

**LEUPA**

**Type B(U) Package to Contain Fissile Substances**

# **QUALITY MANAGEMENT PROGRAM FOR THE LEUPA PROJECT**

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## 1 PURPOSE

1. The purpose of this document is to establish the requirements of this Quality Management Program throughout the different stages of the LEUPA project, consisting of: Design, Procurement / Manufacturing and Assembly, Tests and Verification Tests and Design Approval, Issuing Operating and Maintenance Manuals for the "LEUPA" package.
2. This Program is in accordance with the Quality Policy and Quality Objectives set forth by INVAP's Quality Manual No. CDAD-1001-3MSGC-001 and the Nuclear Projects Division Quality Manual No. CDAD-1005-3MEGC-001 and for this specific project, LEUPA, the specific quality and procedure requirements stated in this program shall also apply.

## 2 REFERENCE

- [1] ISO. *Quality Management System. Fundamentals and Vocabulary*. ISO 9000:2000
- [2] ISO. *Quality Management System. Requirements*. ISO 9001:2008.
- [3] ISO. *Quality Management System. Guidelines for Performance Improvements*. ISO 9004:2000.
- [4] ARN. *Standard for the Transport of Radioactive Material*. AR 10.16.1. Rev. 2. Argentina: ARN (Nuclear Regulatory Authority), 2011.
- [5] CDAD-1001-3MSGC-001 INVAP's Quality Manual ("*Manual de Calidad de INVAP*").
- [6] CDAD-1005-3MEGC-001 Nuclear Projects Division Quality Management Manual ("*Manual de Calidad de la Gerencia de Proyectos Nucleares*").

## 3 ABBREVIATIONS

Abbreviation	Description
LEUPA	Low Uranium Enrichment Packaging
NUPD	Nuclear Projects Division
QMP	Quality Management Program

## 4 PLANNING

### 4.1 Quality Management Program – LEUPA Project

#### 4.1.1 General Requirements for the Quality Management Program

1. The purpose of the documented, established, implemented and maintained Quality Management Program (QMP in Spanish) is to ensure that the quality objectives are met in the LEUPA Project, based on INVAP's Quality policy and objectives, which promote the development and continuous improvement of effectiveness and efficiency of its controlled processes, in accordance with the requirements set forth by ISO 9001:2008 standard, which INVAP adheres to. See APPENDIX I, INVAP's certification.
2. The QMP is based on the **plan, do, check, and act** methodology. This cycle of continuous improvement is applied throughout all phases and processes carried out to obtain the LEUPA Project product.
3. The stages involved in the LEUPA project are: Design, Procurement and Manufacturing, Testing and Approval and Verification Tests, Operation and Maintenance Procedures.
4. This QMP is supplementary to the quality policy, the quality and internal operation objectives of the company set forth in INVAP's Quality Manual No. CDAD-1001-3MSGC-

001 and the Nuclear Projects Division Quality Manual (NUPD) No. CDAD-1005-3MEGC-001 and it will be the specific program applicable during the various stages of the LEUPA Project.

## **4.2 Management Responsibility**

### **4.2.1 Project Manager's Duties**

1. The Project Manager, through directives on quality issues, encourages the raising of awareness in accordance with the quality policy, to ensure that it is understood, implemented and maintained throughout the project. The company's work methodology facilitates the raising of awareness on the importance not only of complying with the project requirements, but also the regulatory aspects applicable to the product.
2. The quality policy, objectives and verification of compliance with the QMP established for the project are the most relevant aspects within the duties of the Project Manager, favoring continuous improvement.
3. This commitment is evidenced in periodic reviews carried out by the Project Manager, whereby an established agenda is submitted for consideration, with work issues considered in the Minutes of the Meeting.
4. The Project Manager identifies the needs regarding facilities, equipment and human resources for the development of the applicable tasks, from the preparation of the quoting throughout the development of the project. This ensures that adequate resources are available to plan, manage, perform and verify works.
5. The Project Manager shall see to:
  - a. Increase the effectiveness and efficiency of the project.
  - b. Keep an open policy with clients, suppliers, and institutional relations to encourage lasting relations.
  - c. Aim at carrying out the project in accordance with high technological standards at a national and international level, ensuring, in turn, public safety and preservation of the environment.
  - d. Ensure among the project's work group participants that quality is in keeping with the requirements of the product.
  - e. Share experience, and promote the exchange of information.
  - f. Seek to lower costs without compromising quality.
  - g. Seek to improve experience and expertise through continuous training.

### **4.2.2 Client-Oriented Approach**

1. The Project integrates its clients (in this case the client is internal), suppliers and related institutions to work together, fulfilling its core principles of honesty, respect and trust with the aim of promoting the benefits of the parties.
2. The relationship with the internal client requirements begins by studying the work quoting, followed by a review of the contract to verify if the company's available resources allow to duly and timely comply with the terms agreed.
3. The allocated budget is periodically reviewed so that changes, if any, are recorded in written documents agreed by the parties.

**4.2.3 Quality Policy**

1. The Quality Policy is based on INVAP's quality manuals and the Nuclear Projects Division (NUPD) quality manuals listed above.

**4.2.4 Planning****4.2.4.1 Quality Objectives**

1. The quality objectives established within the framework provided by and consistent with the quality policy are set forth in the abovementioned quality manuals of INVAP and the NUPD.

