OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

University of Applied Sciences Basel
FHBB
Faculty
Industry
Institute of Environmental Technology

23194

Final Activity report 2005

Implementation of QMS ISO 9001:2000 at NCPC in Central America

Mission 13-22 October 2005

Enclosure 2

Mr. Peter Schönenberger
Resource expert SAQ-Qualicon
Part time lecturer FHBB

Muttenz, November 2005

University of Applied Sciences Basel
Institute of Environmental Technology
St. Jakobs-Strasse 84
CH-4132 Muttenz
Switzerland

Phone +41 61 467 45 05
Fax +41 61 467 42 90
E-mail ifuinfo@fhbb.ch
Internet www.fhbb.ch/umwelt

Content

1 Objectives and content of the 2nd mission to Central America

Duration

13 October-22 October 2005

- NCPC Costa Rica: 13/14 October 2005
- NCPC El Salvador: 17/18 October 2005
- NCPC Guatemala: 19/20 October 2005
- NCPC Nicaragua: 21/22 October 2005

Resource expert
Mr. Peter Schönenberger, SAQ-Qualicon AG, Kirchberg/Switzerland

Backstopping/Responsibility
Mr. Jürg Walder, FHBB/IfU, Muttenz/Switzerland

Objectives

- To find out if the elaborated QM-System is implemented effectively
- Monitoring of previous implementation efforts
- To evaluate if the requirements of the ISO 9001:2000 are fulfilled (deviations)
- To show further necessities to meet requirements of ISO 9001:2000
- To define the next steps and final requirements to get the certification of ISO 9001:2000
- Realization of the examinations for EOQ Quality Systems Manager

Specific content of the individual workshops at NCPC
About 65% to 75% of the planned ISO 9'001 project descriptions and appended documents drafted by the NCPC were available before and during the mission and reviewed by the expert. In order to increase the efficiency the evaluation of the current status of the QM-system was carried out as audit with the relevant checklists (chapter 2) at each NCPC. During the workshops deviations from the project target were recorded and listed together with each NCPC. In addition open questions regarding below mentioned specific content discussed.

- Quality Management in general
  - General requirements
  - Documentation requirements

- Management responsibility
  - Management commitment
  - Customer focus
  - Quality Policy
  - Planning
  - Responsibility, authority and communication
  - Management review

- Resource management
  - Provision of resources
  - Human resources
  - Infrastructure
  - Work environment

- Service realization
  - Planning of product realization
  - Customer-related processes
  - Design and development
  - Purchasing
  - Product and service provision
  - Control of monitoring and measuring devices

- Measurement, analysis and improvement
  - General
  - Monitoring and measurement
  - Control of nonconforming product
  - Analysis of data
  - Improvement

- Realization of an examination with QM-responsible of NCPC to become a "Quality Systems Manager EOQ"

General result:
During each workshop at the NCPC an internal audit was conducted by the expert. All detailed findings are summarized in the present final report which shows further steps that have to be undertaken to establish a well functioning QM-system and to reach the certification acc. to ISO 9001:2000 respectively.

With the support mission and the defined follow-up listed in this report the NCPC will be enabled to finalize all required documents by the end of 2005. It is intended to certify the NCPC in spring of the year 2006 acc. to ISO 9001:2000.

2 Internal QM audit at NCPC

The following checklists were used at each NCPC to evaluate the fulfillment of the ISO 9'001:2000 requirements.

2.1 Remarks on how to use the audit question list / topic list

The column "**Requirement / subject**" refers to questions based on the requirements of ISO 9001:2000. The same numbering of chapters has been used as in the original ISO 9001:2000 standard. Within the text provided there are some chapter numbers put in brackets which means that there are other chapters in the standard which address the same issue.

The **"Doc."** column is only used in cases of necessary further notes of receivers. The defined chapters within the table refer to the chapters in the original standard ISO 9001:2000.

The column **"Documents reviewed"** gives a summary of possible (not necessary) and required documents that were reviewed.

