plants.

f) Centers of Excellence

The Centers of Excellence guarantee the maintenance, development and diffusion of the know-how in the field of the nuclear power plants technologies and nuclear components. It designs innovative nuclear power plants and components, from both technical and safety aspects point of view.

It is subdivided according to the following Technical Units.

- Special Components and Structural analysis (CSA)

The CSA Technical Unit is responsible for the design, analysis and verification of:

- nuclear components such as:
  - reactor assembly and primary loop components
  - fuel handling devices
- advanced/prototypical components, such as:
  - waste containers and related handling devices
  - special cranes (according to their use and/or load conditions)
  - remote control devices and systems for decommissioning
  - fusion reactors components
- metal containment vessels

For the above items, CSA performs the following:

- mechanical design (basic configuration, selection of materials, technologies, assembly and detailed drawings;
- Reactors and Safety (RSC)

The RSC Unit performs activities related to the functional design of nuclear power plants, as well as to the transmutation of the long life high level waste. Concerning these subjects, the RSC Unit provides for:

A. core neutronic and thermo hydraulic design;
B. safety analysis and analysis of plant operational and accidental transients;
C. temperature and pressure transient analysis inside the containment and sub-compartments, in order to define the structures design loads, the post-accident environmental conditions, the supporting systems requirements needed to limit the radioactivity release;
D. definition of the protection and safety systems requirements, of the components design transients and accidents management emergency procedures;
E. reliability and risk assessment analyses;
F. development of phenomenological plant or system/component simulation models;
G. Thermal hydraulic test specification preparation and, in general, specifications related to the RSC Unit fields of application to support the development of New Reactors and/or advanced systems and components. Pre-test and post-test analyses for experimental tests.

In detail, RSC Unit is responsible for the following technical discipline: nuclear calculation, analysis of plant operational transients and control system simulation, abnormal or accidental condition plant analyses, reliability and risk assessment analyses, components and systems thermal-hydraulic simulation, real time applications, software engineering.

Therefore RSC provides its specific support in the following fields:
1. set-up of plant control algorithms using simulation techniques, detailed design of supervision systems and operator’s monitoring systems according to the operating specifications developed by the IEA Unit.

2. analysis of the fluid-dynamic loads on structures, piping and components, as a support to the INI Unit;

3. support to the CSA Technical Unit for the thermal hydraulic analysis/design and calculation of flow induced vibration loads;

4. support to the TDW Unit for specific calculation related to the neutronic transport and radiations propagation.

5. development of the calculation skills in the CFD (Computational Fluid Dynamics) field and their use, when needed, for the Company’s strategic projects.

6. maintenance of the Company’s applications know-how, with particular care for the technical/scientific calculation codes. Implementation, operating reliability and maintenance of the pertaining thermal hydraulic calculation programs.

7. coordination of procurement, management and development of new software programs, in close cooperation with users, storage of such computer programs in the ANN computer program library and users training;

- Decommissioning and Waste Management (TDW)

The TDW Unit performs activities related to the functional design concerning radwastes treatment, conditioning, handling and storage according to their kind and chemical-physical and radiological features, as well as to the decommissioning of both nuclear power or research plants and plants related to the fuel cycle.

Concerning these fields, TDW is mainly engaged in the basic design development and related activities, according to the radiological characteristics of the plant in subject. In detail:

- identification of the best decommissioning strategy aimed to the radiological safety and minimization of the operators’ collective exposure to radiations.
- definition of the adequate decontamination technologies and possible technologies for the components/structures fragmentation/cutting;
- definition of methods and ways for the dismantled components/structures handling and their final disposal (free release or conditioned release of materials or interim storage inside disposal facilities).
- definition of the main equipment general plant lay-out.
- identification of the best methods for radwaste management.
- adequate support to the Product Manager for defining the best concept solution to be proposed during the bidding phase.
During the detailed design phase, besides acting as reference operating interface for the Customer, TDW promotes processes of involvement and implementation concerning the decommissioning matters; in addition, it provides for the activities planning and coordination (also granting for the function of Project Engineer when required) as well as for the congruency verification of the solutions worked out through performance of duly scheduled Design Reviews.

Besides that TDW is responsible for:

- the implementation of the development plans issued within the Decommissioning and Waste Management Unit as defined by the Product Manager;

- the practice and, when necessary, the promotion of further development activities aimed to improve the management/planning instruments related to the decommissioning activities.

Moreover, the Technical Unit is responsible for the following subjects: nuclear calculation for the design of storage devices, calculation of radiations propagation and shielding and radiation dosimetric evaluation related to the professionally exposed personnel, calculation of the radioactive release and evaluation of the related radiological consequence.

Besides that, TDW performs the activities related to the preparation of technical specifications for radiation monitoring systems and radioactive wastes characterization, issue of the related purchase order technical documentation, proposals technical evaluation, follow-up of supplies. This Unit is also responsible for licensing activities, with particular reference to the Applicable Italian Standards for the decommissioning of plants, through a specialized group that also ensures support to the other technical units for similar difficulties for new plants and service activities in Italy and abroad.
1.11 **PROJECT MANAGEMENT (PWR)**

The management of contractual activities is assigned to a Unit named Project Management (PWR).

The Unit is internally structured according to Product Lines which are assigned to a Business Leader.

The Business Leader, is in charge of the total profitability of his own Product Line, guarantees the follow tasks:

- supports the Offer Team for bid preparation, with particular reference to the job order organization, planning and risk analysis;
- outlines the management modality of the job order related to the Product Line according to the specified requirements of product typology, paying particular attention to the optimization of the Supply Chain (e.g. Supply Special conditions, specific methods for suppliers qualification etc.) by defining the methods of the advanced control;
- coordinates the activities of Project Teams which are in charge of job orders related to their Product Line, favouring the standardization of the management methods and performing accurate audits (e.g. Phase reviews aimed to proceed with the different phases of the project);
- guarantees, in accordance with the PWR Manager, the implementation of efficiency programs (e.g. Economic non conformity management)
- monitors the PMs in the management of identified actions for the risks cushion.
- verifies the main Customers Satisfaction, through dedicated initiatives previously agreed with the PMs.
- monitors the costs of R&D related to the various Product Lines.

Within each Product Area, the management activities related to each project are assigned to multidisciplinary Project Teams, structured according to the type of project, within which the **Project Manager (PM)**, assigned by the PWR Manager has the following specific responsibilities

- management of relationships with Customers and/or financing Institutes, concerning each Project;
- management of relationships with Partners and Consortium associates related to the pertaining activities;
- definition, preparation in cooperation with QLT, and approval of specific documents for the Project management (in particular the Operating Project Manual);
- management of all aspects of contracts and orders to suppliers (including changes and claims), and when necessary assigning the technical follow up of
suborders to the Technical Units through the Contract Technical Manager;

- assures the achievement of the Project economical, quality and time goals;

The Project Team, other than the PM, can also be comprised of other professional figures indicated by the relevant Unit, according to the specific co-ordination requirements of the project. The co-ordination of the Project Team is normally undertaken by the Project Manager, apart from special cases indicated during the establishment of the Project Team. The Project Teams report to the relevant Business Leader(s).

The PWR Unit Manager, in case of jobs involving a small management commitment (such as engineering design jobs), can assign the management tasks to an Single Activity Manager (RU), selected in accordance with the PRZ Manager.

The Unique Activity Manager, reports functionally to the Business Leader for all management aspects.

1.12 ANN makes use of the corresponding structures and functions within AEN for the activities related to the Financial Management Control and Risk Management, Procurement and Facility Management, Information Technology, Legal Affairs, Institutional Relations and Administrative, Corporate Auditing.

AEN has been surveyed and is listed as an approved Supplier for such services. For further details on the controls of Procurement activities, see Sections 4 and 7 of this manual.

1.13 **APPLICABLE PROCEDURES**

N-P-ANN-B001 “Bid Process”
Exhibit 1.1 – ANN Functional Organizational Chart of Processes

Exhibit 1.2 – QLT Organization Chart
2. QUALITY ASSURANCE PROGRAM

2.1 Scope

(1) This Section describes the Quality Assurance Program (QAP) established by the QLT Manager in order to implement ANN quality policy related to:

Construction of Section III, Division 1 Components for which overall responsibility is retained and for which fabrication and installation is subcontracted to appropriate Certificate of Authorization Holders at the above location only. This program also includes approval of Supplier of Services, Procurement of Materials from Quality System Certificate Holders with shipment of the materials to other parties for use in components to be certified by ANN.

(2) The Program has been defined in order to satisfy the requirements of the current:
- ASME Code Section III Division 1, and the applicable Sections of the following documents:
- 10CFR 50 App. B - Quality Assurance Criteria for Nuclear Power Plants, if applicable;
- 10CFR Part 21 - Reporting of Defects and Non Compliance, if applicable.

(3) When deemed necessary or as required by the Customer’s specification, the QLT Manager shall issue a PQP to address the Code of Construction Subsections, technical requirements and administrative procedures for the Project. The PQP defines the interface between the various ANN Units and those of the Customer and key Suppliers. It in no way conflicts or negates the QM, but rather complements on interface and administrative matters. It identifies individuals to perform specific tasks for that project. In the case of conflict this QM shall prevail. This PQP shall be handled in the same manner as this QM, including the acceptance of the ANIS.

(4) QM shall be reviewed by the QLT Manager after issue of ASME Code Edition and be updated when necessary.

(5) Objective evidence of such review shall be documented in a Review of Code Edition Report, which shall be made available to the ANIS.

(6) Changes to the QM shall be accepted by the ANIS for the AIA and be implemented not later than six months after issue of the Code Edition. Evidence of ANIS acceptance shall be made available to the ANI by the QLT Manager.

(7) Documents (QM, Design Specifications, technical documents, etc.) revised after Customer approval, shall be sent back to the Customer for new approval.
2.2 QAP DESCRIPTIVE DOCUMENTS

The documents that describe the QAP are the following:

(1) the Company’s Organization (DO) that define the organization structure functions and responsibilities.

(2) Quality Manual N-M-ANN-003, which contains the description of the principles upon which the quality system is based, as well as the indication of the general criteria: organization, management, responsibilities and technical requirements.

(3) Quality Procedures referenced in this and subsequent Sections of the QM and identified as “Travelers” shall hereafter be referred to as “Organization Procedures”.

(4) Communications (CS) that define specific operating methods or temporary assignment of responsibilities.

(5) Technical Documents such as: drawings, instructions, specifications, design plans, documents or Part lists, design analyses, Traveler-QCP, design reports, as-built documents, operating and maintenance and instruction manuals.

(6) PQP and Project Procedures that include the indexing system for identification, collection and filing of documents and records associated to the project.

(7) Operating Instructions (IO) giving explicit rules for implementing Procedure(s).

(8) Records that supply evidence about the activities performed, the implementation of the required quality standard and the company’s QAP effectiveness concerning the implementation of processes and products realized (Section 17).

Exhibits and forms referenced in the QM or in procedures are either attached or accessible at ANN INTRANET PORTAL.
They are controlled in the same way as the QM and procedures.
2.3 **QUALITY MANUAL (QM)**

(1) The CEO assigns the responsibilities for preparation of the QM to the QLT. The QLT Unit prepares, QLT Manager verifies and the CEO approves.

(2) The QLT Manager is responsible to present to the ANIS all proposed revisions to the QM in hard copy form for review and acceptance prior to being placed on the company's server for public access and distributed for implementation. *The ANIS signs and dates* the QM front page for acceptance.

(3) The QLT Manager is responsible for maintaining the original and at least one hard copy of this QM with the dated signatures of all those parties involved, as shown on the cover page, for use by the ANI.

(4) *One copy shall be filed with the AIA*

(5) Hard copy for Surveys: QLT Manager shall provide the Survey Team current necessary number of hard copies versions of the QM for review and use during the Survey.

(6) QLT Manager is also responsible for QM updating and distribution.

(7) **Electronic Distribution:**
   - For access via ANN INTRANET PORTAL an electronic copy of the original file converted to a non editable but printable format is placed on the ANN INTRANET PORTAL server. Any printout of this file indicates the following statement on each printed page: "Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the QM prior to use.
   - The signature of the ANIS shall never be scanned or in any other way stored electronically.
   - In the event of discrepancies between the electronic version and the hard copy version of this QM, signed by the ANIS, the hard copy version shall govern.
   - In case of any conflict in understanding the requirements of this QM, the English hard copy version shall govern.
   - File Distribution: The distribution of the editable electronic version of the QM as a file to be placed on individual computers other than the computer of the Quality Manager is not permitted. The non editable (e.g. pdf format) electronic version of the QM may be distributed the same controlled way as hard copies.

(8) **Hard copies distribution:**
   - A distribution list is used to register the distribution of controlled and uncontrolled copies. Only controlled copies shall be distributed inside ANN and to the AIA. The Distribution List includes:
- Manual identification number, revision and date;
- Controlled copy number;
- Name, Unit/company and Address of the addressee;
- Transmittal number and date;
- Receipt date;
- Notes (if any).

(9) QLT Manager designates the QM copies as controlled or uncontrolled and identifies them on the cover page: controlled copy is identified by a stamp and number whereas the uncontrolled copy is identify as per paragraph (6) above.

(10) Distribution of the revised QM copies shall be made using a QM Transmittal form indicating the number and revision of QM, date of distribution and acknowledgement date.

(11) The ANN QM Holders shall acknowledge receipt by signature and date on the transmittal and return it to QLT within 30 days. If the acknowledgement is not received by the QLT Manager within 30 days after issuance, he shall issue a non-conformity report in order to establish adequate measures to solve such deviation. If external QM holders, except the AIA, do not acknowledge receipt within 90 days their controlled copy reverts to uncontrolled status.

(12) Revisions to the QM shall be identified, controlled and distributed inside and outside ANN in the same way as for the original issue.

(13) Any change to any paragraph of any page shall require a revision of the complete QM. Minor editorial, grammatical or orthographic changes do not require revision of the QM that will be distributed to the same addressee of the current revision.

(14) Exhibits used may slightly differ from the ones attached, but the minimum contents must remain the same. Exhibits different from the ones attached shall be approved by Quality Manager before use and included in PQP if project related or in the Quality Manual next revision.

(15) QLT Manager shall be responsible for assuring implementation of QM revisions within 30 days after the ANIS acceptance.

(16) Revised latest wording of the QM shall be identified using italic letters.

(17) If a translation is prepared, it shall be verified by the QLT Manager and verification shall appear in the front page. The English version of the QM and implementation documents shall take precedence.
2.4 **Management Review of the QAP – Analysis of Data**

(1) At least once a year the QLT Manager prepares the Quality Status Report and submits it to CEO for review of adequacy and the effective implementation of the QAP and identifies the necessary corrective actions in the Quality Status Report. The Quality Status Report is made available to the Management involved in Code work in order to agree in a meeting with the CEO preventive and corrective actions to be implemented. The report covering the Management Review is signed and dated by the CEO.

(2) An overall detailed review shall consider:
   a) results of internal and external audits performed by QLT;
   b) results of audits on QLT;
   c) QAP effectiveness;
   d) revision of QAP caused by technological, quality requirements and organizational changes;
   e) results of Audits performed by Customers, AIA, ASME and the certification organization for the ISO 9000 program;
   f) results of Non Conformance Reports and Corrective Actions Requests.
   g) Supplier non-conformity reports and corrective action request.

(3) The Quality Status Report is based on the Analysis of Data that is a quantitative assessment of the quality performances of ANN. The Analysis of Data takes into account:
   a) the quality records of the year;
   b) the previous year Management Review (Quality Status Report).

2.5 **QAP Application Criteria**

Systematic reviews of the Customer's contractual documents are performed as described below.

Any subsequent change asked by the Customer shall be compared with the original Customer's requirements and the current QAP.

2.5.1 **Order Entry**

*The process of the offer management is described in procedure N-P-ANN-B001 “Bid Process”.*

(1) CSL Manager shall be responsible for the Final Review of Offers.

(2) Upon receipt of the Contract, the applicable Business Unit Leader (see
Section 1.11) shall be responsible to assure verification of consistency of contractual documents enclosed to the Contract with the pre-award proposal documents, by involving the Units that have concurred in proposal preparing.

(3) Evidence of both reviews shall be documented on the «Bid and Contract Review» Form (Exhibit 2.1) and distributed to the involved reviewing Units, as indicated on the bottom of the form, and filed by PRZ.