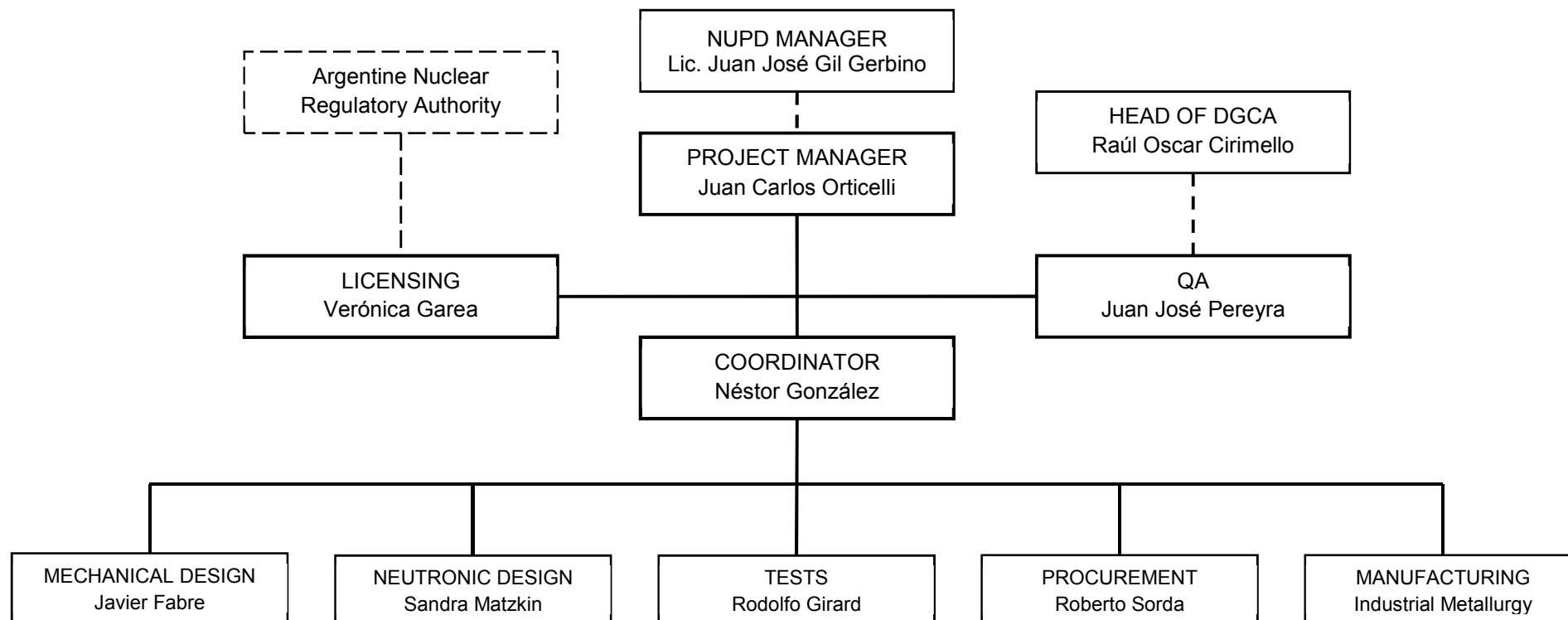
**4.2.4.2 Quality Planning**

1. QMP planning is oriented to compliance with the declared policy and quality objectives as well as the general and specific procedures in this QMP.
2. Changes in the planning and implementation of quality shall not affect the integrity of the system, ensuring the quality of the product.

## 4.2.5 Responsibility, Authority, and Communication

### 4.2.5.1 Responsibility and Authority

#### 4.2.5.1.1 LEUPA Project Organizational Chart





**4.2.5.1.2 Missions and Functions****1. PROJECT MANAGER****a. Mission**

- i. Define, comply with and approve the Project's Quality Policy.
- ii. Carry out the actions and develop the capacity in Engineering, Procurement and Manufacturing, Testing and Validation and Verification Tests, Operation and Maintenance Procedures.

**b. Duties**

- i. Define the product requirements.
- ii. Set Project work lines.
- iii. Evaluate and approve the general action plans.
- iv. Promote updating and improvement of the managed personnel.
- v. Execute the project.
- vi. Take the necessary actions to adapt the capacity to execute the Project to the requirements set forth.
- vii. Establish priorities for works.
- viii. Allocate human and material resources according to the priorities of the Project.
- ix. Approve the QMP.
- x. Make reviews on behalf of the Project Management.

**2. LICENSING****a. Mission**

- i. Generate the necessary conditions to obtain licensing of the LEUPA project by the ARN.

**b. Duties**

- i. Filing all the documentation requested by the ARN.
- ii. Answer all enquiries made by the ARN.

**3. PROJECT'S QUALITY MANAGEMENT****a. Mission**

- i. Define, establish, lead and audit the Project's QMP.

**b. Duties**

- i. Issue the Project's QMP.
- ii. Coordinate and carry out internal audits and report the results to the Project Manager.
- iii. Ensure application of the QMP.
- iv. Verify the implementation of corrective actions arising from audits.

**4. COORDINATOR****a. Mission**

- i. Coordinate the works on Engineering, Procurement and Manufacturing, Testing and Approval and Verification Tests, Operation and Maintenance Procedures.

**b. Duties**

- i. Verify compliance of the input data for the Design.
- ii. Allocate the human resources for the various stages of the Project.
- iii. Keep the Project Manager informed of the status of the works.

**5. MECHANICAL DESIGN****a. Mission**

- i. Design the component so that it complies with the Licensing requirements.

**b. Duties**

- i. Coordinate Mechanical and Thermo-Mechanical Engineering tasks.
- ii. Ensure that the design complies with the established requirements.
- iii. Detail the necessary tests for the validation of the design.

**6. NEUTRONIC DESIGN**

**a. Mission**

- i. Design the component so that it complies with the Licensing requirements from a neutronic standpoint.

**b. Duties**

- i. Ensure that the design complies with the established requirements.
- ii. Detail the necessary tests for the validation of the design.

**7. TESTS**

**a. Mission**

- i. Perform the necessary tests for the component to comply with the Licensing requirements.

**b. Duties**

- i. Coordinate the tasks necessary to carry out the established tests.
- ii. Ensure that all tests are carried out and approved according to the requirements.

**8. PROCUREMENT**

**a. Mission**

- i. Perform the necessary purchases for the project.

**b. Duties**

- i. Issue purchase orders according to the requirements of each sector.

**9. MANUFACTURING**

The component will be manufactured by third parties, who shall meet all Quality requirements and be approved by the Project prior to the beginning of manufacturing.

**4.2.5.2 Coordinate Engineering Tasks, Procurement and Manufacturing, Testing and Validation Tests and Representative of the Director**

1. The Project Manager shall ensure that the PCG of the LEUPA project is established, implemented and maintained.
2. Reporting to the NUPD Division on the performance of the QMP and any need for improvement.
3. Promote awareness by all members of Project LEUPA and other participants, if applicable, to take into consideration all legal and regulatory requirements of the product.