The columns "**Guatemala, El Salvador, Nicaragua** or **Costa Rica**" has been used for the corresponding "audit notes". (short description of the performance, audit result for each NCPC).

The column on the right hand side of each country column contains the evaluation mark. These marks correspond with the question of the standard chapter in the column "Requirement/subject". If there is just one mark around one chapter that means the evaluation for the whole chapter is the same.

Evaluation marks have to be understood as follows: 1 = conformance, 2 = observation (minor nonconformity for which the relevant corrective action will be verified in the next audit), 3 = major nonconformity (re-audit or submission of new documentation by a defined date necessary).

2.2 Detailed evaluation

Chapter of standard: 4. Quality Management System

4.1 General requirements

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Documented processes/procedures and other applicable documents o Process flow charts o Management review o Investment plans o Action catalogs		Obligation to establish and maintain a QMS (s.5.4.2) : • identification and application of quality system processes • determination of sequence and interaction of these processes - determination of process operations and control methods - availability of resources and of informations required for process support and monitoring • process monitoring, measurement and analysis - implementation of necessary actions for continuous improvement of these processes (s. 8.1+8.2.3) • control of outsourced processes	There are no specific defined rules regarding "Signature". Management review is missing / there is no process monitoring, systematic measurement and analysis. There is no specific model or vision	1 1 2 2 3 3 2	Management review is missing / there is no process monitoring, systematic measurement and analysis. The Quality Management manual (overall guide) should be divided and integrated in the corresponding processes	1 1 2 2 2 2 2	Management review is missing / there is no process monitoring, systematic measurement and analysis. There is no valid stategy.	1 1 2 2 2 3 2	Management review is missing / there is no process monitoring, systematic measurement and analysis. The documentation is generally rather comprehensive. Generally, sub-processes should be avoided. There is no specific model or vision	1 1 2 2 2 3 2

4.2 Documentation requirements

4.2.1 General

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Documented procedures o Commitment to continuous improvement o On-going evaluation o Communication within the organization o Description of interactions o Test plans o Process flow charts o Drawings o Organizational charts o Document control o Control of quality records o Control of internal audits o Control of nonconforming product o Control of corrective action o Control of preventive action o Order records o Manufacturing records o Minutes/records o Checklists o Test certificates o Qualification certificates		Documentation must include: - quality policy and quality objectives (s. 5.3, 5.4.1) - quality manual - documents required for process control • documented procedures required by this standard (s. 4.2.4) - quality records	The QM-documentation reflect the whole company. The model, vision and strategy has to be reviewed and if necessary to be adjusted.	2 2 2 1 2	The Quality Management manual (overall guide) should be divided and integrated in the corresponding processes. The QM-documentation reflect the whole company. The model, vision and strategy has to be reviewed and if necessary to be adjusted.	2 1 2 1 1	The QM-documentation reflect the whole company. The model, vision and strategy has to be reviewed and if necessary to be adjusted.	2 1 2 1 1	The documentation is generally rather comprehensive. The QM-documentation reflect the whole company. The model, vision and strategy has to be reviewed and if necessary to be adjusted.	3 1 2 1 1

4.2.2 Quality Manual (must include):											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Documented procedures o Organizational charts o Geographic or technical scope of application • Justification for exclusions from requirements as per Chapter 7 o Process descriptions / flow charts		• Scope of QMS including justification of exclusions (s. 1.2) - Descriptions of procedures and • Interaction between quality system processes (cf. footnote to 4.1 in standard)	Scope of QMS including justification of exclusions should be described in more detail	3 2 1	Scope of QMS including justification of exclusions should be described in more detail	3 1 1	Scope of QMS including justification of exclusions should be described in more detail	3 2 1	Scope of QMS including justification of exclusions should be described in more detail	3 1 1