(4) Business Leader has the responsibility of resolving comments made by the reviewing Units.

(5) Business Leader shall submit the Contract to the CEO for acceptance and signature when pre-established amounts are exceeded. The signed contract is then forwarded by CSL or the CEO to the Customer.

(6) The PWR Manager shall appoint, using a Communication, the Project Manager (PM).

(7) The PRZ Manager shall appoint, if needed, using a Communication, the Project Engineer (PE).

The same procedure shall be used for change order(s).

2.5.2 Job Opening

After acceptance of the Contract, the appointed PM is responsible for

(1) Obtaining from CCP the job number on the basis of:

a) Job description;
b) Starting and ending date;
c) Customer;
d) Order number.

(2) Then he communicates the job opening and distributes contractual documents during a kick-off meeting to be held with the Units involved to introduce them to the job implementation requirements.

A meeting report, including the list of documents and revision or data to be used, shall be prepared by PM and distributed to the Project Team and the Units involved.

As an alternative procedure to kick-off meeting the PM can issue a job opening communication and distribute the contractual documents.

The job opening communication shall include at least:

a) subject
b) delivery date
c) job number
d) Project team leader’s name, if different from PM
e) person involved in the Project team
f) list of contractual documents (i.e. all documents listed in the Contract and its appendices transmitted by the Customer), including revision or date,
g) opening of a data base for the Job Technical Management Documents (GTD)

h) list of pending technical subjects

If change order(s) needed to be included, they shall be reviewed in the same manner as the original contract.

2.6 Indoctrination and Training

(1) Indoctrination and training are planned and performed under the HRS Manager supervision for personnel involved in quality related activities.

(2) The extent of indoctrination and training shall be commensurate with the following:
   - scope, complexity and kind of the activities performed or managed, affecting quality,
   - education, experience and proficiency of the person.

(3) QLT shall prepare an annual indoctrination and training program by Form «Annual Indoctrination and Training Program» (Exhibit 2.2). See also N-P-ANN-N005. This annual Indoctrination and Training program, approved by the HRS Manager and authorized by the CEO, is distributed to the Managers of Technical and Business Units.

(4) Indoctrination. The scope of indoctrination shall include job responsibilities and authority that includes general criteria, technical objectives, applicable Code requirements, regulatory commitments, ANN procedures and quality assurance program requirements.

(5) Training. Training shall be provided, if needed, to achieve and/or maintain proficiency, to adapt to changes in technology, method or job responsibilities.

(6) Personnel identified shall be indoctrinated to comply with the QAP. Indoctrination and training methods will be the following:
   - Personal self-reading/study,
   - Indoctrination and training sessions.

(7) Indoctrination and training sessions shall be performed by QLT or by the applicable Unit Manager as identified on the annual Indoctrination Program and shall be documented on form «Indoctrination/Training Record» (Exhibit 2.3) by the individual who performed indoctrination and training.

Recording shall cover at least duration, date and type of training, subject, signature of participants and instructor.

Personnel performing the training activity or approving procedures shall be considered to be trained in the associated activities and personal self-reading/study shall be performed within 30 days from distribution of the concerned document(s) and recorded in the “Indoctrination and training” form.

"Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use"
(8) Indoctrination and Training Records shall be maintained in the HRS file.

(9) New indoctrination and or additional Indoctrination and/or training shall be required by the responsible Unit Manager because of change of the QAP, job responsibilities, change in technologies, authority and Code changes.

(10) Inspection and test personnel shall be trained under responsibility of QLT Manager according to a training program for the applicable scope of individual activities.

(11) The effectiveness of indoctrination and training shall be evaluated in accordance with N-P-ANN-N005.

(12) Unit Managers are responsible to assign personnel whose capabilities are in accordance with the specified requirements. If Unit Managers determine that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed or be retrained and re-qualified.

2.7 Qualification of Personnel

2.7.1 Qualification of Inspection and Test Personnel

QLT Manager shall ensure that inspection and test surveillance personnel for Items and activities acceptance purposes, are qualified and re-evaluated in accordance with the procedures N-P-ANN-G006 and N-P-ANN-N005, which describe the following requirements:

(1) determination of the candidate education level and industrial experience;

(2) indoctrination and training;

(3) physical aptitude;

(4) test results or results of capability demonstration;

(5) certification of qualification with activities certified to perform;

(6) validity of qualification;

(7) re-qualification.

Following completion of initial indoctrination and training the initial capability shall be determined by the QLT Manager based on education, experience, training and either test results or capability demonstration.

The job performance of personnel shall be re-evaluated periodically not exceeding 3 (three) years.

Any person who has not performed inspection or testing activities in the qualified area for a period of 1 year shall be reevaluated.
2.7.2 Qualification of Quality Assurance Audit Personnel

QLT Manager shall ensure that Lead Auditors and all Auditors are qualified in accordance with the procedure N-P-ANN-G004, which contains the requirements for qualification, certification, maintenance of proficiency and re-qualification.

In particular, Lead Auditors shall be evaluated taking into account the following:
- oral and written communication skill;
- educational level;
- experience;
- professional certification released by external bodies;
- indoctrination and training;
- qualification and written examination;
- participation to audits and Suppliers evaluations;
- various elements such as leadership, sound judgement, maturity, etc.

The procedure specifies how to re-qualify a Lead Auditor when his qualification is expired.
Audit and personnel qualification records are available to the ANI and ASME Survey Team.
The qualification records of the Lead Auditor(s) external to QLT, to be appointed for the performance of audit of QLT shall be reviewed and accepted by the QLT Manager, in accordance with the procedure N-P-ANN-G004, prior to the appointment by the ANN CEO.

2.8 Applicable Procedures

N-P-ANN-B001 Bid Process
N-P-ANN-G004 Qualification and Certification of Quality Audit Personnel
N-P-ANN-G006 Inspection and Test Surveillance Personnel Qualification
N-P-ANN-N005 Proficiency, Training and Awareness of ANN Personnel
RIESAME DELL'OFFERTA E DEL CONTRATTO ATTIVO

BID AND CONTRACT REVIEW

IMPIANTO/PROGETTO:
PLANT/DESIGN

CLIENTE:
CUSTOMER

SCHEDA D'OFFERTA
Offer Form

DATA
Date

COMMessa OFFERTA
Bid sub Number

DOCUMENTI TECNICI DI RIFERIMENTO
Reference Technical Documents

1

CONDIZIONI GENERALI E SPECIALI DI OFFERTA ED ASPETTI QUALITATIVI
General and Particular Bid Conditions and Quality Requirements

2

ASPETTI ECONOMICI / FINANZIARI
Economic / Financial Requirements

3

EVENTUALI AUTORIZZAZIONI/CERTIFICAZIONI DE' ENTI / ISTITUZIONI ESTERNE
Authorities/Certifications by External Boards/Institutions. Etc.

4

EXHIBIT 2.1-a

UNITA' COINVOLTE/ Units Involved

INI
Date

ISC

ISF

IEA

FOP

CSA

RSC

TDW

PRP

QLT

PWR

PRZ

CSL

ESITO/RESULT:

L'ORDINE/CONTRATTO, O SUA VARIANTE, PUÒ ESSERE ACCETTATO?
Can order/contract, or its change, be accepted?

□ SI    □ NO

INI

ISC

ISF

IEA

FOP

CSA

RSC

TDW

PRP

QLT

PWR

PRZ

CSL

Data:
Date

ANN046_B
### RIESAME DELL’OFFERTA E DEL CONTRATTO ATTIVO

**BID AND CONTRACT REVIEW**

Referito a Scheda d’Offerta N°

#### 1) DOCUMENTI TECNICI DI RIFERIMENTO / Reference Technical Documents

- Specifica Tecnica N°: __________________________________________
- (ANN7 Cliente?): __________________________________________

**COMPLETEZZA E CONGRUENZA DELL’ALLEGATO TECNICO ALL’OFFERTA**

- SI [ ]
- NO [ ]

(veicere nota/verbale in allegato)

#### 2) CONDIZIONI GENERALI E SPECIALI DI OFFERTA ED ASPETTI DI GARANZIA QUALITÀ' / General and Particular Bid Conditions and Quality Requirements

- Sono correttamente specificati?
  - LIMITI DI FORNITURA [ ]
  - RESPONSABILITÀ' [ ]
  - GARANZIE [ ]
  - PENALI TECNICHE – GESTIONALI (TEMPORALI) [ ]
  - PIANIFICAZIONE ATTIVITA’ E RELATIVI MARGINI [ ]
  - DEROGHE ED ECCEZIONI [ ]
  - VALUTAZIONE IMPREVisti TECNICI [ ]
  - DEFINIZIONE DELLA CLASSIFICAZIONE DI QUALITÀ’ DELLA FORNITURA [ ]

- E’ stato emesso un PdQ?
- I Fornitori sono nella Vendor List ANN?

#### 3) ASPETTI ECONOMICI/FINANZIARI / Economic / Financial Requirements

- Sono completi e congruenti?
  - PREVENTIVO INCLUSE ASSICURAZIONI PER IL PROGETTO [ ]
  - FORMAT VAE [ ]
  - RISK ANALYSIS [ ]

#### 4) EVENTUALI AUTORIZZAZIONI DI ENTI/ISTITUZIONI ESTERE / Authorizations/Certifications by External Boards/Institutions, if any

- COMPLETEZZA AUTORIZZAZIONI/CERTIFICAZIONI RICHIESTE [ ]

NOTE

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*Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use*.

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[EXHIBIT 2.1-b]
## ANNUAL INDOCTRINATION AND TRAINING PROGRAM

<table>
<thead>
<tr>
<th>CORSO</th>
<th>ARGOMENTO</th>
<th>DATA</th>
<th>N° EDIZIONE</th>
<th>ORE TOT. DEL CORSO</th>
<th>TOT. ORE DI CORSO ANNULE</th>
<th>PERSONE</th>
<th>UNITA</th>
<th>DOCENTE</th>
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</table>

**EXHIBIT 2.2**

---

**DATE:** | **PREPARED BY:** | **APPROVED BY:** | **AUTHORIZED BY:**
---|---|---|---

ANN049_6

---
### EXHIBIT 2.3

**Attention:** This print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against the electronic version of the procedure prior to use.
3. DESIGN CONTROL

3.1 Scope

(1) This section describes measures adopted by ANN through PRZ for defining, planning and controlling the Design activities.

(2) PRZ shall assure that all applicable requirements of the Code and of the Design Specification are correctly transferred into design output documents such as specifications, drawings, procedures and instructions and that these shall be controlled for compliance with Code requirements.

(3) PRZ may require to subcontract preparation of design to an Engineering organization approved as a supplier for such services. Such subcontracted services may include preparation of Design Reports and design output documents for ASME Code Section III, Division 1, components. However, ANN retains responsibility for such activities.

3.2 Design Activities

PRZ defines adequate measures to be adopted for ensuring the following:

(1) planning of design activities
(2) identification and correct use of design inputs
(3) identification and control of design interfaces
(4) design verification
(5) Authorized Nuclear Inspector (ANI) notification of contract receipt and review of design documents

3.3 Contents of Design Specification

The Design Specification provided by the Owner or his designee shall include the following design data, as applicable to each component:

- Plant designation and Customer
- Location
- Functional requirements
- Contained fluids/flow rates
- Pressures
- Temperatures
- Environmental conditions, including radiation
- Considering the necessities to use the methods of Appendix G of ASME Code
- Code Classification
- Boundaries
  - location of interfaces
  - forces, displacements at such interfaces
  - structural characteristics of attached components or structures
- Loads, Loads Combination and Service Limits
- Material requirements, including impact test requirements
- Any special requirements/limitations (e.g. overpressure protection)
- Operability requirements
- Regulatory requirements
- Pre-service examination requirements according to NCA-3252 (c)
- Handling/Storage/Shipping requirements

The Design Specification shall be reviewed under the responsibility of the Technical Unit Manager using the Certified Design Specification Review Checklist Exhibit 3.1, which shall be distributed to the Technical Units involved in the review.

The Design Specification shall include all the information necessary to provide a complete basis for Division 1 component construction and as a minimum the items specified in NCA-3252 (a) and NCA-3252 (c).

The Design Specification shall be certified by a qualified Registered Professional Engineer (RPE) according to Sect. 3.9 of this manual.

A copy of the certified Design Specification shall be made available to the ANI prior to fabrication.

3.4 DESIGN INPUT

The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and on a consistent basis. The design input shall be reviewed and approved by ANN Technical Unit Manager.

(1) Applicable Code requirements and Design Specification are the input for design, as well as the job opening meeting report.

(2) Design Input shall include the review performed by ANN Technical Units on Design Specification for assuring that it includes all Code requirements and it is a complete basis for design. The ANN Technical Unit Manager shall identify the verification method to be used.

(3) The Project Engineer (PE) lists the design input documents and the verification method to be used in the Design Plan.

(4) Deviations from design input data, including the reasons for changes, shall be identified, evaluated, documented and, if acceptable, approved by the relevant Unit Manager (as identified in the PQP, see § 2.1(3)) through authorization of the related documents.
3.5 **Design Process**

Design activities are planned using the «Design Plan», which identifies:

(1) Design input documents;
(2) Design output documents;
(3) Interfaces.

### 3.5.1 Design Plan

(1) The Design Plan shall be prepared by the PE (the PM where the PE has not been appointed) in cooperation with the involved Technical Units, approved by the Business Leader of the correspondence Product Line and authorized by PRZ Manager.

(2) The key elements of the Design Plan are files contained within the GTD.
   - The file entitled Document List is specific for each project and covers a full list of all documents (drawings, specifications and procedures) to be used or prepared.
     It gives the document number, revision status, document title, type (drawing, specification, etc.), author, internal and/or customer approval, schedule date, actual date issued, document transmittal form reference and approval status.
   - The file “WBS“ is in effect a schedule or programming file which shows the defined status of preparation, review and approval of all project documents against a schedule. *It also defines the responsible technical unit in charge of documents development and all technical interfaces*
   - The system for controlled transmittal of elements for Customer approval is through issue of document transmittal form each given an individual identification number and is captioned on the Document List and schedule for both issuance and response from the Customer.

Design Plans are updated following changes to the established design input.

(3) During design, issued documents and their revisions, as well as new documents to be prepared, are recorded using the data base «Technical Management of Documents» (GTD).
GTD provides the updated status of all documents.

(4) Distribution of documents shall be controlled using the GTD *issuing the document transmittals* (see Sect.6 of this manual).

(5) The PE/PM shall specify the Units of measurement to be used for the Contract (as per NCA-1150)

(6) The final design is documented in the Design Report and it shall be
3.5.2 Design Report

(1) The applicable Technical Unit Manager shall be responsible for preparation of the Design Report (refer to Section 6.6 for responsibilities in document issuing of this manual).

(2) The Design Report shall include, as applicable:
   a) reference to Design Specification, including revision used,
   b) general data,
   c) list of drawings, including applicable revision used in construction of the Item,
   d) basic sizing,
   e) analysis of loading,
   f) model of calculation,
   g) structural analysis,
   h) thermal analysis,
   i) fatigue evaluation,
   j) fracture mechanics analysis,
   k) reconciliation with as-built drawings, non conformances and any other change affecting the Design Report,
   l) computer program used,
   m) RPE certification,
   n) Code Class,
   o) Code Edition and Addenda,
   p) Code Cases, when applicable

   The Design Report shall be submitted to the Owner/Owner’s delegate by PM for its review prior to the certification of the Data Report.

(3) Review of Design Report shall be assigned by the applicable Technical Unit Manager.

   For this review Exhibit 3.4.c shall be used.

3.5.3 Drawings

(1) The applicable Technical Unit Manager shall be responsible for preparation, review, approval and distribution of design drawings and for as-built drawings (refer to Section 6.6 for responsibilities in document issuing of this manual).

(2) Drawings shall indicate at least:
   a) correct implementation of NX-1000
b) jurisdictional boundaries

c) materials identification (e.g. part list, bill of materials)

d) tolerances

This information may also be indicated on documents referenced on the drawings.

(3) Revision of drawings shall be managed as per Sect. 3.7. of this manual.

(4) All as-built drawings shall be reconciled with the Design Report.