**4.2.5.3 Internal Communications**

1. The Project Manager shall ensure that proper in-house communication processes be established and that communications are carried out using the QMP of the LEUPA Project.

**4.3 RESOURCE MANAGEMENT**

**4.3.1 Provision of Resources**

1. The Project Manager identifies the necessary facilities, equipment and human resources, since the preparation of the quotation or tender and throughout the development of the Project, and for such purposes, resource requirements are considered to:
  - a. Estimate the costs of the project.

- b. Develop the detailed plan of activities.
- c. Carry out the product meeting the legal and regulatory requirements.
- 2. This ensures that adequate resources are available to administer, manage, perform and verify works.

#### **4.3.2 Human Resources**

##### **4.3.2.1 Overview**

- 1. Human Resources management, through early detection of competences for a particular product and any needs that may arise during its development, prepares or recruits human resources with appropriate experience and training to meet those needs.

##### **4.3.2.2 Competence, Awareness and Training**

- 1. All personnel performing tasks related to design, procurement and manufacturing, integration, testing, control operation and maintenance shall have the proper training based on courses and/or experience to avoid compromising the quality of the product.
- 2. Those in charge of the sectors where these activities are carried out shall detect their personnel's training needs. Once the training need is detected, those in charge report it to the Project Manager.
- 3. The Project Manager is in charge of carrying out the described actions. Records are kept on the education, training, and experience of the personnel. The effectiveness of training and necessary practice is evaluated.

#### **4.3.3 Infrastructure**

- 1. The Project Manager adapts, implements, procures and maintains the building infrastructure, workspace and related services for the proper development of the Project.

#### **4.3.4 Work Environment**

- 1. The Project Manager determines and manages the work environment necessary to meet the requirements of the product.

### **5 DO**

- 1. Applies knowledge acquired to technological developments in the execution of engineering, manufacturing, assembly and commissioning, operation and maintenance of projects for national and international contracts, and the provision of services.
- 2. It is performed based on the experience acquired in all projects completed and presented so far with the participation of experts and the incorporation of the most novel techniques, interpreting and satisfying clients' needs. In this phase, objectives are identified, responsibilities are delegated and resources are allocated in a convenient way.
- 3. There are provisions on this QMP on the documented procedures required, as well as the necessary documents for the company to ensure effective planning, operation and control of processes to obtain the product.

## **5.1 Requirements for the Quality Management Program Documentation**

### **5.1.1 Structure of the Documented Quality Management Program**

- 1. The documented QMP has a four-level structure:
  - a. *Level 1: Quality Management Program*
    - i. The QMP is a document that establishes and determines the mission and functions of the hierarchical structure of the project, and specifies the procedures for the implementation of the QMP.

**b. Level 2: General Procedures**

- i. The general procedures are documents defining the purpose, scope, area of application, person in charge and description of the general activities carried out to implement the QMP. Some of the documents within this level: Control and Issuance of Documentation, Design Control, Product Identification and Traceability, Control of Inspection Equipment, Measurement and Testing, Control of Nonconforming Products, Corrective and Preventive Measures, Internal Audits, etc.

**c. Level 3: Quality Plans and Special Procedures**

- i. **Quality Plans:** These are sets of work instructions defining the sequence of operations to be performed, including tests and inspections. The following are some of the documents within the quality plans: Design Plans, Manufacturing and Inspection and Trial Plans, and Materials Reception Plan
- ii. **Special Procedures:** These are sets of instructions describing the activities necessary to perform a specific work or operation, to test, prove or verify the operation or features of the product, or the efficiency or properties of a manufacturing process. Some of the documents within these procedures: END (visual, dimensional, Penetrants, Paint, Water-Tightness Test, etc.).

**d. Level 4: Forms, Technical Documentation, Contracts, Bibliography**

- i. Forms and Technical Documentation are formats oriented to standardize the various quality records for the management of processes, products and/or services developed by the company.
- ii. Forms: For audits, inspection and testing plans, protocols, nonconformities, deviations, dimensional control, etc.
- iii. Technical Documentation: Drawings, specifications, descriptive reports, calculation memories, data sheets, process diagrams, electrical and instrumentation documents, etc.
- iv. Contracts: Specifications and requirements that the product must comply with.
- v. Bibliography: Standards, Publications, Catalogs, Brochures, Books.

### 5.1.2 Quality Management Program – QMP

1. Describes the QMP and, in turn, is supplemented by the General and Specific Procedures related to the various processes executed and the services provided: Design, Procurement, Manufacturing, Assembly, Testing and Verification and Validation Tests, Operation and Maintenance Procedures.
2. The QMP shall be subject to review if there are changes in regulations, activities or improvements.

### 5.1.3 Control of Documents

1. The QMP sets forth, documents, implements and maintains general and specific procedures to control all documents and relevant records.
2. All related commercial, administrative and technical documents are controlled and filed in the related sectors of the company to the LEUPA Project.
3. The documents are subject to review and approval by authorized personnel of the issuing sector. They shall follow, as applicable, preset formats or templates, stating titles and contents, description of test procedures, etc., to be issued as formal and authorized documents.
4. Valid, legible and easily identifiable documents available at each location where essential operations are carried out, to facilitate the effective operation of the QMP.

5. Invalid or obsolete documents are extracted from their application location by those in charge of this area at each sector. This does not prevent the file sector from keeping properly identified copies of such documents for information, legal or contractual purposes.
6. Relevant documents issued by external sources are identified and their distribution is controlled, for the purpose of being used by the applicable individuals.
7. During interventions or Quality audits at the different phases of the development of the product, it is verified that the currently valid versions of the relevant documents are being used.
8. Changes in documents and data are reviewed and approved by the same personnel who carried out the first review and approval, except other persons are specifically designated.
9. The nature or description of the change is identified on the cover of the document and shall be internally identified with a triangle containing the letter corresponding to the new document to be issued based on the applicable review.
10. The applicable procedures are the following:
  - a. SGIN-2000-EPEGC-001 INVAP's Documents and Records Control (*"Control de los Documentos y Registros de INVAP"*)
  - b. 0903-0000-EDSIN-001 Project's Technical Documents Codes – Minor Nuclear Works - *"Codificador de Documentos Técnicos del Proyecto – Trabajos Nucleares Menores"*).
  - c. 0903-0000-EDSIN-0021 Opening of Micro-Projects and Systems of the Project - Minor Nuclear Works – *"Apertura de Micro-Proyectos y sistemas del Proyecto – Trabajos Nucleares Menores"*).