4.2.3 Control of document											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Document control o Quality Manual o Approval documents o Revision procedures o Approval procedures o Documented procedures o Test plans o Lists of revision o Distribution list o Evidence of issue and receipt o Review of external documents o On-site review		- Review of adequacy prior to issue and approval - Review, up-date and re-approval - Identification of revision status and changes - Steps taken to ensure that relevant documents are available at point of use - Steps taken to ensure that documents are legible and readily identifiable - Identification and controlled distribution of external documents - Steps taken to ensure that the unintentional use of obsolete documents is prevented and that the latter are suitably identified	There is no official release of the Management documentation. The company should go official "live" with the Management-System latest middle of December (binding for all employees). Identification and controlled distribution of external documents should be organized.	2 2 2 2 3 3 2	There is no official release of the Management documentation. The company should go official "live" with the Management-System latest middle of December (binding for all employees). Identification and controlled distribution of external documents should be organized.	2 1 1 2 2 3 2	There is no official release of the Management documentation. The company should go official "live" with the Management-System latest middle of December (binding for all employees). Identification and controlled distribution of external documents should be organized.	2 2 2 2 2 3 2	There is no official release of the Management documentation. The company should go official "live" with the Management-System latest middle of December (binding for all employees). Every document should have a Identification number, a title, "validity (currency) date". and number of pages. Identification and controlled distribution of external documents should be organized.	2 2 2 2 2 2 2

4.2.4 Control of records										
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Control of records o sales and order records o Manufacturing records o Minutes/records o Check lists o Test certificates o Documentation of internal audits o Qualification certificates o purchase records o logistic records		Controls must ensure - Legibility - Identification - storage - Protection from damage - Retrieval - Retention period - disposition	The arrangements to organize the records (documentos de ejecucíon) is generally not fulfilled.	3 3	The arrangements to organize the records (documentos de ejecucíon) is generally not fulfilled	3 3	The arrangements to organize the records (documentos de ejecucíon) is generally not fulfilled	3 3	The arrangements to organize the records (documentos de ejecucíon) is generally not fulfilled	3 3

Chapter of standard: 5. Management responsibility

5.1 Management commitment

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Management review o Written quality policy o Training schedules / evidence o Employee information (notices, agenda of informative events) o Manpower-development plans o Quality plans o Records of defined objectives o Project plans o Investment plans o Plant agreements		• Evidence of quality system effectiveness and continual improvement (s. 8.4+8.5.1) • Determination and communication of customer and statutory and regulatory requirements (s. 5.2) - Establishing of quality policy and quality objectives (s. 5.3 + 5.4) - Conduct of management reviews (s. 5.6) - Steps taken to ensure availability of resources (s. 6)	There is not perceptible an evidence of quality system effectiveness and continual improvement. Because there is no Management review available.	2 3 2 3 1	There is not perceptible an evidence of quality system effectiveness and continual improvement. Because there is no Management review available.	2 2 2 3 1	There is no concept regarding "knowledge-management" There is not perceptible an evidence of quality system effectiveness and continual improvement. Because there is no Management review available.	2 3 2 3 1	There is not perceptible an evidence of quality system effectiveness and continual improvement. Because there is no Management review available.	2 3 2 3 1

5.2 Customer focus

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
• Evaluation of customer surveys • Market analyses • Complaint documentation / analyses • Product validation records • Standards • Customer-satisfaction analyses • external quality costs • ppm-statistics		• Top Management shall ensure the determination of customer requirements and expectation (s.a. 7.2.1 + 8.2.1)	The analysis of client satisfaction has to be implemented	2	The analysis of client satisfaction has to be implemented	1	The analysis of client satisfaction has to be implemented	2	The analysis of client satisfaction has to be implemented	1

5.3 Quality policy

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Corporate guidelines and principles o Written quality policy o Training schedules and evidence o Employee information (notices, meetings etc.) o Management review o Internal audits		- Suitability for organization • Commitment to continuous improvement (s. 8.5.1) • Definition and review of quality objectives - Communication within the organization • On-going review of suitability	There is no specific model or vision. The necessary issues see below "Requirement/subject"(this issues are obligatory)	2 2 2 3 2	There is no specific model or vision. The necessary issues see below "Requirement/subject "(this issues are obligatory)	1 1 2 2 2	There is no specific model or vision. The necessary issues see below "Requirement/subject "(this issues are obligatory)	3 3 3 2 2	There is no specific model or vision. The necessary issues see below "Requirement/subject"(th is issues are obligatory)	2 2 3 2 2