3.5.4 Design Analyses

(1) Design analyses documentation shall be prepared by the applicable Technical Unit (refer to Section 6.6 for responsibilities in document issuing of this manual) and shall include, as applicable:

a) definition of the objective of the analyses,

b) definition of design input and their source,

c) results of literature searches or other applicable background data,

d) identification of assumptions and indication of those that must be verified as the design proceeds,

e) correlation of calculations to component, originator and date,

f) identification of any computer calculation, including computer type, computer program (e.g. name, version), input, output and program verification.

(2) There shall be sufficiently detailed as to purpose, methods, assumptions, design input, references and Units such that a person technically qualified in the subject can review and understand analyses and verify adequacy of results without recourse to the originator. The design analysis documentation shall become a part of the Design Report.

(3) Computer programs, when used, shall be identified by program name, status and version number in the Design Report. The Computer Program Relator (CPR) is responsible for the qualification of the computer programs and their version used for design calculations. The CPR shall charge expert person(s) with the verification of the computer program to be qualified. The qualification process shall be certified by a Quality Engineer on «Qualification Certificate» (Exhibit 3.2) following procedure N-P-ANN-P001.

Quality Certificate shall contain at least:

- Computer Program name and version;
- synthesis of results of test cases verification;
- field of application;
- approximation level of results;
- date and signature of CPR and Quality Engineer.

(4) The results of the Computer Program verification and the «Quality
Certificates shall be stored in the QLT file and made available to the ANI for his review.

(5) Documents relevant to design analysis shall be legible and suitable for reproduction, filing and retrieval.

3.6 DESIGN VERIFICATION

The extent of design verification shall be a function of the importance of safety, the complexity of design and similarity with previous design.

(1) Design activities performed by ANN Technical Units shall be submitted to the verifications, as identified in specific Project Procedures.

(2) Design verification may be performed using one or a combination of 3 methods (Design Review, Alternate Calculations and Qualification Tests), for assessing design correctness, completeness, compliance with the Design Specification and the Code requirements, adequacy and consistency with technical interfaces by competent person(s) or group(s) other than the one(s) who performed the original design.

(3) Technical Unit Manager appoints the persons who shall perform the design verification. This shall be done by competent individuals or group other than those who performed the original design.

(4) The items to be verified shall be indicated on the “Design Verification check List” Form by the Technical Unit Manager (he can use the relevant Form out of Exhibits 3.4.a, 3.4.b, 3.4.c, 3.4.d, 3.4.e, 3.4.f, or the general ANN Form Exhibit 3.3, or a Form provided by the Customer which satisfies this requirement).

(5) The completion of design verification shall be documented on a form described here above. The responsible Technical Unit Manager shall evaluate the verifications and the results shall be incorporated into the design documents.

In case the responsible Technical Unit Manager decides that comments are not to be accepted, he shall justify why the comment was not considered and refer the matter for independent assessment. The result is then documented on the “Design Verification” form (Exhibit 3.3).

(6) The Technical Unit Manager shall file one copy of the Design Verification checklist per job in the Technical Archive.

(7) Verification of design calculations performed by qualified and verified computer programs may be limited to a verification of the correct application of the program and to the verification of input and output data.
3.6.1 Design Review

Design review method shall include, where applicable:

a) design input correctly selected,
b) assumptions necessary to perform the design activity adequately described and reasonably identified,
c) appropriate design method used,
d) design input correctly incorporated into the design,
e) design output reasonably compared to design input,
f) necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures.

3.6.2 Alternate Calculations

Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions, input data used, and the computer program, its associated computer hardware and system software, or other calculation method used, shall also be reviewed. The method to be used and the permissible deviations shall be pre-established by the Technical Unit Manager.

3.6.3 Qualification tests

Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design condition. Operating modes and environmental conditions shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

3.7 Design Changes

(1) Changes to the approved design shall be initiated by the PE and documented in the Change Report Form (Exhibit 3.5).

(2) Changes shall be approved by the same Units that reviewed and approved the original design documents affected and authorized by the PM.

(3) Effects of changes on other Items are duly considered by the applicable
Technical Unit Managers.

(4) Changes shall be clearly identified in the revised documents by a revision index and by a marking or by describing the area or content changed.

(5) Changes to final design shall be reconciled with the Design Report/Design Specification and shall be subjected to the same control as the original design.

(6) Any change shall be made available to the ANI for his review.

(7) Filing of the approved Change Report shall be made by the PE and distribution shall be made according to a distribution list, which includes at least QLT, PE and Technical Unit Managers.

(8) The PE shall follow-up the implementation of the design changes using the applicable records of the GTD.

3.8 Design Activities and Reconciliation

(1) During design activities the applicable Technical Unit Manager shall assure consistency of the Design Report to fabrication drawings (see (2) below).

(2) The Certificate Holder shall prepare a report on the basis of as-built condition which shall include:
   a) drawings referenced on the Traveler-QCP
   b) non conformity reports issued for each drawing used, identified by number and revision.
   This report shall be signed and dated by the Certificate Holder and be sent to the applicable Technical Unit Manager.

(3) In case of discrepancy the applicable Technical Unit Manager shall be responsible for reconciliation of calculation according to as-built drawings. Technical interface control shall be assured by PE.

(4) The applicable Technical Unit Manager shall reconcile the as-built condition to the Design Report. When reconciled, he shall sign and date the Final Design Report.

(5) The applicable Technical Unit Manager shall provide for certification of the Design Report by a RPE (when required) other than the individual certifying the Design Specification.

(6) The Design Report and its revisions shall be made available to the ANI for review and shall be submitted by the PM to the Owner/Owner’s designee for review and documentation of review.

(7) Documentation of review and acceptance by the Owner/Owner’s designee for correctness and completeness shall be attached to the Design Report and made available to ANI before Certification Mark stamping and certification of the Data Report.
3.9 **Registered Professional Engineer (RPE)**

(1) The QLT Manager is responsible to verify the qualification records of the RPE, to ensure he complies with the requirements of Appendix XXIII of Section III. The qualification of the RPE is valid for three years. This verification refers to:

- certification in at least one State of the United States or Province of Canada;
- education degree;
- annual self review;
- Code knowledge;
- experience and/or training in specialty field for which he performs certifying or review activities;
- continuous activity log.

(2) The RPE qualification shall be documented in the Check-list for Evaluation Registered Professional Engineer (Exhibit 3.6) signed and dated by QLT Manager. The RPE shall be included in the “Evaluated Supplier List”. RPE Records shall be filed and maintained by QLT Manager.

(3) RPE subcontracted shall receive a controlled copy of the QM.

3.10 **Applicable Procedures**

- N-P-ANN-D001  Design control
- N-P-ANN-P001  Management and Qualification of Calculation Programs
### Certified Design Specification Review

**Check List**

- **Project No.:**
- **Design Specification No.:**

**Component:**

Are the following points (in accordance with NCA 3252) at least met?

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
<th>NA</th>
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</thead>
<tbody>
<tr>
<td>1. The functions and boundaries of the items covered?</td>
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<tr>
<td>2. The design requirements, including all required overpressure protection requirements?</td>
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<td>3. The environmental conditions, including radiation?</td>
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<td>4. The Code classification of the items covered?</td>
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<td>5. Material requirements including impact test requirements?</td>
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<tr>
<td>6. Additional fracture mechanics data for base metal, weld metal, and heat affected zone required to use Figure G-2210-1 in accordance with G-2110 (b)?</td>
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<tr>
<td>7. When operability of a component in a requirement, the Design specification makes reference to other appropriate documents which specify the operation requirements?</td>
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<tr>
<td>8. The effective Code Edition, Addenda and Code Cases to be used for construction?</td>
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<tr>
<td>9. RPE's certification, and sign and stamp on the cover sheet?</td>
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<td>10. The Design Specification shall identify those components and/or parts that require a preservice examination and shall include the following:</td>
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<tr>
<td>10.1 Examination:</td>
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<tr>
<td>10.1.a Edition and Addenda of Section XI to be used?</td>
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<tr>
<td>10.1.b Category and method?</td>
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<td>10.1.c Qualifications of personnel, procedures and equipment?</td>
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<td>10.2. Welds:</td>
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<tr>
<td>10.2.a Surface conditioning requirements?</td>
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<tr>
<td>10.2.b Identification/marketing system to be used?</td>
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</table>

**Remarks:**

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**Exhibit 3.1**

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**Date:**

**Technical Unit Manager's Signature:**

---

*Attention: this printout is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against the electronic version of the procedure prior to use.*
**EXHIBIT 3.2**

**Limiti di Applicabilità dei Risultati/Limits of applicability:**

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<th>FIRMA HRS</th>
<th>SIGNATURA</th>
<th>DATA</th>
<th>FIRMA RIFERENTE</th>
</tr>
</thead>
</table>

Sulla base del PIANO DI VERIFICA in riferimento e della sintesi dei risultati delle verifiche, SI DICHIARA che il Programma in oggetto è da considerarsi QUALIFICATO nei limiti sopracitati.

On the basis of the [VERIFICATION PLAN] and short description of verification results, WE DECLARE that the Computer Program in subject is considered QUALIFIED, within the above indicated limits.

**ANNO31_3**

**ANN002_5**
"Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use."
### DESIGN VERIFICATION CHECK-LIST

#### ANALYSIS - CALCULATIONS

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<th>POINTS TO BE CHECKED</th>
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<th>R</th>
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<tbody>
<tr>
<td>1</td>
<td>Are document title and revision complete and correct?</td>
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<tr>
<td>2</td>
<td>Were design inputs correctly selected and incorporated?</td>
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<td>3</td>
<td>Was an appropriate design, analysis or calculation method used?</td>
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<tr>
<td>4</td>
<td>Have the versions of the computer codes employed in the analysis been certified for application? If not, has sufficiently information been provided to enable verification of the program and results?</td>
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<td>5</td>
<td>Were the used computer code(s) applicable for modeling the physical phenomena and the structures/systems/components relevant for analysis?</td>
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<tr>
<td>6</td>
<td>Has sufficient information about computer model(s) and run(s) been provided?</td>
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<tr>
<td>7</td>
<td>Have necessary assumptions to perform design, analysis or calculation been adequately documented, justified, described and are they reasonable? When necessary, are assumptions identified for subsequent re-verification once completed the detailed design activities?</td>
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<td>8</td>
<td>Have applicable codes, standards and regulations, including issue and addenda, been properly identified and their requirements met?</td>
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<tr>
<td>9</td>
<td>Have design input and verification requirements for interfacing organizations been specified, where necessary?</td>
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<td>10</td>
<td>Are the incorporated acceptance criteria of design documents sufficient to allow verification that design requirements have been satisfactorily met?</td>
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<td>11</td>
<td>Is design output reasonable compared to design input?</td>
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<tr>
<td>12</td>
<td>Are results and conclusions clearly stated?</td>
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<td>13</td>
<td>Has applicable construction and operating experience been considered?</td>
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<tr>
<td>14</td>
<td>Are specified materials compatible among them and with the design environmental conditions to which material will be exposed?</td>
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<tr>
<td>15</td>
<td>Have technical change request and other design changes approved to date been considered and incorporated where appropriate/required?</td>
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<tr>
<td>16</td>
<td>Is the document presented sufficiently clear and detailed to to purpose, method, assumptions, design input, references and units?</td>
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**EXHIBIT 3.4-a**

R = REMARKS:

| Verifier’s Signature: _______________________________ | Date: ___________________ |

ANN073_3

ann073/Design Verification Check List Analysis Calculation
## DESIGN VERIFICATION CHECK-LIST

### DRAWINGS & ISO

<table>
<thead>
<tr>
<th>#</th>
<th>POINTS TO BE CHECKED</th>
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<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Document title and table of revision completeness and correctness</td>
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<td></td>
</tr>
<tr>
<td>2</td>
<td>ASME Code requirements statement</td>
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<tr>
<td>3</td>
<td>Conformance with ASME Code and other applicable rules and regulations</td>
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<td>4</td>
<td>Conformance with requirements of scope of delivery</td>
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<tr>
<td>5</td>
<td>Full and correct application of inputs</td>
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<tr>
<td>6</td>
<td>Specification of sufficient dimensions and tolerance requirements to permit fabrication and inspection</td>
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<td>7</td>
<td>Correct tolerances</td>
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<td>8</td>
<td>No conflict between the item(s) shown and design requirements and compatibility with the major component or system of which it is a part</td>
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<td>9</td>
<td>Acceptable interfaces (pipe connections, installation). Check of item(s) shown for interface agreement with mating components shown on complementary drawings</td>
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<tr>
<td>10</td>
<td>Boundary control (classification)</td>
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<tr>
<td>11</td>
<td>Can the item be produced?</td>
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<tr>
<td>12</td>
<td>Information agreement with geometrical details of the design calculation</td>
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<tr>
<td>13</td>
<td>Verification of welding and inspection technique</td>
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<tr>
<td>14</td>
<td>Accessibility for maintenance, IST and repair activities</td>
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<td>15</td>
<td>Consistency with P&amp;ID</td>
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<td>16</td>
<td>List of revisions check with TOC and with Archive of Electronic Files</td>
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<tr>
<td>17</td>
<td>Integration of Design Change proposal</td>
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<tr>
<td>18</td>
<td>System and layout verification</td>
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<td>19</td>
<td>Pipe Support List verification</td>
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<td>20</td>
<td>Penetration List verification</td>
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<tr>
<td>21</td>
<td>Mechanical modules construction sequence</td>
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<tr>
<td>22</td>
<td>Civil modules construction sequence</td>
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<tr>
<td>23</td>
<td>Formal control of the drafting good execution rules</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>Is the drawing scale correct? (see point 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Sections, views and details are correct?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Are the text fonts, layers and line thicknesses correct?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Has the bill of material been completed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXHIBIT 3.4-b**

R = Remarks:

Verifier's Signature: ____________________________  Date: ________________
### DESIGN VERIFICATION CHECK-LIST

#### PROJECT

**N.**

#### APPROVER

- **Name:**
- **Signature:**
- **Date:**
- **ANSWER WITHIN:**

#### DESIGN REPORT

#### DOCUMENT(S) N.: 

<table>
<thead>
<tr>
<th>#</th>
<th>POINTS TO BE CHECKED</th>
<th>OK</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are document title and revision complete and correct?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Is Design Report or Load Capacity Data Sheet based on the design and service loading conditions specified in the Design Specification and have all requirements of the Design Specification been considered?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Are applicable Code Edition and Addenda, and Code classification clearly referenced?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Do analytical results clearly confirm adequate design?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Is a general description of the method used for analysis included?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Are reference sources listed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Are used computer programs properly identified and described?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Are used drawings, calculations, computer printouts, and sketches included?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Are boundary and interface conditions adequately and appropriately considered?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Are used analytical and/or experimental methods and assumptions appropriate and correctly applied?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Are areas, having the most severe stress condition for design conditions or for any specified condition, listed along with the stress values?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Has Design Report or Load Capacity Data Sheet been certified to be correct and in accordance with the requirements of NCA-3555 by one or more RPE’s? (where required by Customer)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### EXHIBIT 3.4-c

**EXHIBIT 3.4-c**

R = REMARKS:

- 
- 
- 
- 
- 

Verifier’s Signature: __________________________ Date: __________
## Design Verification Check-list

### Points to be Checked

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<thead>
<tr>
<th>#</th>
<th>Points to be Checked</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Document title and revision completeness and correctness</td>
</tr>
<tr>
<td>2</td>
<td>Scope of work/supply clearly stated</td>
</tr>
<tr>
<td>3</td>
<td>Reference sources list</td>
</tr>
<tr>
<td>4</td>
<td>Code and standard requirements</td>
</tr>
<tr>
<td>5</td>
<td>Technical requirements</td>
</tr>
<tr>
<td>6</td>
<td>Battery limits clearly stated, classification of supply (nuclear, seismic, quality)</td>
</tr>
<tr>
<td>7</td>
<td>Compatibility of specified materials among each other and with the design environmental conditions to which material will be exposed</td>
</tr>
<tr>
<td>8</td>
<td>Maintenance, repair and pre/in-service inspection requirements</td>
</tr>
<tr>
<td>9</td>
<td>Documentation requirements (identification, records, number and type of copies, delivery)</td>
</tr>
<tr>
<td>10</td>
<td>Right to access</td>
</tr>
<tr>
<td>11</td>
<td>Material/item identification, marking</td>
</tr>
<tr>
<td>12</td>
<td>Inspection, test, examination requirements</td>
</tr>
<tr>
<td>13</td>
<td>Deviation or Nonconformance requirements</td>
</tr>
<tr>
<td>14</td>
<td>Cleanliness, packaging, shipping and storage requirements, shipping destination (DDP, DDU, FOB, ...)</td>
</tr>
<tr>
<td>15</td>
<td>Certification requirements including requirements for third party surveillance</td>
</tr>
<tr>
<td>16</td>
<td>Methods of acceptance</td>
</tr>
<tr>
<td>17</td>
<td>QA records requirements</td>
</tr>
<tr>
<td>18</td>
<td>Mandatory information required in NCA-3250 for Design Specification</td>
</tr>
</tbody>
</table>