#### 5.1.4 Records Control

1. The Project complies with documented procedures for the classification, distribution, filing, maintenance and disposal of quality records. It keeps a file of quality records such as: Plans for Supplier Qualification, Assessment and Quality, Personnel Training, etc., according to their location and preservation times. These records show what has been done so far and prove that the requirements set forth have been met and that the quality program is effective.
2. To such purposes, there are general records, such as "suppliers' assessment", kept at the Quality and Environmental Management Division. In the case of quality records for the project itself, these are on the same files as the LEUPA Project within the Nuclear Projects Division.

## 5.2 PRODUCT REALIZATION

### 5.2.1 Product Realization Planning

1. Planning begins with a review of the quoting and continues throughout the project development. Planning identifies the requirements and provides for proper controls, processes, equipment and human resources to meet them. The planning process includes the following activities:
  - a. Identification of product quality requirements and assurance that all applicable procedures and work instructions meet said requirements.
  - b. Identification and adoption of controls, processes, equipment, human resources and skills necessary to ensure the required quality.
  - c. Assurance of compatibility of the design, manufacturing process and procurement, procedures for testing and validation tests.
  - d. Identification of proper control points and the right timing during the development of the project.

- e. Clarification of acceptance criteria for the required specifications. The purpose is to only use objective criteria for acceptance requirements, and, for such purposes, a document is developed with the exact criteria for acceptability.
- f. Identification and preparation of quality records.
2. Documented procedures are established to control inspection and test activities to verify compliance with specified product requirements. The occurrence of the inspections and tests are defined in the plans and records (plan of inspection and tests, reports and protocols) derived from that activity and are part of the product quality file.

## **5.2.2 Client-Related Processes**

### **5.2.2.1 Determination of Product Requirements**

1. The contract review begins with a preliminary evaluation or analysis of the business to decide whether to quote or not. At this stage, the client's requirements are analyzed, as well as those which were not specified by the client but are necessary for the intended use of the good to be quoted. Based on this analysis, an assessed is made on whether the Company is or may be in a position to meet the contractual requirements if the offer is accepted or the tender awarded. If the decision is to quote, a team is assigned for the commercial and technical preparation of the offer, which is considered and approved at management level prior to presentation.
2. Product requirements relating to the system, subsystems, components, assemblies, subassemblies, or parts are identified and documented by the interfaces and personnel in charge of the technical aspects of the work. The requirements for test activities, those arising from the applicable standards and regulations, and all other requirements that the organization deems relevant are also identified.
3. Incomplete, ambiguous or conflicting requirements are solved with those in charge of defining them.
4. Also, the group participating in the execution of the Project considers regulations, standards and product-related regulatory issues.

### **5.2.2.2 Review of Product Requirements**

1. Any change or amendment to the contract or product arising from a change or new requirement, agreed at managerial level or by the project managers, with prior analysis of the impact on cost and schedules, is recorded and reported to the Project's management so that they can adapt their actions based on these changes.
2. All review, acceptance, and modification records are kept in a formal file at the Management or Division of the Project to which the Project belongs.

### **5.2.2.3 Communication with the Client**

1. For LEUPA project, since the client is internal, but also in charge of the project, this link that applies for other projects is not established.

## **5.2.3 Design and Development**

### **5.2.3.1 Planning of Design and Development**

1. The Project Manager is in charge of the related detailed planning. This includes planning for the control, verification and validation of the design.
2. Plans are prepared for each one of the design and development stages and activities, describing and defining the responsibilities to be carried out. These activities are assigned to personnel qualified and equipped with adequate resources. Plans are reviewed as the Project evolves.
3. Planning and regular reviews ensure that the design:
  - a. Ensures the preset useful life for the product.



- b. Minimizes or eliminates potential sources of human failure.
- c. Allows for an easy assembly, test, fault isolation and repair without compromising safety, reliability and performance of the product.
- d. Has the suitable margins for the applications the product will be used for.
- e. Has a cost compatible with the planned budget.

#### **5.2.3.2 Input Elements for the Design and Development**

1. Input requirements for the design relating to components, assemblies, or parts are identified and documented by the interfaces and personnel in charge of the technical aspects of the work.
2. The design specification is a statement of functional requirements applicable to some extent to the physical or testing requirements. The specification of the design evolves during the life of the project and reflects progressive refinements in performance, design, configuration, and test requirements.
3. The standards or regulatory provisions the product must comply with are included as input data for the design, and, when applicable, information from previous similar designs is also included.
4. For the design control, the following procedures shall be used: Development and Design Control ("*Control de Diseño y Desarrollo*") No. CDAD-2004-3PSGC-001 and Specific Development and Design Plan Guide ("*Guía de Plan de Diseño y Desarrollo Específico*") No. CDAD-2004-3PSGC-002.

#### **5.2.3.3 Results of the Design and Development**

1. The results of the design as regards components, assemblies or parts are documented and stated in such way that they can be verified and validated by comparing them with input requirements.
2. The results allow to verify that:
  - a. Design requirements are met.
  - b. All the information for procurement, production and service transactions is provided.
  - c. Further, other manufacturing features, acceptance criteria, correct and safe product operation, including storage requirements, handling, operation, maintenance, etc. are included.
3. All designs are reviewed and approved in the sector in charge of execution prior to release for approval.

#### **5.2.3.4 Review of the Design and Development**

1. This review is performed on a specific design at any level, at every stage and in the sector where that design was created. It consists of verifying that the stage of the design meets output data requirements, the use of criteria and current or suitable design techniques, and the adoption of suitable materials. Functional and specific properties demonstrations are carried out, when applicable.
2. Within the Design Control Plan established to ensure that the system meets the specified requirements, there are activities which allow verifying the design at the different stages.