5.4 Planning

5.4.1 Quality objectives

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Internal/external target agreements (business plans, project plans, quality assurance agreements) o company-related o product-related o customer-related o general Employee information o Records of employee interviews o trend analysis		• Determination on the basis of data and parameters (s. 8.4+8.5.1) - Alignment with quality policy • Alignment with product requirements (s. 7.1)	Agreements/ Goals should be harmonized with the strategy and model. Alignment with product requirements is fulfilled.	2 2 2	Agreements/ Goals should be harmonized with the strategy and model. Alignment with product requirements is fulfilled.	2 2 1	There is no approved strategy. Agreements/ Goals should be harmonized with the strategy and model. Alignment with product requirements is fulfilled.	2 2 2	Agreements/ Goals should be harmonized with the strategy and model. Alignment with product requirements is fulfilled.	2 2 1

5.4.2 Quality management system planning											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Documented procedures o Investment plans o Strategic plans o Quality plans o Production plans o Resource plans / records o Documented procedures / process descriptions o Work and test plans		• Steps taken to ensure that quality objectives and - requirements outlined in 4.1 are satisfied • Steps taken to ensure that changes to the QMS do not impair integrity - Documentation		2 2 3 1		1 1 2 1		2 2 2 2		2 2 2 1

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Documented procedures (QM) o Job / function profiles o Requirement profiles		- Definition and communication of responsibilities and authorities • ensuring by top management	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	3	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	3	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	3	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	3

5.5.2 Management representative										
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Organizational chart and organizational structure o QMR appointment letter o QMR function profile o QMR job profile o Status report /Q analyses o Internal audit reports o Reports re quality situation o Statistical evaluation		- Appointment and announcement of an independent member of the management responsible for this task Tasks: - Quality system establishment - Reporting to top management • Sensitization to customer requirements	The overall responsible person of the QMS has to be defined and documented.	3	The overall responsible person of the QMS has to be defined and documented.	3	The overall responsible person of the QMS has to be defined and documented.	3	The overall responsible person of the QMS has to be defined and documented.	3

5.5.3 Internal communication										
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Minutes and reports of meetings o Team training and other meetings o Notice boards, internal magazines o Audio-visual and electronic media o Agenda of company events o Circular letters o Statistics o Reports on quality system effectiveness		• Establishment of suitable communication processes within the organization (s. a. 7.2.3) • Communication regarding quality system effectiveness	Quality Management has to be an action issue within every meeting	2 2	Quality Management has to be an action issue within every meeting	1 2	Quality Management has to be an action issue within every meeting	2 2	Quality Management has to be an action issue within every meeting	1 2

5.6 Management review

5.6.1 General

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Management-review report o monthly management reports o controlling reports o finance reports o Q-reports o supplier evaluations o logistic reports		- Regular review of quality system - Assessment of opportunities for improvements to quality policy and quality objectives - Recording of the need for changes to the quality system	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3

5.6.2 Review input

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Management-review report o Customer-satisfaction analyses o Process analyses o Evidence of corrective and preventive action o Resource deployment and application planning o Benchmarking results o Quality analyses o Risk analyses (technical/economic) o Internal audit reports o Process audits o Product audits / reports o Action reports o Investment planning		Management review must include: • audit results • customer feedback • process performance and product-conformity • status of preventive and corrective action • follow-up action from previous management reviews • changes that could affect the quality system • recommendations for improvement (s. 8.1+8.2+8.4+8.5)	The management-review is not available and has to be established	 3 3 3 3 3 3 3	The management-review is not available and has to be established	 3 3 3 3 3 3 3	The management-review is not available and has to be established	 3 3 3 3 3 3 3	The management-review is not available and has to be established	 3 3 3 3 3 3 3