R = Remarks:

Verifier's Signature: ___________________________ Date: _____________________

---

*Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use.*
<table>
<thead>
<tr>
<th>POINTS TO BE CHECKED</th>
<th>OK</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are document title and revision complete and correct?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Is material or item to be fabricated and/or controlled clearly identified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Is operation sequence sufficiently detailed and correct?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Do analytical results clearly confirm adequate design?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Are applicable documents (specifications, procedures, instructions, drawings, codes and standards, etc..) correctly referenced?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Are there available spaces for inspection points, records and signature?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Are used computer programs properly identified and described?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Is the certificate to be provided indicated?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Are inspection points indicated?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EXHIBIT 3.4-e**

<table>
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<tr>
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Verifier's Signature: __________________________ Date: ________________
EXHIBIT 3.4-f

"Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use"
EXHIBIT 3.5

### TECHNICAL CHANGE DESCRIPTION

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<tr>
<th>DESIGN CHANGE</th>
<th>DEVIATION</th>
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<tbody>
<tr>
<td>DOCUMENTS TO BE CHANGED</td>
<td>UNIT</td>
</tr>
<tr>
<td>DOCUMENTS TO BE CHANGED</td>
<td>UNIT</td>
</tr>
</tbody>
</table>

### NOTES:

- PREPARED BY:
  - PROJECT ENGINEER
  - Signature: [Signature]
  - Date: [Date]
- APPROVED BY:
  - DESIGN MANAGER
  - Signature: [Signature]
  - Date: [Date]
- REVIEWED BY:
  - ANS/QLT
  - Signature: [Signature]
  - Date: [Date]
- AUTHORIZED BY:
  - PROJECT MANAGER
  - Signature: [Signature]
  - Date: [Date]

### ATTACHMENTS:

- REQUIRED
- NOT REQUIRED

### DISTRIBUTION:

- QLT
- PM

---

Ansaldo Nucleare S.p.A.: Corso F. M. Perrone, 25 - 16152 Genova – Italy; +39 010 6551, Fax +39 010 655 8532; http://www.ansaldonucleare.it

ANN002_5
# Check List for evaluation of

## NAME OF PROFESSIONAL ENGINEER:

<table>
<thead>
<tr>
<th>#</th>
<th>Item to be checked</th>
<th>Reference</th>
<th>Check Results</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Is the Professional Engineer registered in at least one of USA state or Province of Canada?</td>
<td>Appendix X0011001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Is the Certificate still valid?</td>
<td>Appendix X0011002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Is the specialized field appropriate (design report and design specification) for the services which are required by the RPE?</td>
<td>Appendix X0011003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Has the RPE four (4) years of relevant application experience?</td>
<td>Appendix X0011004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Has the RPE at least two (2) years of application experience in the specialty field for which the services are required?</td>
<td>Appendix X0011005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Is the RPE knowledgeable of the specific Code requirements pertaining to his specialty field?</td>
<td>Appendix X0011006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Does the RPE keep current his knowledge of the Code requirements to the last edition of the ASME BPE?</td>
<td>Appendix X0011007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Does the RPE continue his professional development in his specialty field by personal study and experience?</td>
<td>Appendix X0011008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Does the RPE continue his professional development in his specialty field by attendance of appropriate courses, seminars, Society meeting, and technical committee meetings?</td>
<td>Appendix X0011009</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Has the RPE provided a self-review establishing that this qualification meet the requirements of Appendix X0011010</td>
<td>Appendix X0011011</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Has the RPE been inteviewed on the ANS Quality Assurance Program and on the Procedures applicable to the activity?</td>
<td>Quality Assurance Program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Is the RPE knowledgeable of the actions to determine if a condition is reportable in accordance with 10 CFR Part 21 (N-P-ANN-0007 procedure)?</td>
<td>N-P-ANN-0007</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Approved by: __________________________
Signature: __________________________
Date: __________________________

**EXHIBIT 3.6**

---

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4. PROCUREMENT DOCUMENT CONTROL

4.1 Scope

This section defines the methods adopted by ANN for preparation and control of Procurement Documents in order to assure that design basis and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of material, Items and services. To the extent necessary the Procurement documents shall require suppliers to have a quality program consistent with the requirements of this QAP.

4.2 Procurement Document Content

The Procurement Document used by ANN consists of Purchase Order text (Exhibit 4.1) and supporting documents such as Design Specification, Design Report, Purchase Technical Specifications, Drawings, Material Specifications, Quality Requirements with technical and other requirements for material, Items and services to be purchased.

The following provisions shall be included, as applicable, that Procurement Documents shall require Supplier to provide a Quality Assurance Program consistent with the applicable requirements of ASME Code Section III.

The PO shall include the provision that when the Supplier has the legal/administrative address different from the location shown on his certificate and the PO has to be sent to the legal address, the PO must be integrally forwarded by this office (legal/administrative address) to the Certificate Holder/Supplier location where the code activities will be performed.

4.2.1 Scope of work

The definition of the scope and type of work to be performed by the Supplier shall be included in the Purchase Order scope.

A Supplier shall be defined as follows:
- Certified Material Organization (CMO)
- Certificate Holder (CH)
- Approved Supplier of Subcontracted Services (ASSS)

4.2.2 Contractual Documents

The Purchase Order text shall list the applicable ASME Code Edition, Addenda and Code Cases, Code Class and other supporting documents, as applicable.
4.2.3 Technical Requirements

Technical requirements shall be specified by reference to specific drawings, specifications, Codes, standards, regulations, procedures, or instructions, including revision thereto that describe the material, items and services to be furnished and limitation of supply (e.g. PTS).

The procurement documents shall provide for identification of test, inspection, method of acceptance of ANN for monitoring and evaluating the supplier’s, acceptance criteria for determining acceptability of items or services, performance as well as handling, storage and shipping requirements, the type of certification requested such as Certified Material Test Report (CMTR), Partial Data Report, and that repair of material by welding shall not be allowed without prior approval by ANN.

4.2.4 Quality Assurance Program Requirements

1) The procurement documents shall require that the supplier have a documented quality assurance program that implements the applicable requirements of the NCA-4000 or NCA-3800 and 10CFR50 App. B as applicable. The extent of the program shall depend upon the type and use of the material, items or service being procured.

2) The procurement documents to CH and CMO shall require the Supplier to incorporate appropriate quality assurance program requirements in sub-supplier procurement documents. NCA-4000 or NCA-3800 and 10CFR50 App. B are required to be included in sub-suppliers’ QA program as applicable.

3) The exemption for small products under provision of NX-2600 is not used by ANN.

4.2.5 Right of Access

The procurement documents shall provide for access to the Supplier’s facilities and records for inspection or audit by the ANN Representatives, Customer Representatives and Authorized Nuclear Inspector (ANI).

4.2.6 Documentation Requirements

1) The procurement documents shall identify the documentation required to be submitted for information, review, or approval by ANN. The time of submittal (interval/dead line as applicable), identification, numbering and classification shall also be established.

2) When ANN requires the Supplier to maintain specific quality assurance records, the retention times and disposition requirements shall be specified.

3) A statement which requires as applicable:
   • the Quality System Certificate (QSC), expiration date,
   • Quality Manual revision and date,
• the applicable Certificate of Authorization Number and expiration date
• confirmation of the use of the Quality Program.

4.2.7 Non-conformances, changes and deviations

The procurement documents shall include ANN requirements (e.g. NQA-1 and 10 CFR PART 21, if applicable) for reporting and approving disposition of non-conformances, deviations and processing design changes.

4.2.8 Spare and Replacement Parts

The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality assurance related data required for ordering these parts or assemblies.

4.3 Responsibility

4.3.1 Purchase Request

Technical Unit Managers are responsible for preparation of the Purchase Request, based on contractual and technical requirements and the Part List, and make available the supporting documents (e.g. PTS for key components and parts) to AEN Purchasing Unit.

Technical/Purchase Specifications (PTS) are the key documents for describing the controls and interface between ANN and Suppliers of NPT stamped Items. PTS is prepared, checked/approved and issued as shown in § 6.6.

The scope of PTS will vary depending on the product/item to be procured but should address, as a minimum:

1. Scope
2. Applicable documents, including requirements for submission and approval;
3. Equipment description: reference to Customer specifications including Codes;
5. Material requirements including any additional testing;
6. Manufacturing requirements covering fabrication, welding, NDE, cleaning, etc.;
7. Testing and Inspection requirements, including pre-service and in-service requirements, use of Quality Control Plans and intervention of ANN inspections;
8. Packing and shipping requirements;

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(9) Quality assurance requirements;

(10) Documents including those required at bid stage and QA records;

(11) Special requirements including spare parts, Manufacturer’s Data Report, nameplate or marking.

The review of the PTS shall be documented using design verification checklist (Exhibit 3.4 d).

Purchase Request and attached procurement supporting documents shall contain, as a minimum:

- type and scope of supply,
- Supplier quality system requirement,
- Code, QA and other technical requirements,
- date and SAP electronic signatures based on the authorization levels indicated in the table below.

Responsibilities for preparation, approval, review and authorization of Purchase Request are listed below:

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>PURCHASE REQUEST</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREPARATION</td>
<td>Technical Units Manager</td>
</tr>
<tr>
<td>APPROVAL</td>
<td>PM</td>
</tr>
<tr>
<td>REVIEW</td>
<td>QLT Manager</td>
</tr>
<tr>
<td>AUTHORIZATION</td>
<td>Business Leader</td>
</tr>
</tbody>
</table>

4.3.2 Purchase Order

Responsibilities for preparation, approval, review and authorization of Purchase Order are listed below.
4.3.3 Supporting Documents

Responsibilities for preparation, approval, review and authorization of supporting documents are listed in Sect. 6.6 of this manual.

4.4 PROCUREMENT DOCUMENT REVIEW

1) A review of the procurement documents and changes thereto shall be made to assure that documents transmitted to the prospective Supplier include appropriate provisions to assure that material, Items or services will meet the specified requirements listed in Sect. 4.2 of this manual. Changes made as a result of the proposal evaluations or pre-contract negotiations shall be incorporated into the procurement documents.

2) Procurement documents shall be prepared, approved, reviewed and authorized in accordance with Sect. 4.3 of this manual, prior to order award. ANN fixes the maximum price of the Purchase Order and if the suppliers’ proposals exceed this price, AEN must ask the relevant ANN PWR Manager for authorizing that exceeding. This authorization shall be documented.

3) Review of Purchase Order shall be performed by personnel with access to pertaining information and an understanding of requirements and intent of the procurement documents through the “Procurement Document Review” form, (Exhibit 4.2).

4) Review shall be made by ANN Technical Unit Manager responsible for the Purchase Request, QLT Manager using the Check List (Exhibit 4.3) and the applicable Business Leader or Project Manager (PM) to verify consistency with Purchase Request and shall cover the Items listed in Sect. 4.2 of this manual.

5) Then the filled in forms with the ANN review and approval is sent to AEN
and the Purchase Order shall be signed by AEN without changing any technical and delivery issues and with the requirement indicated at point 2).

4.5 **Procurement Documents Distribution**

1) The AEN Purchasing Unit Manager shall send the Purchase Order and its revisions to the Supplier with supporting documents, as applicable.

2) An electronic copy of the Purchase Order will be available to ANN people in the SAP system. When distributed in paper copy, it shall be sent to PM, the Technical Unit Manager for the Purchase Request and QLT, using the “Purchase Order Distribution List” (Exhibit 4.4).

3) Distribution of supporting documents shall be made as per Sect.6 of this manual.
4.6 **PROCUREMENT DOCUMENT FILING**

Purchase Requests and Purchase Orders text are filed in the SAP data base Confidential file. They shall be made available for Audits even if documents are subject to confidentiality. Procurement supporting documents are filed as per Sections 6 and 17 of this manual.

4.7 **PROCUREMENT DOCUMENT CHANGES**

Review of procurement document changes shall be made by the same persons and same control applied in preparation of original documents. Review consists of:

- determination of any additional or modified design criteria;
- analysis of exceptions requested by Supplier and their effects.

4.8 **APPLICABLE PROCEDURES**

- **N-P-ANN-E001 Procurement Process**
<table>
<thead>
<tr>
<th>Order</th>
<th>Amnd. Date</th>
<th>Date amnd.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Department:** PRC

**Subject:**

**Ansaldo Nucleare awards the present order at the conditions in the same listed**

**Delivery terms**

**Payment conditions**

The data indicated here beside shall be shown up on the correspondence relevant to the present order. The correspondence shall be addressed as stated below. Ansaldo Nucleare will not be liable for the consequences of possible forwarding made not in accordance with instructions. This correspondence shall be forwarded:

- Commercial correspondence: Ansaldo Nucleare - Purchasing (c/o Ansaldo Energia) * Via Lorenzi, 8 - 16152 Genova

- Administrative correspond.: Ansaldo Nucleare - Amministrazioni - Finanza-Controllo (c/o Ansaldo Energia) * Via Lorenzi, 8 - 16152 Genova

- Remaining correspondence and test notices: Ansaldo Nucleare - Responsabile PO * C.so Perrone, 25 - 16161 Genova

- Quality correspondence: Ansaldo Nucleare - Quality * C.so Perrone, 25 - 16161 Genova

<table>
<thead>
<tr>
<th>Internal notes</th>
<th>Supplier code</th>
<th>Responsible PO</th>
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<tbody>
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<td></td>
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</tr>
</tbody>
</table>

**Currency**

<table>
<thead>
<tr>
<th>Currency total amount</th>
<th>For internal use only Euro</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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**EXHIBIT 4.1**
**VERIFICA ORDINATIVO**

**PROCUREMENT DOCUMENT REVIEW**

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<td>N°A N.:</td>
<td>FORNITORE:</td>
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<td>Purchase Request N.:</td>
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<td>COMMessa:</td>
<td>ORDINE:</td>
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<td>Job number</td>
<td>order</td>
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Firma Approvigionatore:  
(purchaser’s signature)

**SPAZIO RISERVATO ALL’ENTE RICHIEDENTE N°A**  
(space reserved to the Purchase Request Issuing Department)

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<thead>
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</thead>
<tbody>
<tr>
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<tr>
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<td></td>
</tr>
<tr>
<td>remarks</td>
<td></td>
</tr>
</tbody>
</table>

FIRMA:  
(signature)  
Data:  
(date)

**SPAZIO RISERVATO ANN/QLT (vedere Check-List)**  
(space reserved to ANN/QLT (see Check-List))

<table>
<thead>
<tr>
<th>BENESTARE:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>authorization</td>
<td></td>
</tr>
<tr>
<td>COMMENTI:</td>
<td></td>
</tr>
<tr>
<td>remarks</td>
<td></td>
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</tbody>
</table>

FIRMA:  
(signature)  
Data:  
(date)

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<tr>
<th>EXHIBIT 4.2</th>
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**SPAZIO RISERVATO AL GESTORE D’ORDINE**  
(space reserved to the Purchase Order Manager)

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FIRMA:  
(signature)  
Data:  
(date)

**CONCLUSIONI DI AEN/PRC**  
(AEN/PRC conclusions)

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</tbody>
</table>

FIRMA:  
(signature)  
Data:  
(date)
### CHECK LIST FOR PROCUREMENT DOCUMENT REVIEW

**Purchase Request N°:**

**Purchase Order N°:**

#### Subject:

<table>
<thead>
<tr>
<th></th>
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**LEGEND:**

- Y = Yes
- N = No
- NA = Not Applicable

#### Remarks:

**Signature** ____________  **Date** ____________

---

**EXHIBIT 4.3**

"Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use"
## LISTA DISTRIBUZIONE ORDINI ANN

### PURCHASE ORDER DISTRIBUTION LIST

<table>
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<th>ORDINE:</th>
<th>PURCHASE ORDER</th>
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### NOTE:

**NOTES**

### DISTRIBUTION LIST

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<th>N. COPIE</th>
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**RICHIEDENTE:**

TECHNICAL UNIT MANAGER - 1

**AUTORIZZANTE:**

BUSINESS UNIT MANAGER - 1

---

**EXHIBIT 4.4**

---

**FIRMA:**

**DATA:**
5. INSTRUCTIONS, PROCEDURES AND DRAWINGS

5.1 Scope

(1) Activities affecting quality are regulated and performed by ANN in accordance to a system of technical and management documents described by this section.