#### **5.2.3.5 Verification and Approval of the Design and Development**

1. The acceptable method for approval is by means of calculations, although for the LEUPA project validation will be necessary with the tests required by the ARN in its regulations applicable for this type of package.
2. After having completed successful verification at all stages and levels, acceptance tests are carried out, which constitute an instance of approval because they provide evidence that the product complies with the requirements and allows release after having complied with

the provisions of the ARN, which will participate in such tests. These activities include functional tests of the product under operating conditions.

#### 5.2.3.6 Control of Changes in the Design and/or Development

1. Changes in the design or development are identified and recorded. Such changes are reviewed, verified, validated and approved with the necessary method based on the complexity of the item.
2. A record is kept on the results of the review of changes and other adopted actions.
3. Engineering changes shall be made applying procedure No. CDAD-3001-3PSGC-018 for the Use of Engineering Changes ("*Utilización de Modificaciones de Ingeniería*").

#### 5.2.4 Procurement

##### 5.2.4.1 Procurement Process

1. In the Project, procurement Purchases are carried out through INVAP's Supplies Division, the Head of Quality Management of the Project ensures, through established procedures, that purchased products meet the specified requirements.
2. INVAP's Supplies Division is governed by the Quality and Environmental Manual of the Supplies Division (CDAD-1003-3MEGB-006 – "*Manual de Calidad y Ambiental de la Gerencia de Abastecimiento*"), and the General Procurement Procedure No. C134-0000-3PEGB-001 ("*Procedimiento General de Compras*").
3. The Quality Manager, with the participation of specific technical sectors of each particular area, carries out the following activities:
  - a. Evaluate, qualify and select suppliers based on their qualifications to meet the requirements of the purchase or subcontract, its quality system and any other assurance aspect of the product. Using the following procedures: Suppliers Qualification ("*Calificación de Proveedores*") No. CDAD-2006-3PSGC-001, Suppliers Economic and Financial Assessment ("*Evaluación Económica Financiera de Proveedores*") No. CDAD-2006-3PSGC-007 and Suppliers Performance Rating ("*Calificación de Desempeño de Proveedores*") C240-0000-3PEGB-004.
  - b. They define the type and scope of the control exercised on each supplier. This depends on the type of product, the influence of the product supplied in the quality of the final product and, when applicable, the quality audit and/or background reports proving the capacity of suppliers.
4. The Quality Manager establishes and keeps quality records of accepted suppliers and a file with the performance assessment of those suppliers. Suppliers with an unsatisfactory assessment may be re-evaluated, upon their request, if they consider they have solved the non-conformities stated in the previous evaluation.

##### 5.2.4.2 Procurement Information

1. Procurement documents contain the data clearly describing the requested product, including, when applicable, the following information for each item:
  - a. Type, class, grade or other precise identification, quality level (for the determination of the level, the procedure used is Quality Level Determination ("*Determinación de Niveles de Calidad*") No. CDAD-3001-3PSGC-009).
2. Name or other identification, manufacturer code, specifications, drawings, plans, applicable regulations, process requirements, inspection instructions and any other relevant technical data, including the requirements for qualification or acceptance of the product, the procedures, the equipment for the process and personnel.
3. To complete negotiations regarding a purchase, a Purchase or Delivery Order is submitted to the supplier. Before issuing this document, it is subject to final review and approval to



ensure that the requirements specified by the requestor and/or those agreed with the supplier are met.

#### 5.2.4.3 Verification of the Purchased Product

1. The Quality Manager or the person appointed by the Quality Manager inspects the parts and/or products, using purchase data and technical specifications for each item as reference.
2. The consistency between the item entered, the related purchase data and requirements is verified. Further, the existence of the requested documentation attached is verified (for instance: quality reports, test results, certificates of chemical analysis of the materials, etc.).
3. To determine the scope and nature of the receipt inspection, reliability criteria, the result of inspections and controls carried out at the supplier's premises (if any), supporting documentation of tests performed and results, and lessons learned from other experiences with the same type or category of products are considered. Inspections or tests to be performed for a certain product are the responsibility of the receiving sector prior to reception or determined by an accepted methodology.
4. Reception documentation is kept, including documents sent by suppliers.
5. The applicable procedures are Level "A" Items Quality Requirements ("*Requisitos de Calidad para artículos Nivel "A"*") No. CDAD-3001-3PSGC-013 and Level "D" Commercial Materials Quality Requirements ("*Requisitos de Calidad para Materiales Comerciales Nivel "D"*") No. CDAD-3001-3PSGC-016, as requirements to make the purchase request and also reception by the company.

#### 5.2.5 Manufacturing and Provision of the Service

##### 5.2.5.1 Manufacturing Control

1. Operations directly affecting quality are identified, developed, controlled and maintained, ensuring that they are carried out under controlled conditions. This includes:
  - a. Existence of documented and approved Procedures, Instructions, and Inspection Plans.
  - b. Existence of applicable current and controlled documentation.
  - c. Use of suitable and maintained equipment.
  - d. Proven, approved or released processes, if applicable.
  - e. Compliance with adopted standards and regulations.
  - f. Use of calibrated measurement tools with the accuracy required to measure the parameter.
  - g. Adequate environment for the development of the process.
  - h. Trained personnel with the necessary skills to carry out the operation.
  - i. Monitoring of process parameters and product features.
  - j. Protection of the product until its delivery to the client at destination.
2. To prepare the Testing and Inspection Plan (TIP) carried out for a certain item, Procedure No. CDAD-3001-3PSGC-019 is used. This plan documents the following:
  - a. Manufacturing and inspection sequence from the reception of the material to the final product.
  - b. Applicable documentation, regulations and standards.
  - c. Applicable procedures.
  - d. Those who execute or are in charge of the manufacturing operation.
  - e. Those who execute or are in charge of the inspection and testing activities.
  - f. The codes of the protocols resulting from inspection and testing activities.