5.6.3 Review output											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Management-review report o Business plan o Strategic plans o Investment plans o Human-resources plans o new objectives o Projects o action plans		Decisions and actions shall include: • improvement of the effectiveness of the QMS and its processes • product improvements • resource needs	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3	The management-review is not available and has to be established	3 3 3

Chapter of standard: 6. Resource management

6.1 Provision of resources

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Investment plans o relating to personnel o relating to equipment o relating to real estate o Staffing schedules o Other target plans		- Determination and provision of resources required for: - implementing, maintaining and continually improving the quality system - ensuring customer satisfaction	The determination and provision of resources required for implementing, maintaining and continually improving the quality system is implemented. There is just one systematically destination of the client satisfaction in training.	3 2	The determination and provision of resources required for implementing, maintaining and continually improving the quality system is implemented. There is just one systematically destination of the client satisfaction in training.	2 2	The determination and provision of resources required for implementing, maintaining and continually improving the quality system is implemented. There is just one systematically destination of the client satisfaction in training.	3 2	The determination and provision of resources required for implementing, maintaining and continually improving the quality system is implemented. There is just one systematically destination of the client satisfaction in training.	3 2

6.2 Human resources

6.2.1 General

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality Manual o Job / function profiles o Employment contracts o Manpower-development plans o Qualification documentation o Records of employee interviews o Employee certificates o qualification matrix		Personnel performing work affecting product quality must be competent based on: - education - training - skills - experience.	See 6.2.2	2	See 6.2.2	2	See 6.2.2	2	See 6.2.2	2

6.2.2 Competence, awareness and training									
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Records of quality requirements o Job / function profiles o Induction plans o Records of employee interviews o Training schedules o Training certificates o Records on the evaluation of training effectiveness o Training objectives o Training benefits o Training efficiency o Company benefits o practice in the trained part		- Determination of training needs - Provision of appropriate training • Evaluation of training effectiveness • actions of awarenessbuilding measures for the relevant activities and for the achievements of the objectives - Maintaining of relevant records	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	3	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	2	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	3	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	2

6.3 Infrastructure

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Workplace investigations o Investment plans o Maintenance and servicing plans and records o Records of process capability studies o Records of o supplier evaluation o (including service providers)		• Determination, provision and maintenance of infrastructure, e.g.: • buildings, workplace and associated utilities • process equipment, hardware and software • support services (such as transport or communication)		1		1		1		1

6.4 Work environment

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Evidence of instruction in occupational safety o Evidence of the satisfaction of statutory and regulatory requirements or conditions o Maintenance / servicing plans (records) o Workplace investigations o Benchmarking re work environment o Employee - satisfaction analyses o Analyses re labor turnover / absenteeism		• Definition and control of work-environment factors needed to achieve product conformity.		1		1		1		1

Chapter of standard: 7. Product realization

7.1 Planning of product realization

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Project-strategy approaches o Specifications o Quality plans o Project-development plans o Milestone plans o Feasibility records o Measurement and test strategies o Logistic strategies o Records relating to risk assessment and process evaluation (technical, economic) o FMEA o criteria for process release		Planning and development of product-realization processes. Such planning must take the following points into account: • quality objectives and product requirements - the need to establish or provide product-specific processes, documents and resources - product-specific verification, validation, monitoring, inspection and test activities and criteria for product acceptance • appropriate records to provide documented evidence for the realization of product and process (s. 4.2.4)	General the requirements are met – some specific steps like client needs, project plan, verification and validation have to describe more specific and in more detail.	1 1 2 1	General the requirements are met – some specific steps like client needs, project plan, verification and validation have to describe more specific and in more detail.	1 1 2 1	General the requirements are met – some specific steps like client needs, project plan, verification and validation have to describe more specific and in more detail.	1 1 2 1	General the requirements are met – some specific steps like client needs, project plan, verification and validation have to describe more specific and in more detail.	1 1 2 1