(2) This system identifies the following kind of documents:
   a) management and organization documents;
   b) technical documents;
   c) procurement documents.
   d) Supplier documents

(3) All above documents are available for use by appropriate personnel and the ANI.

5.2 Management and Organization Documents

Management and organization documents establish the activities to be performed and related methods of implementation as well as tasks and responsibilities.
They consist of the following:
- Quality Manual
- Organization Procedures
- Communications
- PQP and Project Procedures
- Operating Instructions

5.2.1 Quality Manual

Quality Manual content is described in § 2.2(2) of this manual.
Quality Manual is issued and signed as per Section 6 of this manual.

5.2.2 Organization Procedures

Documents which control the development of the activities or the connection among the ANN Units (see § 2.2(3)). Organization Procedures are controlled as per Section 6 of this manual.

5.2.3 Company’s Organization and Communications

Documents which control specific organizational matter, signed as per Section 6 of this manual.
5.2.4 **PQP and Project Procedures**
Documents which control the development of the activities or the connection among the activities related to a specific project. Project Procedures are issued by the relevant Business Leader or by the QLT Manager depending on the subject. See § 2.1(3) for the PQP description.

5.2.5 **Operating instruction**
_They regulate, coherently with the procedures, the operational details of processes and of relationship between company Units. They specify, where appropriate, the forms to be used._

5.3 **TECHNICAL DOCUMENTS**
(1) Technical documents issued by ANN Technical Units are the following:
   a) Drawings
   b) Specifications
   c) Procurement Documents
   d) Design Specifications
   e) Design Plan
   f) Check-lists
   g) Part Lists
   h) Design Analysis
   i) Procedures
   j) Traveler - QCP
   k) Design Report
   l) As-built documents
   m) Operating and Maintenance Manuals and Instructions

(2) They include or reference acceptance criteria, as necessary, determining that activities described have been accomplished satisfactorily.

5.4 **PROCUREMENT DOCUMENTS**
The purchase activities carried out by ANN are performed according to the following kinds of documents:

(1) Purchase Requests (RdA): they are forwarded to the AEN Purchasing Unit for purchasing Items and services. All technical and quality documents for transferring ANN requirements to Supplier are attached to these documents, as per Sect.4 of this manual.

(2) Purchase Order: it includes all commercial administrative conditions and technical quality requirements to be met by Supplier, as detailed in Sect. 4
of this manual.

5.5 Supplier Documents

Supplier documents to be supplied, with the time schedule, are defined in the procurement documents (e.g. PTS - see § 4.3.1) and are received and controlled by the PM as per § 7.6.

QLT is responsible for handling Traveler-QCPs, Non-conformances and Corrective Actions from the Suppliers. The Technical Unit is responsible for design activities related to Supplier’s requests (e.g. for changes/deviations). The status of all Supplier’s documents shall be maintained in the GTD.

6. DOCUMENT CONTROL

6.1 Scope

(1) This section describes the system adopted by ANN for the control of documents as indicated in Sect. 5 of this manual. This control includes identification, preparation, approval, issue, filing, distribution, access to the ANN INTRANET PORTAL as well as correction and revision of documents, such as paper copy, microfilm, and as electronic offset.

(2) “Technical Management of Documents” (GTD) provides identification and status of revisions of documents issued by ANN and includes documents from Customers, Partners, Licensees, Manufacturers, Suppliers, etc., in order to avoid utilization of obsolete documents.

- Access is controlled to the GTD by password.
- The level of access is also controlled through the same password, and covers, but is not limited to, the levels “read only”, “input/modify data” and “issuance of data”.

The information per project within the system broadly addresses:

- ANN documents,
- Customer documents,
- Supplier documents.

Only the latest applicable and properly approved documents are accessible and retrievable.

With the revision or change/amendment of a document, the current valid revision/edition is sent to the Technical Archive.

The Technical Archive Management will advise all recipients, as indicated on the GTD Distribution List for that document, by e-mail about its

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archiving and new issue/revision. This e-mail serves as internal transmittal, acknowledgement of the e-mail is automatically recorded by opening the e-mail.

The overall responsibility for maintenance of the system is assigned for each project to the designated PM.

Disposal of superseded documents is the responsibility of the person who received the copy by Distribution List of the GTD.
Superseded documents can only be consulted through the Technical Archive.

(3) Managing of Codes and Standards, including their identification and distribution, is performed and filled by QLT.

6.2 MANAGEMENT AND ORGANIZATION DOCUMENTS

(1) The management and organization documents are prepared, reviewed for adequacy, approved for release and issued as follows:

a) Quality Manual (QM)
QM is prepared by a Quality Engineer, , and submitted to a complete review by ANN Units using the form Verification Plan Organization Documents (Exhibit 6.2).
Review results of ANN Units shall be collected and evaluated by QLT Manager using form Organization Documents Verification Extent and Results (Exhibit 6.1).
QM is verified by the QLT Manager and approved by the CEO. Distribution is performed as per Sect. 2.3 of this manual.

b) Organization Procedures
Organization Procedures are prepared by a Quality Engineer (delegated for each job by the QLT Manager) and reviewed by all Units concerned using the form “Verification Plan Organization Documents” (Exhibit 6.2). Review results of Units shall be properly processed for consistency by QLT Manager using form Exhibit 6.1.
Organization Procedures are issued by the applicable Unit Manager and approved by the CEO.
The QLT Manager is responsible for Managing using GTD and for electronic distribution of the original file converted to a non editable but printable format using the “Distribution List” of the GTD. Any printout of this file indicates the following statement on each printed page: "Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the Procedures prior to use”

C) Communications “CS”
Communications are issued by HRS and approved by CEO. Communications are distributed by ANN INTRANET PORTAL.
d) **PQP and Project Procedures**

   Project Procedures are prepared by QLT or Technical Unit, reviewed by the PE, approved and issued by the relevant Business Leader or by the QLT Manager depending on the subject. Managing of Project Procedures is performed using GTD and their distribution using the “Distribution List” of the GTD.

e) **Operating Instruction**

   The instruction is issued by the Unit Manager in charge of the document issue and then transmitted, in final version with all verification documentation and the related synthesis for the authorization of his Manager.

(2) **Management and Organization Documents indexing:**

   a) The QLT Manager is responsible to establish an indexing system for identification, collection and filing of documents associated to this Quality Assurance Program (QAP).

   The identification system is the following:

   \[
   \text{N-xx-ANN-Y zzz}
   \]

   where

   - \(N\) → NUCLEARE
   - \(xx\) → type of document \(M = \text{QM}\)
   - \(P = \text{Organization Procedure}\)
   - \(IO = \text{Operating Instruction}\)
   - \(CS = \text{Communication}\)
   - \(Y\) → type of document pertaining category, not used for the QM (see Exhibit 6.6)
   - \(zzz\) → progressive number per category

   b) Project Procedures are identified in accordance with the indexing system specific to the project.

   c) Management and Organization Documents are stored in the Technical Archive.

6.3 **TECHNICAL DOCUMENTS**

(1) The Unit Manager responsible for issuing the documents provides for identification, authorization process and filing, conceived in accordance with Project Procedures and with Forms «Technical Documents Cover Page», «Drawings Format» (Exhibits 6.3a through 6.3d and 6.4) in accordance with Sect. 6.6 of this manual.

(2) Technical documents shall be prepared by a Technical Unit involved, reviewed in accordance with Sect. 6.6, of this manual, issued and distributed only after authorization of the issuing Unit Manager. This authorization allows beginning the activities related to documents controlled distribution, recording, and filing.

(3) The «Distribution List» in GTD shall be prepared by the relevant Unit

---

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Manager responsible for authorization using the GTD. This document also includes the request for archiving and for reproduction.

(4) He sends the technical documents to the Archive for registration and further distribution.

(5) Technical Archive performs:
   a) acceptance control and registration of the document into GTD system.
   b) storage of the original hardcopy (cover page) and, in the case of past contract the related microfilm. For current and future contracts, .pdf files are prepared and controlled in accordance with procedure N-P-ANN-H010.
   c) distribution as per Distribution List.

(6) Distribution to Customer is controlled by the Project Manager (PM) using the GTD Distribution List and a transmittal.

(7) Changes to controlled documents include:
   a) review and approval by the same organization who performed the original review and approval unless another organization is designated,
   b) access for the reviewer to background data and information,
   c) distribution to the previous addressee.

6.4 TRAVELER - QCP

In case ANN is Code marking with N Designator a component then a Traveler – QCP (Exhibit 6.5) shall be prepared to describe the activities associated with the final Hydrostatic Testing, inspection, stamping and Code Data Report. The Traveler-QCPs shall describe the sequences of the job processing, references to requirements, procedures and revision, responsibilities for the performance and surveillance of activities, reviews and hold points.

The Traveler-QCPs shall be prepared, checked and authorized according to Sect. 6.6, of this manual, prior to the start of Code activities. Quality Inspector shall review the QCP and related document with ANI for the selection of his inspection points.

Performance of review and hold points shall be initialed and dated by the person who designated review and hold points.
6.5 Certified Material Test Report, Certificate of Compliance, Certificate of Conformance

6.5.1 Certified Material Test Report (CMTR)

(1) The CMTR is a document (Exhibit 6.8) attesting that the material is in accordance with specified requirements, including the actual results of all required chemical analyses, tests and examinations.

(2) When required chemical analyses (including melting mill heat analysis), heat treatment, tests, examinations, or repairs are subcontracted, the approved supplier's certification for the operations performed shall be furnished as an identified attachment to the Certified Material Test Report. When operations other than chemical analysis, heat treatment, tests, examination, or repairs, that require maintenance of traceability are subcontracted, these operations and the approved suppliers performing them shall be listed on the Certified Material Test Report, or the approved suppliers certification for the operation may be furnished as an attachment to the Certified Material Test Report.

(3) The CMTR shall certify that all test results and operations performed by ANN or ANN's Suppliers are in compliance with the requirements of the material specification and ASME Sect. III. The certification of the CMTR shall include as minimum the applicable requirements of NCA-3860 and Appendix P-1000 such as:

- Actual results of chemical analysis
- Melting method
- Test results
- NDE performed
- Conformity to dimensional requirements (if applicable)
- Material specification reference
- Repairs and related radiographic films, if any
- Heat treatment (for austenitic stainless steels and high nickel alloys, statement of the minimum solution annealing temperature)
- Visual and dimensional inspection
- Material identification and marking
- Certification statement (QSC number the and expiration date see 6.5.4)
- Supplementary requirements, if any
- Reference to Non Conformance Reports (NCR) if applicable
- Code Edition and Addenda
- Code Class
- Attachments

(4) Tests, examinations and operations to be performed are determined by QLT Manager and are documented in relevant reports which are the basis for the preparation of the CMTR. The CMTR shall be prepared
and be certified by the Material Organization responsible or by Quality Inspector as per Sect. 6.6 of this manual.

6.5.2 Certificate of Compliance (CoC) for Materials

(1) The CoC is a written statement attesting that the materials are in accordance with specified requirements, as required by NX-2130, NCA-3860 or NCA-3689.

(2) Material identification shall be described in the CoC. The CoC shall be prepared and certified by the Material Organization, or by Quality Inspector as per Sect. 6.6 of this manual.

6.5.3 Certificate of Conformance

(1) The Certificate of Conformance is a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements. For ANN Certificate of Conformance, it shall also identify that deviations from purchase order or specification requirements have been resolved or justified.

(2) CMTR or CoC shall be attached to the Certificate of Conformance.

(3) Certificate of Conformance shall be issued and certified by Quality Inspector.

6.5.4 Quality System Program Statement

CMTR, CoC and Certificate of Conformance shall indicate, as applicable:
- the Quality System Certificate number and expiration date; or revision and date of the applicable written qualified Quality System Program or Identification and Verification Program;
- Certificate of Authorization number and expiration date.
### 6.6 Preparation, Approval and Authorization of Technical Documents

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<th>TRAVELER QCP</th>
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- Technical Unit: CSA, INI as applicable
- Technical Unit: CSA, RSC, TSW, INI as applicable
- When decided by the Authorizer or in case of Supplier's document coming from the Approver.

Approval = review
Authorization= approval for release and issuance

In the event that technical documents are provided by a supplier of engineering services then the procedure for control of review, approval and authorization for issuance shall be contained in an annex to this section which shall be mandatory for that project.

The acceptance of the annex by CEO, QLT Manager and ANIS shall follow the same procedure as changes to this QM.

### 6.7 Procurement Process Documents

Documents related to purchase activities are managed and filed as per Sect.4 of this manual.

### 6.8 Applicable Procedures

- N-P-ANN-H002 Management of Organizational Documents
- N-P-ANN-H010 Technical Documents Archive
### EXHIBIT 6.1

**3) RISOLUZIONE DELLE EVENTUALI OSSERVAZIONI/RESOLUTION OF POSSIBLE REMARKS:**

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Sulla base dei risultati della verifica, si dichiara che i documenti elencati al punto 1 possono essere EMESSI.

**DATA**

FIRMA AUTORIZZATORE: 

**date**

authorizer's signature

---

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**EXHIBIT 6.2**

**TIPO DI VERIFICA RICHIESTA**  
Kind of verification required:

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NOTE del Verificatore/Verifier's NOTES:

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**A** - Signed  
**C** - Confidential
### EXHIBIT 6.3-a

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**EXHIBIT 6.3-a**

**Attention:** This print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against the electronic version of the procedure prior to use.

---

**Electronic filename:** ann019 Documenti Tecnici

**Electronic format:**

**Description:**

- Commessa
- Off. N.
- Unità emittente
- Issued by
- Classe Ris.
- Class

- Cliente
- Customer
- Ordine/Contratto
- Order
- Iter Cliente
- Customer iter

**Redazione e Data**
- Prepared by:
- Date

**Controllo/Approversazione e Data**
- Checked by:
- Date

**Autorizzazione emissione e Data**
- Authorized by:
- Date

**Revisione**
- Revision

**Causale Rev.**
- Rev. Code

**Descrizione**
- Description

---

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**EXHIBIT 6.3-b**
INDICE/SUBJECT

1. TITOLO 1 ................................................................. 4
1.1 Titolo 2 ................................................................. 4
1.1.1 Titolo 3 ................................................................. 4

EXHIBIT 6.3-c
1. **TITOLO 1**

1.1 **Titolo 2**

1.1.1 **Titolo 3**

**EXHIBIT 6.3-d**
EXHIBIT 6.4

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**EXHIBIT 6.5**

*Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use.*

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**DOCUMENTAZIONE**

- Documents used:
  - N.
  - REV.
  - Data/Type

**DOSSIER**

- Area
- Verso

**VERSO**

- Area
- Doss/Type
RELEVANT CLASS OF COMPANY MANAGEMENT SYSTEM DOCUMENTATION

A ♦ GENERAL
B ♦ COMMERCIAL
C ♦ JOB MANAGEMENT AND CONTROL
D ♦ DESIGN
E ♦ PROCUREMENT
F ♦ SITES
G ♦ QUALITY
H ♦ DOCUMENTATIONS, FORMS MANAGEMENT
I ♦ MATERIALS MANAGEMENT
L ♦ ADMINISTRATION (BUDGET CONTROL, ADMINISTRATIVE REPORTING)
M ♦ FINANCE (PLANNING AND CONTROL, CASH MANAGEMENT, BANK GUARANTEE)
N ♦ PERSONNEL (TRAINING, QUALIFICATION)
P ♦ INFORMATION SYSTEM
Q ♦ SERVICES GENERAL AFFAIRS
R ♦ PLANNING, PRODUCT DEVELOPMENT, RESEARCH
S ♦ ENVIRONMENTAL AND SAFETY
V ♦ VARIOUS
W ♦ PROJECT STRUCTURE, RESPONSIBILITY
Y ♦ CONTRACTUAL REQUIREMENTS, REGULATIONS, AUTHORIZATION PROCESS

**EXHIBIT 6.6**
## Certified Material Test Report Verification Check-List

**Supplier:**

**Purchase Order:**

**Material:**

**Material Specification:**

**Supplier CMTR No:**

<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>YES</th>
<th>NO</th>
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<td>Test results</td>
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<td>Repairs and related radiographic films</td>
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<td>8</td>
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<td>9</td>
<td>Visual and dimensional inspection</td>
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</tbody>
</table>

**Remarks:**

**Inspector Signature:**

**Date:**

---

**Exhibit 6.7**

---

**Ansaldo Nucleare S.p.A.:**

**Corso F. M. Perrone, 25 - 16152 Genova – Italy;**

**+39 010 6551, Fax +39 010 655 8532, http://www.ansaldonucleare.it**

**ANN002_5**
Certified Material Test Report

CERTIFIED MATERIAL TEST REPORT

<table>
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<tbody>
<tr>
<td>Customer:</td>
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<td>Customer P.O.:</td>
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<tr>
<td>Address:</td>
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<td>Material Marking:</td>
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<td>Supplementary requirements:</td>
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<tr>
<td>Reference to NCR</td>
<td></td>
</tr>
<tr>
<td>Attachments:</td>
<td></td>
</tr>
</tbody>
</table>

CERTIFICATION STATEMENT

This certification affirms that contents of the attached reports are correct and accurate and they have been examined by Ansaldo Nucleare, as foreseen in the order.