#### 5.2.5.2 Validation of Processes for Service and Manufacturing Operations

1. Processes for which good execution cannot be verified by means of inspections and subsequent tests must be carried out by qualified personnel and subject to continued monitoring and control of selected parameters representative of the evolution of the process. These critical processes are identified during the programming and analysis stage of activities which affect quality.
2. Some of the processes considered special are:
  - a. Industrial X-Ray (according to procedure No. CDAD-3002-3PSGC-001).
  - b. All types of welding (welders and welding operations shall be qualified in accordance with the ASME IX code).
  - c. Ferroxil Test (pursuant to procedure No. CDAD-3002-3PSGC-007, prior to welding)
3. Members of the personnel in charge of carrying out or inspecting processes and relevant operations from the quality standpoint, receive the necessary training and courses provided by the Company or external entities. Certifications and revalidations (if applicable) of each individual are attached to the component's quality records.

#### 5.2.5.3 Identification and Traceability

1. In manufacturing activities, the traceability of outsourced materials or services leads to knowledge of suppliers and procurement management.
2. The personnel or sector involved in the manufacturing and inspection of a product is recorded in the Inspection and Testing Plan.
3. The Inspection and Testing Plan (and related quality protocols) at the manufacturing, assembly and mounting stages provide relevant information which allows to develop a product's background. This knowledge provides the possibility of detecting the causes or activities related to nonconformity and thus take preventive and corrective actions.
4. The status of the product regarding inspection and test is identified through the appropriate means to indicate conformity or nonconformity of the product in relation to the inspections and tests. The identification of inspection and test status is maintained throughout the entire construction of the product, in order to ensure that only products which have passed the required inspections and tests be used and integrated.
5. The applicable procedure is the Identification of Parts and Equipment procedure (*"Identificación de Piezas y Equipos"*) No. CDAD-3001-3PSGC-006.

#### 5.2.5.4 Client Property

1. Since the Client in the LEUPA project is the project itself, this section does not apply.

#### 5.2.5.5 Product Preservation

1. A documented procedure is established to manage handling, storage, packaging, preservation, transportation and delivery of the product. General Packing Procedure (*"Procedimiento General de Embalaje"*) No. CDAD-3001-3PSGC-028.

##### 5.2.5.5.1 Handling and Transportation

1. In cases where the handling may damage the product, procedures are established to avoid or minimize risks. If the products being manufactured or finished have to be transported, aspects related with transportation are considered (environmental conditions, means of transportation, land routes, etc.).

##### 5.2.5.5.2 Storage

1. Products in the reception stage as well as those being prepared or completed are placed on premises or areas meeting the preservation requirements of the product to prevent damage or deterioration during each transition.
2. These warehouses have in and out controls for products, as well as controls on their destinations.

**5.2.5.5.3 Packing**

1. When planning the packing of any product, the design and manufacturing take into consideration for instance mechanical protection, electromagnetic protection, protection against pollution and the need for controlled environments.

**5.2.5.5.4 Storage**

1. If for any reason the product is left in the custody of the Company, the necessary actions for preservation are ensured.

**5.2.6 Control of Measurement and Follow-Up Devices**

1. INVAP maintains and applies the Verification and Calibration of Instrumentation & Measurement Equipment procedure ("*Verificación y Calibración de Instrumentos y Equipos de Medición*"), No. CAD-3001-3PSGC-002. All the equipment is used to ensure that measurement errors are known and consistent with the required precision.

**6 CHECK**

1. This is performed through the QMP containing the necessary methodologies and procedures for quality assurance and control, as well as resources for its maintenance and continuous updating.

**6.1 MEASUREMENT, ANALYSIS AND IMPROVEMENT****6.1.1 Overview**

1. The necessary measurement, follow-up, analysis and improvement processes have been developed and applied to prove conformity of the product, ensure operation of the QMP and improve its effectiveness and efficiency.

**6.1.2 Measurement and Follow-Up****6.1.2.1 Client Satisfaction**

1. In this specific project, the client is the LEUPA project itself.

**6.1.2.2 Internal Audit**

1. Internal audits are carried out periodically to verify compliance with the Quality System according to procedure No. CDAD-3001-3PSGC-020; the implementation of corrective and preventive actions is verified, as well as the effectiveness of the actions taken, the improvement of the system and whether it complies with the requirements under the SO 9001:2000 international standard.
2. Audits are planned and carried out pursuant to a pre-established program.

**6.1.2.3 Follow-Up and Measurement of Processes**

1. All processes carried out by the company for its products or projects are the basis for the calculation of continuous improvement which is also considered "evolutionary" and subject to improvement. Analysis of the results and trends as the result of the calculation of indicators which are established on a quarterly basis by the Administration and Finance Division and made available to the General Management in the Continuous Improvement Plan ("*Plan de Mejora Continua*") No. CDAD-3001-3PSGC-042.

**6.1.2.4 Follow-Up and Measurement of the Product**

1. Documented procedures are established to control inspection and test activities to verify compliance with specified product requirements. A product's manufacturing process generally involves the reception of materials, manufacturing and inspection, assembly and final tests phases.

2. The timing of inspections and tests are defined in the related manufacturing and inspection plans, and the records (reports and protocols) derived from that activity, and are part of the product quality file. The procedures used in these inspections are those indicated in paragraph 8, which contains a list of applicable procedures.
3. As evidence of the completion of all inspection and test activities, these shall be documented in reports and protocols. These records indicate if the products have met acceptance requirements or not; further, the Quality personnel involved are indicated. Quality records are kept by Quality Managers.

### 6.1.3 Control of Nonconforming Products

1. Items, services and processes that do not meet the specified requirements are identified and safety implications are reported to management. As a result, the items, services and processes are accepted, rejected, repaired or reworked accordingly. These products are clearly identified to avoid unintended use or installation.
2. The two main roles as regards nonconformities:
  - a. Ensure the provision of resources to identify, report, solve and prevent nonconformities.
  - b. Solve professional criteria differences on specific issues.
3. The Project's Quality Manager is in charge of implementing the procedures to identify, document, classify, analyze, correct, delete and follow-up nonconformities in the activities, items, services and processes where nonconformities may appear.
4. Members of the personnel are encouraged to participate in the implementation and maintenance of systems, and suggest improvements where their specific experience may be valuable.
5. Members of the personnel in charge of classifying, analyzing and resolving nonconformities have suitable experience and expertise in their respective areas, and have access to relevant information regarding nonconformities. They are not affected by concerns regarding costs and deadlines, which would exert pressure to resolve nonconformities prematurely.
6. Reworked, repaired and replaced items are inspected and tested according to the original specifications.
7. The applicable procedure to control nonconformities is the Procedure for Nonconformities ("*Procedimiento de No Conformidades*") No. CDAD-3001-3PSGC-047.