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Order letter o Customer inquiries o Records of consultations with customers o specifications o drawings o Trend analyses o Competitor analyses o Research re standards and statutory requirements		Determination of: • product requirements including delivery and post-delivery support • requirements not stated by the customer but necessary for the use • statutory and regulatory requirements - all additional requirements laid down by the organization	The corresponding determination of client-needs should be improved	2 2 3 2	The corresponding determination of client-needs should be improved	2 2 2 2	The corresponding determination of client-needs should be improved	2 3 2 2	The corresponding determination of client-needs should be improved	2 2 2 2

7.2.2 Review of requirements related to the product

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Evidence of quotations, contracts, contract review o Documentation of amendments o Feasibility analysis records o Feasibility studies o Confirmations of orders o calculations o price lists o delivery schedules		Review of product requirements prior to commitment to supply product to customer. The following must be ensured: - definition of product requirements - elimination of contradictions - contract review • feasibility · technical · commercial · qualitative • documentation and understanding of amendments	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	 2 2 2 2 2	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	 2 2 2 2 2	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	 2 2 2 2 2	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	 2 2 2 2 2

7.2.3 Customer communication								
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala	Nicaragua
o process description o work instructions o projects o Customers' product specifications o Inquiry documents o Contracts o Confirmation of order o Advertising material o Customer surveys and reports of customer visits o Customer-satisfaction analyses o Queries, complaints o Complaint analyses o Customer requests for changes		Determination and implementation of communication with customers concerning: • product information • inquiries, contracts or order handling, including amendments • customer feedback, including customer complaints		1		1	1	1

7.3 Design and development

7.3.1 Design and development planning

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Project plans o Design and development plans and flow charts o Milestone plans o Measurement and test plans o Verification and validation specifications o Approval provisions o Responsibility matrix o Risk assessment		Planning and controlling of design and development; in this context, the following aspects must be defined: - design and development stages - review, verification and validation process - responsibilities and authorities - actualization of plans • interfaces and communication between the various groups involved	The environmental project should be planned in a more effective way. The documentation of client needs is incomplete.	3 2 3 2	The environmental project should be planned in a more effective way. The documentation of client needs is incomplete.	3 2 3 1	There is no clear delimitation to the marketing process. The environmental project should be planned in a more effective way. The documentation of client needs is incomplete.	3 2 3 3	The environmental project should be planned in a more effective way. The documentation of client needs is incomplete.	2 2 3 1

7.3.2 Design and development inputs											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua		
o Specifications / terms of reference o Statutory and/or regulatory implementing guidelines o Result reports from previous similar design and development activities o Evaluation of customer-requirement analyses o Patent research o Approval documents o trend in customer complaints o trends (statistics) o guarantees evaluations o FMEA's		Determination and recording of input relating to product requirements. This includes - functional and performance requirements - applicable statutory and regulatory requirements • previous design and development results obtained in connection with similar products - other requirements (price, service life, recyclables) - adequate, clear-cut requirements	The determination and recording of input relating to product requirements has to be improved	2 2 2 2 2	The determination and recording of input relating to product requirements has to be improved	2 2 2 2 2	The determination and recording of input relating to product requirements has to be improved	2 2 2 2 2	The determination and recording of input relating to product requirements has to be improved	2 2 2 2 2	

7.3.3 Design and development outputs

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o drawings o FE-calculations o QM-plans o Acceptance certificates o Order documents containing specifications o Risk analyses (e.g. FMEA) o Test records (for production, verification and validation) o Approval documents o sample test		Design and development output must: - meet input requirements for design and development • provide information for purchasing, production and service provision - reference product acceptance criteria - specify product characteristics essential for its safe and proper use	The design- and development outputs should be established more consequent.	2 2 2 2	The design- and development outputs should be established more consequent	2 2 2 2	The design- and development outputs should be established more consequent	2 2 2 2	The design- and development outputs should be established more consequent	2 2 2 2