All tests results and operations performed by the material organization and their subcontractors included in the reports are in compliance with the material specification and the specific applicable material requirements: ASME Sect. III NB and ASME sect. II part ______ edition.

ASME Sect. III NCA 3860 and NCA 3855.5 and the material specification _______ requirements are met.

EXHIBIT 6.8
7. CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Scope

(1) This section describes the measures to be taken for ensuring that purchased Items and services are in compliance with the Procurement Documents requirements for Code activities.

(2) ANN provides for:
   a) procurement planning;
   b) evaluation and selection of Suppliers;
   c) surveillance of Suppliers;
   d) auditing of Suppliers;
   e) method of acceptance of Items and services;
   f) collecting and updating Suppliers’ quality information.

7.2 Procurement Planning

(1) Procurement activities are planned and documented by Project Manager (PM) for each project, before starting procurement, in order to assure a systematic approach to procurement process and interface compatibility.

(2) Procurement documents (including the PTS) preparation, review, change control and organization responsibilities are documented as per Sect. 4 of this manual.

(3) Selection and evaluation of Suppliers (Certified Material Organization, Certificate Holders and Suppliers of Subcontracted Services) shall be performed as per Sect. 7.3 of this manual. Proposal evaluation and award as per Sect. 7.3.1 of this manual.

(4) Supplier performance assessment shall be made by surveillance, inspection, surveys and audits, as applicable, including notification for hold and witness points, as per Sect. 7.8.2 of this manual.

(5) Control of nonconformance shall be performed as per Sect. 15 of this manual.

(6) Corrective actions shall be controlled as per Sect. 16 of this manual.

(7) Methods of acceptance of materials, Items and services shall be defined in the procurement documents and shall be controlled as per Sect. 4 of this manual.

(8) Quality assurance records associated with procurement shall be controlled as per Sect. 17 of this manual.
7.3 Selection of Suppliers

1) Procurement shall be made from suppliers listed on the Evaluated Supplier List.

Possible suppliers can be:

- CH having the proper scope for procurement of components or installation services
- CMO or CH with supply of material in their scope for procurement of materials
- Approved Supplier of Sub-contracted Services

2) QLT Manager prepares and updates the Suppliers status of qualification, providing the Evaluated Suppliers List, whenever there is a change. When required by the contract, the Evaluated Supplier List shall be submitted to the customer for approval. Evaluated Suppliers List shall include:
   a) Supplier name, location
   b) ASME certificate Number and expiration date, when applicable,
   c) Date of last survey or audit if approved by ANN,
   d) Scope of Items or services to be supplied or any limitation,
   e) Date of last updating.

3) When a Purchase Order is placed with an agent of a Supplier, agent’s name, address and scope of activity shall be specified in the evaluation report and in the Evaluated Suppliers List. ANN’s PO shall include the following statement: “This Purchase Order shall be transmitted without any change of the scope and content, including all technical requirements, to the Qualified Vendor. The material shall be shipped to ANN customer”.

7.3.1 Bid Evaluation

Bid evaluation shall determine the extent of conformance to the procurement documents. This evaluation shall be performed by the same individuals or organization involved in the procurement process. Prior to the award of the contract through AEN Purchasing Unit, ANN shall resolve unacceptable quality conditions resulting from the proposal evaluation.

7.4 Approval Process of Suppliers

(1) QLT Manager is responsible for Supplier surveys, audits and evaluation. Business Units, Technical Units and AEN Purchasing Unit can participate at Supplier evaluation, for assessing specific aspects.

(2) In case of supplies of materials, parts or components Safety Related Non-ASME Code, in accordance to the requirements of ASME NQA-1, 10CFR50
App. B, etc., the evaluation of technical capabilities and quality requirements shall be performed through an Audit.

(3) In case of supplies of materials, parts or components Safety Related ASME Code III, the evaluation of technical capabilities and quality requirements is performed through the verification of the documentation sent by Supplier together with the Informative Questionnaire ANN124 and through an Audit, if necessary, according to the contractual requirements. **QLT Manager shall verify the scope and validity of the relevant ASME Certificate of Authorization.**

(4) Prospective Suppliers of Sub-contracted Services are evaluated on the basis of a survey, in accordance with the controls of Sect. 18 of this manual, of their facilities to determine their capability of providing services of the quality required and to demonstrate this quality prior to award of a contract, except as in (6) below.

(5) Specific check-lists are drawn up by the QLT Manager, when applicable, for verifying adequacy of Suppliers quality assurance program to meet Code and ANN requirements.

The Supplier shall document his quality assurance or quality system program in a Quality Assurance/Quality System Manual to be submitted to QLT for review and acceptance.

Non compliances detected during the survey are documented on the “Evaluation Report” (Exhibit 7.1) as requirements for corrective actions and they shall be closed before placing the purchase order.

Surveys on Suppliers activities include, but are not limited to the following, as applicable:

a) Preliminary quality meetings for establishing an understanding between ANN and Supplier regarding provision and specification of procurement documents;

b) Review and approval of Supplier technical, processes and quality documents;

c) On-site Audits;

(6) For subcontracting RPE, qualification shall be the responsibility of the QLT Manager, as outlined in Sect. 3.9 of this manual.
7.5 **Supplier audits and evaluation**

(1) Certified Suppliers holding a valid ASME Certificate shall be required to send a copy of their Certificate(s) upon renewal, during the interval in which Item, materials or services are supplied.

(2) ASSS shall be subject to triennial audits covering applicable elements of the supplier’s established quality system that is consistent with the requirements of the NCA 3800 supplemented by annual evaluations of the supplier’s quality system, including a review of the history of conditions adverse to quality, nonconformances, and corrective actions documented by QLT Manager.

(3) QLT Manager may at his discretion replaces the annual evaluation by annual Audit

(4) Audits shall be conducted in accordance with Sect. 18 of this manual.

7.6 **Control of supplier generated documents**

(1) The PM receives documents from Suppliers for information or approval, and provides for their processing following the surveillance requirements defined by ANN on the procurement documents.

(2) Type and scope of verification shall be indicated in the “Design Verification Check-List” form (likewise Sect. 3.6 (4) ), of this manual, by the applicable Technical Unit Managers. Verification can be extended to the Customer, if required.

(3) The applicable Technical Unit Managers are responsible for distribution and filing of Suppliers Documents through the GTD.

(4) Supplier generated documents shall be available to the Authorized Nuclear Inspector (ANI).

7.7 **Control of Changes on Items and Services**

ANN shall assure that changes on technical procurement documents are controlled and documented in accordance with Sect. 3.7 of this manual.

7.8 **Acceptance of Materials, Items and Services**

The methods adopted by ANN for certifying the acceptance of materials and Items from a Supplier are: Source Inspections, CMTR, CoC, Certificate of Conformance, Code Data Report or Partial Data Report, as applicable.
(1) Acceptance of material/Item and services shall be based on the inspection by the Quality Inspector that the material/Item being furnished complies with the procurement requirements.

(2) Safety related Items shall be inspected by the Quality Inspector at the Suppliers' workshops in compliance with the Procurement documents requirements.

(3) Method of acceptance shall be specified in procurement documents (e.g. PTS).

(4) Result of the inspections of material/services received are filed in the QLT file by QLT Manager and are used for supplier evaluation.

7.8.1 Source Inspection

(1) When source inspection is required by ANN procurement documents, source inspection shall be performed by the Quality Inspector at intervals consistent with importance and complexity of the Item or service. Source inspection requirements are established by QLT complying with contractual requirements and job planning.

(2) In more detail, inspection points are defined by Suppliers' Quality Control Plans (QCP) which specify main fabrication and control phases, their connection and reference to the applicable documents. Moreover on the QCP the records issued for each phase, as required, are listed.

7.8.2 Inspection Points

(1) Quality Inspector notifies the Supplier about his designated inspection points.

(2) Inspection points are indicated in the Supplier's QCP and are identified as follows:
   a) Hold point
      Work cannot be carried out without participation of the ANN Quality Inspector who designated the hold point.
   b) Notification point
      ANN requires to be notified before proceeding, work can proceed without participation only in case of waiver by the appointed Quality Inspector, providing that notification is performed within the contractual terms.

(3) Notification is performed by Supplier for each order in writing.

(4) QLT can also perform unannounced inspections in order to verify specific aspects of the supply.

(5) Quality inspection activities are documented by one or more of the
following methods:

a) Signature on inspection/test/examination records issued by Suppliers;

b) Signature of QCP phases which have been witnessed;

c) Issue of the “Inspection Report” (Exhibit 7.2);

(6) Following final inspection acceptance of materials and Items shall be documented by the Quality Inspector using the “Inspection Report” after review of the CMTR performed by filling the CMTR Verification Check-List (Exhibit 6.7) and the “job final documentation package”.

7.8.3 Certificate of Conformance

When a Certificate of Conformance is used, the following minimum criteria must be met:

(1) Certificate shall identify the purchased material or equipment, such as by purchase order number.

(2) Certificate shall identify procurement requirements met by purchased material or equipment, such as codes, standards and other specifications. This may be accomplished by including a list of specific requirements or by providing a copy of purchase order and procurement specifications or drawings, together with a suitable certificate. Procurement requirements identified shall include any approved change, waiver, or deviation applicable to material or equipment.

(3) Certificate shall identify any procurement requirements that have not been met, together with justifications and means for resolving non-conformances.

(4) Certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose responsibilities and position are described in ANN’s or Supplier’s quality assurance program.

(5) Certification system, including procedures to be followed issuing a certificate and administrative procedures for review and approval of certificates, shall be described in Supplier’s Quality Assurance Program.

(6) Means shall be provided to verify validity of Supplier’s certificates and effectiveness of certification system, such as during performance of audits of Supplier or independent inspection or test of Items. Such verification shall be conducted by QLT at intervals commensurate with Supplier’s past quality performance.

7.8.4 CMTR and Certificate of Compliance

CMTR and CoC contents shall be as stated in Sect. 6.5 of this manual.

7.8.5 Data Report and Partial Data Report

Stamped Items are certified on the applicable Code Data Report or Partial Data
Report providing that all Code requirements are met (see § 6.6 and Sect.10) of this manual.

7.8.6 Acceptance of Services only

Manager of the Unit requesting Service shall accept the service procured such as: design, mechanical/chemical laboratory, RPE activity, NDE, calibration, auditing and consulting services by any or all of the following:

1. technical verification of data produced;
2. surveillance activity;
3. audit reports by auditors;
4. review of objective evidence for conformance to procurement documents requirements such as certification, design reports, etc.;
5. records of qualification of personnel;
6. procedures.

7.9 Source Verification

Source verification may be used and shall include monitoring, witnessing or observing of selected activities such:

a) Traceability control
b) Control of changes and nonconformance
c) Review
d) Review of Suppliers’ CMTR, CoC and Certificates of Conformance;
e) Participation at mandatory hold points;
f) Final tests;
g) Verifications of QA records;
h) Final inspection.

7.10 Authorization for Shipping

Authorization for shipping of accepted Items shall be released by the PM on the basis of shipping approval indicated by the Quality Inspector on the “Inspection Report”.

7.11 Control of Suppliers’ Non Conformances

Suppliers’ Non Conformances are managed as indicated in Sect. 15 of this manual.

7.12 Applicable Procedures

N-P-ANN-E001 Procurement Process
**EXHIBIT 7.1**

La Ditta è stata indicata IDONEA a fornire. The Company is accepted for the following kind of supplier:

### Reserve:

La riserva di manodopera considera risorse in caso di ordine e non risorse propri del luogo della manifattura o di riferimento.

The above reserves are to be considered mandatory for purchase order and shall be solved before the beginning of related activities.

### Notes:

**Exhibits with supporting documents:**

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<thead>
<tr>
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<tr>
<td>Manuale di Q. di Ditta</td>
<td>Document Type</td>
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<td>Company Q.A. Manual</td>
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**EXHIBIT 7.2**
8. IDENTIFICATION AND CONTROL OF ITEMS

8.1 Scope

(1) This section describes the measures to be taken for identification, traceability and control of Items, in order to ensure their proper use and installation.

(2) ANN will be using Suppliers with their own system for identification and control of Items. The PM will assure, by review of the Suppliers’ documents (see § 5.5) that their system is complete and ties up with the unique identification assigned by ANN for the nameplate and MDR.

(3) In order to satisfy the above, ANN performs the following activities:
   a) issuance of technical documents related to identification, traceability and control of Items;
   b) specification of requirements for identification, traceability and control of Items to Suppliers;
   c) verification of Suppliers’ documents describing identification and traceability during fabrication;
   d) verification of systems for identification, traceability and control of Items implemented by Suppliers in order to assess their compliance with the applicable requirements;
   e) ANN requirements for identification and control of materials and fabricated Items shall be specified in procurement documents as per Sect. 4 of this manual.

8.2 Identification and Traceability

Technical Units Managers prepare and issue the following documents giving requirements for identification, traceability and control of Items:

(1) Purchase Documents indicating identification numbers/serial numbers of Items to be supplied.

(2) Design documents, indicating identification and control methods, including traceability and marking transfer requirements, as applicable.

(3) Quality requirements, defining means for ensuring Supplier’s compliance with requirements for identification and control.
8.3 IMPLEMENTATION

(1) Suppliers are required to establish and document, through adequate written instructions or procedures, a system for ensuring compliance of Items supplied with related documentation.

(2) Physical identification shall be used whenever possible. If physical identification is not possible or not sufficient, other means shall be defined. Identification is guaranteed by physical marking on Items or by documents indicating their traceability criteria. Identification marking and labeling must be unambiguous and permanent and shall not be detrimental to the Items. Identification methods are also applicable to rejected materials that are pendent on final disposition.

(3) Quality Inspector performs surveillance on identification and traceability at the Suppliers.

9. CONTROL OF PROCESSES

9.1 SCOPE

The control of processes is through the interface with approved Suppliers. The only exceptions are activities associated with the final Hydrostatic Testing, inspection, stamping and Code Data Report. This Section describes measures adopted by ANN in order to ensure that processes that affect, control or verify quality are performed under a controlled system.

9.2 ANN PROCESS CONTROL

ANN measures adopted to control processes are identified in process control documents such as Traveler-QCPs (Exhibit 6.5). See § 6.4.

9.3 CONTROL OF SUPPLIERS’ PROCESS

Measures adopted by ANN for control of Suppliers’ and fabricators’ processes are specified in procurement documents for Item and material, as per Sect. 4 of this manual.
10. INSPECTIONS

10.1 SCOPE

(1) This Section describes the measures adopted by ANN in order to ensure adequate and correct implementation of the inspection program for Items and materials.

(2) ANN requirements for inspection of materials and fabricated Items shall be specified in procurement documents as per Sect. 4 of this manual.

10.2 INSPECTION PERSONNEL

Inspections shall be performed by Quality Inspectors qualified according to Sect. 2.7.1 of this manual.

10.3 FINAL INSPECTION OF ITEMS

(1) In order to evaluate compliance of Items completed with the applicable requirements, QLT provides for final inspection prior to shipping.