### 6.1.4 Data Analysis

1. Indexes stated in paragraph 6.1.2.3 are analyzed within the context and objectives of the quality policy and the current situation. This analysis is carried out by all the hierarchical personnel related to quality aspects and is finally the main target of management reviews.
2. Many of these indexes are established at a general or specific level for a specific work and can be obtained periodically during the development of a project or work to analyze its evolution and for the project management to take corrective/ preventive actions if necessary.

## 7 ACT

1. For all products and/or services, corrective and preventive actions apply, and these are, in turn, derived from the analysis of nonconformities.
2. The QMP leads to performing works which are properly planned, properly executed, reliably verified and systematically improved.

## **7.1 Review by the Project Manager**

### **7.1.1 Overview**

1. Regular meetings are held to review the status and operation of the QMP. At a minimum, the Project Manager, the Coordinator, area managers and the Project's Quality Manager shall attend this meeting.

### **7.1.2 Information for the Review**

1. The agenda of topics to be considered will be prepared by the Project's Quality Manager on the sheet of minutes of the meeting, which may contain items pending from the previous meeting and those arising during the current period.
2. Those who participate in the review make the applicable contributions according to their areas, information collected during the period in question.

### **7.1.3 Results of the Review**

1. The results of the review shall include decisions and actions related to the items considered, which will be recorded in the minutes of the meeting.

## **7.2 Improvement**

### **7.2.1 Continuous Improvement**

1. The continuous improvement of the effectiveness of the QMP is one of the Company's permanent objectives, and for such purposes, it relies on the use of the quality policy, the quality objectives, the results of internal audits, the analysis of indicators, corrective and preventive actions and review by the directors.

### **7.2.2 Corrective Actions**

1. The organization and operation of the Company allow for the detection of nonconformities and the record and understanding of the lessons learned. There are procedures relative to the review of the quality system, the treatment of nonconformities, and the gathering of lessons learned. Corrective and preventive actions resulting from the analysis of these aspects contribute to the continuous improvement of the quality system.
2. Aspects of the procedures related to corrective actions include:
  - a. Effective consideration of clients' issues and reports of unsatisfactory products.
  - b. Investigation of the causes for nonconformities concerning products, processes and the quality system, and recording the results of the investigation.
  - c. Determination of the necessary corrective action to eliminate the causes of nonconformities.
  - d. The compilation of records on corrective actions taken.
  - e. The application of controls ensuring that the corrective action is taken, and that it is effective.

### **7.2.3 Preventive Actions**

1. Aspects of the procedures related to preventive actions include:
  - a. Permanent identification of potential nonconformities and their causes.
  - b. Use of appropriate sources of information, such as processes and working operations affecting the quality of the product, reports of nonconformities, results of audits, quality records and client complaints, to detect, analyze, and eliminate potential causes of nonconformities.
  - c. Initiation of preventive actions and the application of controls to ensure their effectiveness.

- d. Confirmation that the relevant information on the actions taken are sent for Review by Management.
  - e. Lessons learned from recently completed Projects.
  - f. Continuous improvement of processes.
2. The applicable procedure is procedure No. CDAD-3001-3PSGC-044, Procedure for Corrective and Preventive Actions (*"Procedimiento para Acciones Correctivas y Preventivas"*).

## **8 LIST OF APPLICABLE PROCEDURES**

1. Below is a list of the procedures that will be used in addition to those already mentioned specifically within this QMP for the "LEUPA" project:
- a. CDAD-3002-3PSGC-005 Visual Control Procedure (*"Procedimiento de Control Visual"*)
  - b. CDAD-3002-3PSGC-006 Dimensional Control Procedure (*"Procedimiento de Control Dimensional"*)
  - c. CDAD-3002-3PSGC-002 Penetrants Procedure (*"Procedimiento de Líquidos Penetrantes"*)
  - d. 0908-LE02-3BSIN-002 Validation Tests Specification (*"Especificación de Ensayos para Validación"*)

## **9 ANNEX I: INVAP'S CERTIFICATION**

1. ISO 9001:2008 certification for INVAP S.E. and ISO 14001:2004 certification for INVAP S.E. are attached.



**BUREAU VERITAS**  
Certification



## INVAP S.E.

HEAD OFFICE: AV. COMANDANTE LUIS PIEDRABUENA 4950, SAN CARLOS DE BARILOCHE,  
PROVINCIA DE RIO NEGRO  
ARGENTINA

This is a multi-site certificate, additional site details are listed in the appendix to this certificate

*Bureau Veritas Certification certify that the Management System of the  
above organisation has been audited and found to be in accordance  
with the requirements of the management system standards detailed below*

*Standard*

## ISO 9001:2008

*Scope of certification*

DISEÑO, CONSTRUCCION, PUESTA EN MARCHA, OPERACION Y  
MANTENIMIENTO DE: PROYECTOS AEROSPACIALES, PROYECTOS  
TECNICOS GUBERNAMENTALES, PROYECTOS NUCLEARES, PROYECTOS  
INDUSTRIALES, PETROQUIMICOS Y ENERGETICOS, AUTOMATIZACION  
INDUSTRIAL Y PROYECTOS ROBOTIZADOS.

DESIGN, CONSTRUCTION, COMMISSIONING, OPERATION AND MAINTENANCE  
OF AEROSPACE PROJECTS, GOVERNMENT TECHNICAL PROJECTS, NUCLEAR  
PROJECTS, INDUSTRIAL, PETROCHEMICAL AND ENERGY PROJECTS,  
INDUSTRIAL AUTOMATION, AND ROBOTICS.

Certification cycle start date: **21 de Mayo de 2012**

Subject to the continued satisfactory operation of the organisation's Management System,  
this certificate expires on: **20 de Mayo de 2015**

Original certification date: **05 de Noviembre de 1999**

**Certificate No. AR-0232523**

Version 00, Revision date: **21 de Mayo de 2012**

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Organismo  
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Organismo de Certificación de  
Sistemas de Gestión de Calidad  
OCSGC 003

  
Ing. Marta G. Paz



Local office: BVQI Argentina S.A. - Av. Alem 1134, Piso 8°- Ciudad Autónoma de Buenos Aires, Argentina

Further clarifications regarding the scope of this certificate and the applicability of the management  
system requirements may be obtained by consulting the organisation. To check this certificate validity  
please call +54 11 4000 8100.

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**BUREAU VERITAS**  
Certification

**Certification**  
Awarded to  
**INVAP S.E.**

AV. COMANDANTE LUIS PIEDRABUENA 4950, SAN CARLOS DE BARILOCHE, PROVINCIA DE RIO NEGRO  
SEE APPENDIX FOR SITES  
ARGENTINA

Bureau Veritas Certification certify that the Management System of the above organisation  
has been audited and found to be in accordance with the requirements of the management  
system standards detailed below

Standards

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**ISO 14001:2004**

Scope of supply

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DISEÑO, CONSTRUCCION, PUESTA EN MARCHA, OPERACION Y MANTENIMIENTO DE: PROYECTOS  
AEROSPAZIALES, PROYECTOS NUCLEARES, PROYECTOS INDUSTRIALES, PETROQUIMICOS Y  
ENERGETICOS, AUTOMACION INDUSTRIAL Y SISTEMAS ROBOTIZADOS, EN LA REPUBLICA ARGENTINA.  
DISEÑO, FABRICACION, MONTAJE, INSTALACION Y MANTENIMIENTO DE EQUIPOS DE COBALTOTERAPIA,  
SIMULADORES, ACCESORIOS Y DISPOSITIVOS PARA RADIOTERAPIA, COMERCIALIZACION Y SERVICIO  
TECNICO DE ACELERADORES LINEALES PARA RADIOTERAPIA, EN LA REPUBLICA ARGENTINA.

DESIGN, CONSTRUCTION, COMMISSIONING, OPERATION AND MAINTENANCE OF AEROSPACE  
PROJECTS, NUCLEAR PROJECTS, INDUSTRIAL, PETROCHEMICAL, AND ENERGY PROJECTS,  
INDUSTRIAL AUTOMATION, AND ROBOTICS, ALL WITHIN THE ARGENTINE REPUBLIC.  
DESIGN, MANUFACTURE, ASSEMBLY, INSTALLATION, AND MAINTENANCE OF COBALT  
THERAPY UNITS, SIMULATORS, ACCESSORIES, AND SERVICES TO BE USED IN RADIATION  
THERAPY TREATMENTS, MARKETING AND TECHNICAL SERVICING OF RADIATION THERAPY  
LINEAR ACCELERATORS, ALL WITHIN THE ARGENTINE REPUBLIC.

<i>Evaluation date:</i> <b>10 de Mayo de 2011</b> <i>Next evaluation date before:</i> <b>06 de Abril de 2014</b> <i>Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until:</i> <i>First Original Approval Date: 06 de Junio de 2005 / Last Expiry Date: 22 de Abril de 2011</i> <i>To check this certificate validity please call +54 11 4000 8116</i> <i>Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation</i>	<i>Original Approval Date:</i> <b>07 de Julio de 2011</b>  <b>06 de Julio de 2014</b>	
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**Ing. Marta G. Paz**  
**Date: 23 de Agosto de 2011**  
**Certificate Number AR-0231995 v01**

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APPENDIX OF SITES

Certificate number

**AR-O231995 v01**

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20 LETRAS	RUIZ MORENO 363	S. C. DE BARILOCHE	RIO NEGRO
ARRAYAN	ELFLEIN 1211	S. C. DE BARILOCHE	RIO NEGRO
D.E.M	FRANCO 3423	C. A. DE BUENOS AIRES	BUENOS AIRES
ESMERALDA	ESMERALDA 356	C. A. DE BUENOS AIRES	BUENOS AIRES
LABORATORIO DE ANALITICA - CAB	AV. BUSTILLO KM 9	S. C. DE BARILOCHE	RIO NEGRO
MENDOZA	MENDOZA 220	S. C. DE BARILOCHE	RIO NEGRO
MODESTA VICTORIA	BOTE MODESTA VICTORIA 4750	S. C. DE BARILOCHE	RIO NEGRO
MORENO	F. P. MORENO 1043	S. C. DE BARILOCHE	RIO NEGRO
OFICINA TECNICA CORDOBA	AV. COLON 3850	CORDOBA	CORDOBA
REMEDIOS DE ESCALADA	REMEDIOS DE ESCALADA 344	S. C. DE BARILOCHE	RIO NEGRO

Ing. Marta G. Paz

 Date: **23 de Agosto de 2011**  
 Page: **1 / 2**

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**INVAP S.E.**

APPENDIX OF SITES

Certificate number

**AR-O231995 v01**

EDIFICIO	DIRECCION	LOCALIDAD	PROVINCIA
PLANTA DE TRATAMIENTOS SUPERFICIALES DE METALES - CAB	AV. BUSTILLO KM 9	S. C. DE BARILOCHE	RIO NEGRO
QUIMEY QUIPAN	RUIZ MORENO 310	S. C. DE BARILOCHE	RIO NEGRO
SANTA CRUZ	SANTA CRUZ 1579	S. C. DE BARILOCHE	RIO NEGRO
SEDE CENTRAL	AV. COMANDANTE LUIS PIEDRABUENA 4950	S. C. DE BARILOCHE	RIO NEGRO
TALLER DE FABRICACIONES MECANICAS - CAB	AV. BUSTILLO KM 9	S. C. DE BARILOCHE	RIO NEGRO
VILLA GOLF	AV. BUSTILLO KM 27	S. C. DE BARILOCHE	RIO NEGRO
SORIA MORIA	AV. BUSTILLO KM 27	S. C. DE BARILOCHE	RIO NEGRO

Ing. Marta G. Paz

Date: **23 de Agosto de 2011**

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