(2) Final inspection is planned on Traveler-QCPs (Exhibit 6.5), or on the supplier’s QCP.

(3) ANN final inspection includes, as applicable:
   a) verification of compliance with Code, Design specification and ANN requirements;
   b) a review of records concerning results and resolution of non-conformances identified during manufacturing and fabrication activities against the records specified in the procurement documents (e.g. PTS);
   c) verification of records completeness and correctness;
   d) verification of MDR and Partial Data Report and associated documentation and verification of NPT nameplate stamping;
   e) Report of hydrostatic Test witnessed by the Authorized Nuclear Inspector (ANI).

(4) During final inspection, aspects concerning completeness, correct identification, adequacy of packing, correct address verification as required.

(5) Final inspection is carried out and certified by Quality Inspectors signing the related Traveler-QCP and issuing the “Inspection Report” (Exhibit 7.2), and/or the Supplier’s QCP.

(6) Positive result of final inspection enables Quality Inspector to accept...
10.4 Certification Mark with N Designator stamping of NPT-Items procured from Certificate Holders

(1) ANN Quality Inspector shall verify, prior to application of Certification Mark with N Designator, whether the subcontracted Certificate Holder has:
   a) certified the Partial Data Report,
   b) stamped the Item with the Certification Mark with NPT Designator
   c) completed the installation or field assembly with proper certification, as applicable

(2) Sequence for application of Certification Mark with N Designator and completion of Data Report shall be determined by agreement between the ANI and ANN, e.g.:
   a) evidence of Owner review attached to the Design Report,
   b) certification of Data Report by the QLT Manager,
   c) making available Data Report signed by the QLT Manager to ANI including all documentation,
   d) signature of the Data Report by the ANI,
   e) stamping, when authorized and witnessed by the ANI.

(3) Certification Mark stamping shall be performed under direct control of the Quality Inspector.
QLT Manager shall have control and custody of ASME Certification Mark.

(4) ANN can apply the Certification Mark with N designator to components in the field or other location without having the N Certificate of Authorization extended to a field or other location if ANN elects to subcontract the performance of the component pressure test. ANN shall be responsible for supervising, witnessing and accepting the pressure test and assuring that the test is controlled with the Suppliers’ approved program by ANN.

10.5 Stamping and Nameplate

(1) Certification Mark with N Designator stamping of components shall be performed under direct control of the Quality Inspector.

(2) Certification Mark with N Designator stamping of components and Data Report signature shall be coordinated with ANI by a Quality Inspector. Alternatives to application of a stamped nameplate shall be subject to acceptance by ANI prior to implementation.

(3) Certificate Mark with N Designator stamping shall comply with one of the
two figures below as applicable:

If MDR is registered with the National Board (NB), the NB stamp and registration number shall be applied.
10.6 Control of National Board Numbers and Submittal of Data Report to the National Board of Boiler and Pressure Vessel Inspectors

(1) Registration of Data Report with the National Board of Boiler and Pressure Vessel Inspectors shall be performed when required by the applicable Jurisdiction or by the Customer in the contract or when considered desirable by ANN, at the following address:

The NATIONAL BOARD of BOILER and PRESSURE VESSEL INSPECTORS
1055 CRUPPER AVENUE
COLUMBUS, OHIO 43229-1183
USA

(2) National Board number starting with 1 shall be assigned without prefixes or suffixes, skips or gaps of unused numbers or duplication of numbers by the Quality Inspector.

(3) Quality Inspector shall maintain the National Board Numbers Log (Exhibit 10.1) with date of issue, type of Item and class, Manufacturer’s serial number and location, date of Data Report submittal to National Board.

(4) The original of the Data Report shall be submitted by the Project Manager to the National Board of Boiler and Pressure Vessel Inspectors not later than 30 days after Certification Mark with N Designator stamping. Other Copies as required will be distributed to the Owner, the Customer and the ANI.
<table>
<thead>
<tr>
<th>NATIONAL BOARD NUMBERS LOG</th>
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<tr>
<td>ITEM</td>
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</table>

**EXHIBIT 10.1**

*Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use.*
11. TEST CONTROL

11.1 Scope

(1) This section describes the measures that ANN imposes on Supplier for preparation and implementation of tests performed by the Supplier and witnessed by Quality Inspector.

(2) Test requirements and acceptance criteria for testing of Code Items fabricated by the Supplier are specified in Procurement documents, see Sect. 4 of this manual.

(3) These requirements shall ensure that tests:
   a) are planned and adequately defined by documents which provide test requirements and acceptance criteria;
   b) are kept under control [see Sect. 10.3 of this manual];
   c) are adequately reported;
   d) results are adequately evaluated.

11.2 Final Hydrostatic Test

(1) The final hydrostatic test shall be planned and witnessed by a Quality Inspector as indicated on the Traveler-QCPs, and Supplier’s QCP.

(2) Final hydrostatic test of subcontracted Items shall be performed according to a test procedure, in compliance with NX-6200, prepared by the Supplier and approved by the applicable Technical Unit Manager.

(3) This procedure shall specify:
   a) applicable documents
   b) range and accuracy of the pressure gauge to be used
   c) test medium
   d) test temperature
   e) calibration of pressure gauge and location
   f) qualification of test personnel
   g) gradient for pressure increase, decrease
   h) duration
   i) documentation
   i) position of the Item, vent, drain and clean.

"Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against the electronic version of the procedure prior to use"
11.3 Test Records

(1) Final hydrostatic test report shall, as a minimum, identify procedure requirements, as follows:
   a) Item tested
   b) date of test
   c) tester or data recorder
   d) type of observation
   e) results and acceptability
   f) action taken in connection with any deviations occurred
   g) person evaluating test results
   h) identification of calibrated gauges used.

(2) Test record shall be signed by qualified Supplier inspectors and reviewed and accepted by the qualified Quality Inspector who witnessed the hydrostatic test.

(3) Authorized Nuclear Inspector shall witness final hydrostatic test.

12. Control of Test and Measuring Equipment

12.1 Scope

(1) This section describes ANN requirements imposed on Supplier for ensuring that tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated and adjusted at specified intervals to maintain accuracy within specified limits. ANN will specify in procurement documents the Code requirements the Supplier must comply with (e.g. NCA-3858.2, NCA-4134.12).

(2) Measuring and test equipment must:
   a) have suitable characteristics for the intended use;
   b) be identified and controlled according to specific procedures and instructions;
   c) be calibrated, adjusted and maintained at specified intervals with traceability to national standards;
   d) the standard use for calibration shall have an accuracy at least four time greater than the equipment to be calibrated
   e) be provided with documentation certifying their correct calibration including “as found” and “as left”.

(3) Requirements for control of test and measuring equipment for inspection, examination and test shall be supervised, witnessed and accepted by ANN’s
personnel, assuring compliance with Suppliers accepted program.

12.2 **Pressure Test Gages**

Pressure test gages used in Final Hydrostatic Test shall be in compliance with NX-6400 requirements.

13. **Handling, Storage and Shipping**

13.1 **Scope**

This Section describes the methods imposed on Suppliers for handling, storage and shipping of Items or materials, in order to prevent damage or deterioration. ANN carries out the following activities:

1. PRZ specifies the Customer and Code requirements (e.g. NCA-4134.13) the Supplier must comply with (for protection, cleaning, handling, packaging, shipping, storage and preservation, marking, labeling, local regulation, safety requirement) in procurement documents;

2. PRZ reviews and approves the procedures issued by Suppliers concerning the above activities, including identification of special handling of such equipment and the training of operators using such equipment.

3. **Quality Inspector** verifies the activities related to cleaning, handling, packaging and shipping of Items at Suppliers’ workshop, during manufacturing/fabrication and before authorization for shipment.

13.2 **Control of the Activities**

13.2.1 **Protection Requirements**

The applicable Technical Units Manager, as applicable, is responsible for defining the protection requirements to prevent damage, deterioration or contamination of Items during handling, storage, and shipping.

13.2.2 **Control before Shipping**

When specified by the applicable Traveler - QCP, Quality Inspector verifies whether cleanliness, packaging and preparation for shipping comply with requirements.

13.2.3 **Shipment of Material from CMO**

When ANN procures materials they shall be delivered directly to the party where the material would be needed (ANN’s customers for components to be certified by
ANN). Release for delivery shall be under the following conditions:

1) Material procurement documents will require the CMO to provide a QCP to ANN applicable to the order. The Quality Inspector will establish a hold point on the shipping operation (See also 10.3)

2) The Quality Inspector will as a minimum review and accept the CMO’s CMTR and evidence of physical marking prior to releasing the material to the party

3) An on-site inspection could be made that would cover:
   a. The condition and quantity of the material
   b. Material marking
   c. Certification (CMTR), and Packing and handling requirements and an Inspection Report (Exhibit 7.2) would be made

4) The Quality Inspector will issue a formal release to ship the material from the CMO

5) The Quality Inspector will issue a CMTR or CoC with their NCA-3862.2 Quality System Program (see 6.5). The CMTR or CoC will include a statement that no inspection of the material has been performed by ANN (if that is in fact the case) and that all nonconforming conditions must be reported to the ANN for resolution.
14. STATUS OF INSPECTIONS AND TESTS

14.1 Scope

This section describes the criteria adopted by ANN and imposed on Suppliers to be sure that measures are defined and correctly implemented for identifying status of inspections and tests performed on Items/services.

1. The purpose of these measures is to ensure, by adequate methods, that Items are not installed or used without having satisfactorily passed the required inspections and tests.

2. Status of inspections and tests performed by Quality Inspectors of supplied stamped Items is documented on Supplier’s Quality Control Plan and ANN’s Traveler – QCP, if applicable (see § 6.4).

3. ANN requirements for inspection and test status shall be specified in the procurement documents.

14.2 Criteria and Methods

In order to satisfy the above requirements Technical Units or QLT, as applicable, shall specify:

1. Items/materials inspections and tests status must be clearly indicated on Item/material/services or related documents in order to prevent inadvertent use.
   Methods to be adopted include use of stamps, tags, worksheets, labels or other means for ensuring a clear and durable identification.

2. In particular, these systems are also adopted for identifying non-conforming Items (see Sect. 15) of this manual.

3. Application and removal of these identifications can be performed only by the personnel authorized for such activity.

14.3 Quality Surveillance by QLT

During Inspections, Surveys and Audits at Suppliers’ Organization, QLT personnel shall assess if status of inspections and tests is adequately indicated and related to Item and material.
15. CONTROL OF NON CONFORMING ITEMS

15.1 Scope

(1) This section describes the measures adopted by ANN for management of non-conforming Items, materials and services to prevent inadvertent or unauthorized use.

15.2 ANN Responsibility

ANN is responsible for:

a) definition of the requirements applicable to non-conforming Items and materials and services control requirements (e.g. 10 CFR PART 21 or other);

b) evaluation of nonconformance notified by Suppliers in accordance with requirements of 10 CFR PART 21, if applicable or other Customer requirements;

c) inspections, surveys and audits at Suppliers’ organizations in order to assess correct management of non-conforming Items and materials, as applicable;

d) registration of non-conformances detected by QLT and the Supplier on the GTD electronic data base system. From this system it is possible to produce for each order a Non Conformance Log (Exhibit 15.1)

e) follow up of implementation of the corrective actions originated by non conformances.

f) Reporting deviation/non conformance to the Customer or as per 10 CFR PART 21 requirements, if required.

15.3 Identification of Non Conforming Items

(1) A nonconformance is a deficiency in a characteristic, documentation, or procedure that renders an Item or activity unacceptable or indeterminate.

(2) If personnel of ANN finds a non-conforming Item, he shall initiate a Non-Conformance Report (NCR) (e.g. Exhibit 15.2), detailing the nonconformance and related disposition.

Non conforming Items and materials shall be duly identified to indicate clearly and adequately their status.

(3) In order to prevent inadvertent or unauthorized use of non-conforming Items or materials, they shall be segregated, when practical.

(4) NCR shall be forwarded to QLT Manager for registration on the GTD system and further processing.
15.4 Disposition of Nonconformance and Related Documents

(1) Personnel involved in disposition of nonconformance shall have the adequate understanding of the requirements and access to pertinent background information and demonstrated competence in the specific area they are evaluating.

(2) Suppliers are required to follow their procedure for nonconformance management and also in addition the ANN requirements for those non-conformances subjected to ANN approval.

(3) Procurement documents specify that non-conformances of Supplier are subject to ANN approval.

(4) Suppliers' and ANN's non-conformances are processed as follows:

   a) Suppliers' NCR shall be issued in accordance with their quality procedures. Quality Inspector verifies completeness of NCR and passes the information to QLT.

   b) ANN NCR shall be issued by Quality Inspector.

   c) The disposition, such as: use-as-is, reject, repair/ rework, of nonconforming Items shall be identified and documented on the NCR. The Technical Unit Manager shall be responsible for the written technical justification that the repair, or use-as-is disposition complies with the Code. Non-conformances to design requirements dispositioned as use-as-is or repair shall be subject to design control reviews commensurate with those applied to the original design. The as-built records shall reflect the NCR number allowing the traceability to the deviation.

   Use-as-is is a disposition assigned to an Item previously identified as nonconforming after reconciling Design Output Documents with the Item's as-built condition and verifying that applicable requirements of the Code, Customer requirements and this QAP have been met.

   Repair/Rework are processes for physically restoring a nonconformance to a condition such that an Item complies with Code requirements.

   d) The ANI shall be kept fully informed about ANN’s NCR’s.

   e) Project Manager reviews non-conformances when they are to be submitted to Customer’s approval.

   f) Quality Inspector shall sign nonconformance for final verification.

(5) Quality Inspector must verify correct disposition of nonconformance originated by ANN according to this Quality Assurance Program, Code requirements and Customer requirements.

Correct disposition of non-conformances originated by Suppliers shall be assessed by Quality Inspector to verify implementation and close out.
Repai/seed/ed Itens are re-examined in accordance with applicable procedures and original acceptance criteria in compliance with the Code. The impact of the disposition on the Traveler/QCP is assessed and documented on NCR (Exhibit 15.2).

(6) QLT Manager is authorized to stop fabrication until the dispositions of nonconformance are approved as included in the contract with the Supplier.

(7) Documents concerning non-conformances and their disposition are recorded and attached to related Quality Control Plan, by Supplier, so that all NCR are an integral part of Final Documentation Package.

(8) All nonconformance documentation is made available by the QLT Manager to the ANI.

(9) For each NCR the QLT Manager shall indicate in box 7 (Exhibit 15.2) the extent to which this Non Conformance shall be subject to CAR as per Section 16 of this manual.

15.5 **Applicable Procedures**

N-P-ANN-G007 Reporting of Defects and N/C as per 10 CFR PART 21 requirements
EXHIBIT 15.1
## EXHIBIT 15.2

### Non-conformance description - Description de la non-conformité

| Cliente | Contratto | Commissa

| Impianto/Progetto | Oggetto | Fornitore | Ordine | Perfermatore | Livello di Qualità/QCP |

| Nome | Firma | Data | Specifica/Disegno | Potential 10 CFR 21 | Si | No |

| Use As Is | Repair | Reject | Other | Approvazione Cliente | Customer's Approval/Approbazione du Client |

| Nome | Firma | Data | Approvato da |

| Ente/depot | Project Manager | Ente/depot | QLT |

| Data/valore | Data/valore | Data/valore | Data/valore |

| FIRMA/Signature | FIRMA/Signature | FIRMA/Signature | FIRMA/Signature |

### Allegati

| Allegato | Verifica della Risoluzione | Accettazione ANI |

| QLT: Data/valore | Data/valore | Data/valore |

### Azioni correttive

| Azioni correttive |

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16. CORRECTIVE ACTIONS

16.1 SCOPE

This section describes methods adopted by ANN to identify and document conditions adverse to quality in order to correct such conditions, to eliminate causes and to preclude recurrence with appropriate and documented corrective actions.

16.2 RESPONSIBILITY

16.2.1 The QLT Manager is responsible for:

1. Identifying all conditions adverse to quality, as well as deficiencies in the implementation of the Quality Assurance Program (QAP) by audits, inspections, tests and non-conformance reports;

2. Documenting such conditions using the Corrective Action Request (CAR) forms (Exhibit 16.1.a and 16.1.b); other form required by the customer shall include the minimum contents of the Exhibit 16.2.1b);

3. Reporting the CARs to the appropriate level of management in order to take adequate corrective or preventive actions and required follow up; receipt with a propose corrective action shall be acknowledged within one month. Following receipt of the returned CAR, QLT Manager shall accept the proposed corrective action This is documented on the CAR;

   The adequacy of proposed corrective measures, as a result of audits and surveys, shall be evaluated, as scheduled, and accepted by the Lead Auditor, who also ascertains, through follow-up, their correct implementation;

   The agreed time for completion is recorded on the Corrective Action Request form;

   Submit the CARs, related to Customer audit of ANN QAP and related to Contract requirements, to related Customer representatives for evaluation, approval and follow-up;

4. Reviewing and evaluating the significant conditions adverse to quality to determine the existence of trends;

5. Supporting the ANN Units to identify causes of such conditions;

6. Performing follow up reviews to determine, as scheduled, the corrective actions implementation and their effectiveness;

7. Performing audits, both internal and at Suppliers, to assess the correct
management of corrective actions process and to determine whether actions taken have been and continue to be effective;

(8) providing for the necessary modifications to the QAP procedures as result of corrective or preventive actions;

(9) registration of CARs and related follow up by QLT Manager in the List of Corrective Action Requests (Exhibit 16.2).

16.2.2 ANN Units

Involved ANN Unit Manager(s) is/are responsible for:

(1) identifying causes of deficiencies, such as those resulting from design reviews, individual observations and adverse trends;

(2) the determination and the implementation of the adequate corrective actions;

(3) notifying QLT regarding the completion of the corrective actions requested within the dead line.

16.2.3 Suppliers

Procurement documents shall require the Suppliers to comply with the Code, ANN requirements through procedures included in their own quality assurance program in order to determine causes of conditions adverse to quality and implement corrective actions taking also into account of non conformance type and relevance and their possible repetition to prevent recurrence.

Suppliers are required to submit their corrective actions, related to both services and Items, to QLT who is responsible to follow-up the completion of the corrective actions requested within the dead line.

16.3 APPLICABLE PROCEDURES

- N-P-ANN-G005 Corrective and Preventive Actions
### EXHIBIT 16.1-a

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**Da compilare a cura del Responsabile dell’Azione** / by the Action Responsible

1) Analisi delle cause/Root cause analysis

2) Valutazione dell’impatto su prodotti, attività o documenti/Impact Assessment on related items, activities or documents

3) Azioni da intraprendere per la correzione/Actions to take for the correct

4) Azioni da intraprendere per precludere la ricorrenza/Actions to preclude the recurrence

**EXHIBIT 16.1-b**

5) Azione correttiva ad interim (se applicabile)/Interim corrective action (if applicable)

6) Data prevista per il completamento dell’azione identificata/Due date for completion of action identified

7) La deficienza potrebbe creare dei pericoli per la sicurezza nucleare di un componente di base consegnato? (Se sì, è richiesto di valutare ulteriormente questa carenza: ad esempio così come richiesto dalla procedura N-P-ANN-0007 in accordo al 10CFR PART21)! Could the deficiency create a substantial nuclear safety hazard in a delivery basic components? (If yes, it is required to further evaluate this deficiency: for example as required the procedure N-P-ANN-0007 in accordance with 10CFR PART21)?

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EXHIBIT 16.2
17. QUALITY ASSURANCE RECORDS

17.1 Scope

(1) This section describes the measures to be taken to ensure issue, control, storage, retrieval of documentation for Items supplied by ANN. This documentation is called “Quality Assurance (QA) Documentation”.

(2) For this purpose, ANN performs the following activities:
   a) establishment and implementation of a system for identification, preparation, collection and storage/retrieval of QA Documents;
   b) specification issued to Suppliers of requirements for QA Documents.

17.2 QA Documentation

(1) ANN has established:
   a) responsibilities of Unit Managers involved with QA documentation management and storage;
   b) index for documents/records collection and filing (see Sect. 6.2 (2) and 6.3 (5) of this manual). Records shall be indexed and all records indexed shall be made available to the ANI and the Owner;
   c) methods for documents identification and correlation with Items;
   d) QA documentation storage periods.

(2) All documents, unless otherwise specified by the Code, laws or contracts, are stored including the latest revision for at least ten years after expiration of contract warranty or completion of Data Report.

(3) Documentation and its registration are available to the Customer and the ANI.

(4) Preventive actions shall be applied by all personnel involved in this Quality Assurance Program (QAP) that QA records in their possession are protected against losses and damage until they are filed in the archive.

(5) Control of Access is described in procedure N-P-ANN-H010.

17.2.1 Technical Archive

(1) Technical documents are checked by the delegate for the Technical Archive for compliance with the requirements of the procedure N-P-ANN-H010. They are stored in the Technical Archive, with all precautions for protecting them against accidental deterioration (fire, flood, moisture, infestations, etc.).

(2) In the Technical Archive, each document is subjected to a double filing in
order to guarantee its preservation; originals of current revisions are stored in the current file, while microfilm copies, hard copies or electronic files are stored in the "security" file.

(3) Technical Archive stores copies of all revisions, even if obsolete, in order to assess documents history. In this file organization documents issued by ANN, license documents, technical documents issued by Customers and Suppliers are stored.

(4) Technical Archive stores all documents other than those mentioned in paragraphs 17.2.2 through 17.2.4 below and also stores the original of Management and Organization Documents, QA records related to ANN design verifications and Manufacturer records (Suppliers final job documentation package) (See 17.4).

17.2.2 “QLT” File

Documents classified as “non permanent” such as Suppliers evaluation, tests/acceptance, Audits, and meetings issued by QLT, as well as Non-Conformance Reports, Corrective Actions Requests, Personnel’s Qualification Records, Inspection Reports, Final Test/Acceptance Reports, ANN Quality Status Reports and Qualifications of Computer Programs are stored in the “QLT” File at QLT Unit.

17.2.3 AEN File

Complete purchase order documentation, classified as “non permanent”, is stored at AEN Purchasing Unit.

17.2.4 “HRS” File

Documents classified as “non permanent” such as documented training are stored in the “HRS” File at HRS Unit.

17.3 CONTROL OF THE DOCUMENTATION

(1) Documents and their correction shall be considered valid records only if signed and dated by personnel authorized for their issue as per Sect. 3, 4, 6, 7 of this manual.

(2) Technical documents and data are registered by the relevant Manager who establishes the Distribution List (See Sect. 6) of this manual. The delegate for the Technical Archive acknowledges receipt, registers date of filing using the Technical Documents Management (GTD) and provides distribution and storage.

(3) Retrieval for information of paper documentation is controlled by the form (Exhibit 17.1). Microfilms are accessible in the Technical Archive under surveillance of the delegate for the Technical Archive.
(4) ANN Suppliers are required to establish a system for document management in order to demonstrate their quality related to supply and pertaining activities.

(5) Requirements for documents preparation, collection, storage and delivery to ANN will be indicated in the procurement documents.

(6) Supplier records shall be accessible to ANN or Customer and ANI. They shall not be disposed until applicable requirements of Code and procurement documents are met.

(7) ANN shall be responsible for all lifetime and non-permanent QA records while in their possession. The list of documents forms the basis of the Records Index.

17.3.1 Lifetime QA Records

Lifetime QA records shall include, as applicable, at least the following:

1. Index of the lifetime records. Indexing system shall be defined in the procedure N-P-ANN-H003;
2. Code Data Reports
3. Design Specification, given by the Owner through the Customer and certified by RPE;
4. Design output documents including Design Report;
5. Certified Material Test Report (CMTR) and documentation used by manufactures providing traceability to location used;
6. Overpressure Protection Report
7. Copy of all filled in and approved Traveler - QCP including:
   a) heat treatment records in the form of charts or certified summaries,
   b) final hydrostatic test reports,
   c) final NDE reports,
   d) complete set of final radiographs, specified by Owner for section XI application,
   e) weld procedures,
   f) repair records;
8. Complete set of welding procedure specifications;
9. Nonconformance reports that affect the above records shall be incorporated in records;
10. Qualification certificates (Exhibit 3.2) pertaining to computer programs verification/validation;

Lifetime records shall be preserved in the Technical Archive for the period required by contractual documents.
17.3.2 Non Permanent QA Records

Non permanent Quality Assurance records shall be indexed and include at least the following:

- QM
- Design procurement and Organization Procedures
- Installation and NDE procedures
- Personnel qualification records
- Purchase orders (at AEN)
- Audit and survey reports
- Final radiographs not covered in Table NCA 4134.17-1, Record 15
- Calibration records
- Process sheets, travelers, or check lists
- Joint-welder identification records when such records are used in lieu of physical marking of welds

They are filed whether in “QLT” file, AEN file or Technical Archive and their retention period shall be a minimum of 10 years after revision or being invalidated or at the completion of the Data Report. Purchaser record (Purchase orders and all procurement records) retention period shall be a minimum of 15 years. Nonconformance reports, which affect those records listed and are not incorporated into the record, shall be retained for the retention period applicable to the record the nonconformance report affects.

17.3.3 Material Procurement

These shall include, as minimum:

- PO
- Traveler-QCP/ Customer QCP
- Release notice
- Full copy of CMTR

17.4 Final Job Documentation Package

Upon completion of a job, the entire file of lifetime records contained in the Final Job Documentation Package shall be submitted to the Customer with transmittal letter by the Project Manager.

17.5 Applicable Procedures

N-P-ANN-H003 Control of Records
N-P-ANN-H010 Technical Documents Archive
**EXHIBIT 17.1**

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(*) E' emessa la compilazione di una richiesta unica solo in caso di prelievo di documenti con numerazione consecutiva.
The filling up of a single request is allowed only for retrieval of documents with consecutive identification number.

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18. AUDITS

18.1 Scope

This Section describes the methods adopted by ANN for establishing and implementing the Audit program to assess adequacy, effectiveness and implementation of the Quality Assurance Program (QAP) and surveys and audits of Vendors and Suppliers.

18.2 Planning of Audits and Surveys

1. Internal and external Audit or Surveys are planned annually by the QLT Manager using the Audit Schedule. He shall periodically review and revise, as necessary, the Audit Schedule whether it provides an adequate coverage to all Code activities and the status of audits according to the QAP.

2. For internal Audits, the QLT Manager specifies frequencies, depending on extent, complexity and development of each project, however assuring an annual interval for all areas involved in the QAP.

3. External audits and surveys are planned, and introduced in Audit Schedule, and controlled as per § 7.3

4. Unannounced Audits may be performed.

5. The ANN CEO shall appoint the Lead Auditor, who shall audit QLT activities.

6. Lead Auditors selected shall be independent from any direct responsibility for performance and supervision of the activities being audited. This also applies to the selection of auditors.

18.3 Preparation of Surveys and Audits

1. The QLT Manager or ANN CEO selects the Lead Auditor and the Auditors to conduct audits who do not have direct responsibility for performing the activities being audited.

2. Qualification of Audit Personnel shall comply with Sect. 2.7.2 of this manual.

   Lead Auditor shall review the qualification and capability and instruct the Audit Team members about the scope of the Audit.

3. Personnel belonging to other ANN Units may participate as observer to external Audits and Surveys.

4. Lead Auditor, assisted by the other Team members, prepares the Audit
Plan, which defines the following Items:

a) audit scope and extent
b) schedule
c) areas and activities to be audited and involved Units to be notified
d) applicable documents and requirements including revisions
e) audit personnel
f) procedure or checklist based on Supplier Quality System, Manual/Procedures.

(5) The Lead Auditor is responsible for Team instruction, Audit organization and evaluation of results as well as for establishing and maintaining contacts with the Units to be audited.

(6) The Lead Auditor sends communication about the content of the Audit to Units to be audited, not less than 5 calendar days before the Audit.

(7) If external or subcontracted Auditors are utilized, the QLT Manager shall review auditors qualifications for compliance to paragraph 2.7.2 and to Code. They shall receive training about ANN’s QAP. The acceptable auditor(s) shall be listed on the Evaluated Suppliers List. The qualification records shall be maintained by the QLT.

18.4 PERFORMANCE OF SURVEY AND AUDITS

Audits are conducted by the Lead Auditor on the basis of the Audit Plan and written procedure and Check List. The Check-list may consist of marked-up a procedures.

Their main purpose is the evaluation of the following aspects of organizations audited:

(1) availability of QA requirements (manual/procedures used by the Unit to be audited);
(2) Quality Assurance general knowledge at appropriate levels;
(3) compliance of the elements selected for the audits with procedures and applicable requirements for effective implementation of the QAP;
(4) adequacy, actuality, effectiveness of implemented QAP;
(5) objective evidence of documents audited shall be documented.

Conditions requiring prompt corrective action shall be reported immediately to the management of the audited organization.

18.5 AUDIT REPORT

(1) The Lead Auditor, assisted by the other Team members, prepares and signs the Audit report (Exhibit 18.1). The Audit report shall include the
following information, as appropriate:
a) description of the audit scope,
b) identification of the auditors,
c) identification of persons contacted during audit activities,
d) summary of audit results, including a statement on the effectiveness of
   the QAP elements which are audited,
e) description of each audit finding in sufficient detail to enable corrective
   action to be taken by the audited organization or units.

Audit report shall be distributed to the Units audited and to the ANN CEO.

(2) Corrective Actions required become an integral part of the Audit Report.

18.6 Corrective Actions

Corrective Actions Requests, as a result of Audit, are controlled as per Sect.16
of this manual.

18.7 Recommendations and Observations

If specified by the Audit objectives, recommendations for improvements should
be presented. It is be emphasized that recommendations are not binding. ANN
examines recommendation in the subsequent Audit on evaluated activity.

18.8 Audit Documentation

(1) Documents concerning Audit activities are collected and stored by QLT
   and include:
   a) Audit Schedule and Audit Plan;
   b) Audit Report with complete Check-list and Corrective Actions Requests,
      if any;
   c) Written replies to Corrective Actions Requests about actions to be
      performed including the assessment of their correct implementation by
      Lead Auditor.

(2) The above documentation shall be made available to the Authorized
    Nuclear Inspector (ANI).

18.9 Applicable Procedures

- N-P-ANN-G008 Audits
Exhibit 18.1

Attention: this print-out is an uncontrolled copy and may not be the current revision. It is necessary to verify this printout against electronic version of the procedure prior to use.
19. AUTHORIZED INSPECTION AGENCY

19.1 Scope

(1) This Section describes relationship and interfaces between ANN and the ASME Accredited Authorized Inspection Agency (AIA) for all activities required by the Code.

19.2 Authorized Inspection Agency (AIA)

(1) AIA is an organization that is accredited by ASME for inspection services as required by ASME Section III Subsection NCA.

(2) QLT shall verify AIA certificate of accreditation in accordance with the current ASME QAI-1.

19.2.1 ANN-AIA Interfaces

(1) The QLT Manager shall be the AIA official contact in ANN. He administers, on behalf of ANN CEO, the Inspection Service Agreement between AIA and ANN and administers contact with Authorized Nuclear Inspector Supervisor/Authorized Nuclear Inspector (ANIS/ANI) for Quality Assurance Program activities. The QLT Manager will keep the ANI bound diary.

(2) The original of the Quality Manual is submitted to the ANIS for his acceptance. A controlled copy of the same is given to the ANI for his use and controlled copy is filed with the AIA.

(3) This Quality Manual and related procedures are given to the ANI together with any other document referenced by the Quality Assurance Program (QAP).

(4) If, for any reason, the QAP is revised, it is necessary to inform the ANIS and receive written acceptance before implementing any revision of the Quality Manual.

(5) ANN shall provide for any administrative service and working facility for the ANI, to assist him in his duties during his stay in ANN.

(6) QLT shall keep the ANI informed of the progress of the work and shall notify him in advance when an Item is ready for any inspection point as identified on the Traveler-QCP.

(7) ANN shall provide ANIS/ANI free access to:
   a) any ANN or subcontracted area concerned with the fabrication, test, inspection and examination or supply of nuclear Items constructed in...
accordance with the ASME Code applicable requirements;
b) any ANN or Supplier generated document and any report, record or certificate of Items, which are referenced in this Quality Manual or required by the Code;
c) any other document covering QA activities referenced in this Quality Manual.

(8) The QLT Manager shall assist the ANIS during his audits and the ANI in fulfilling Code activities and his monitoring.

(9) All the above mentioned documents shall be available to the ANI for review and/or acceptance, as applicable.