7.3.4 Design and development review

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Intermediate / final design and development reports o Appropriate test records, e.g. of laboratory or field testing o Minutes of meetings o Milestone and phase reviews o FMEA o Models and simulations o Approval documents		- Systematic review of design and development at suitable stages (s. 7.3.1) - to assess their ability to fulfill requirements • to identify problems and propose necessary action - The results of the review and the necessary action must be documented. (s. 4.2.4)	Sensible mile-stones should be introduced	3	Sensible mile-stones should be introduced	1	Sensible mile-stones should be introduced	3	Sensible mile-stones should be introduced	2

7.3.5 Design and development verification											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua		
o Test plans (verification requirements) o Prototypes / test samples o Test records / reports o Records of alternative calculations /analyses o Test / simulation reports o Records of experiments / trials o Description of follow-up measures o Approval documents		Design and development verification must ensure that: - design and development outputs satisfy design and development input requirements (s. 7.3.1) - follow-up action is defined - verification results have been documented. (s. 4.2.4)	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 2 2	The terms of validation and verification do not exist in the vocabulary of the Management-system *Documentation*	2 2 2	The terms of validation and verification do not exist in the vocabulary of the Management-system *Documentation*	2 2 2	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 2 2	

7.3.6 Design and development validation											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Test plans (validation requirements) o laboratory tests o environmental tests o Results of pilot series / field testing o Test records / reports o (possibly from customers, too) o Results of -life testing o field testing o Evaluation results from other bodies o Validation approvals		Design and development validation must ensure: (s. 7.3.1) - fitness for use - partial validation, if applicable • validation prior to product delivery, if possible - documentation (s: 4.2.4)	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 3 3 2	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 2 3 2	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 2 3 2	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation	2 2 3 2

7.3.7 Control of design and development changes											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua		
o Documented requests for changes (e.g. by the customer, production, ...) o New revision stage of e.g. specifications, drawings, process descriptions, test procedures, measurement systems, o Comments, test reports in connection with changes o Approval documents in connection with implemented changes o Communication of changes to customers, units o Withdrawn documents o history of changes		This involves review of the following aspects: - identification and documentation of changes • review, verification, validation and approval prior to implementation • review of effects of changes in design and development and of follow-up action on product • documentation of review results (s. 4.2.4)	The identification and documentation of changes regarding of environmental is not established	3	The identification and documentation of changes regarding of environmental is not established	3	The identification and documentation of changes regarding of environmental is not established	3	The identification and documentation of changes regarding of environmental is not established	3

7.4 Purchasing

7.4.1 Purchasing process

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Product specifications o Supplier's quality system documentation o Checklist o Evidence of supplier evaluation o List / database of approved suppliers o Evaluation criteria o complaints o statistics o specifications		The purchased product must conform to product requirements. The supplier must be evaluated and criteria for such evaluation established. The following aspects must be considered in the purchasing process, e.g.: - external product quality - factors of influence - supplier capability - criteria for supplier selection, regular evaluation and re evaluation - documentation of evaluation (s. 4.2.4)	There is a described purchasing-process. Some issues have to be added within the process-documentation. There has to be a difference between existing and new clients.	 2 2 2	There is a described purchasing-process. Some issues have to be added within the process-documentation.	 1 2 2	There are lists of suppliers. There is a described purchasing-process. Some issues have to be added within the process-documentation.	 2 2 2	There is a described purchasing-process. Some issues have to be added within the process-documentation.	 1 2 2

7.4.2 Purchasing information									
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Product specifications o Order forms o purchasing specifications in EDP o Order lists, piece lists o Performance / delivery contracts o Quality assurance agreements o Order approval documents		- Purchasing information must describe the product to be purchased. Such information must include, where appropriate, a description of the requirements pertaining to: - product approval, procedures, processes, facilities and equipment - personnel qualification - the quality system. - The adequacy of requirements must be ensured prior to their communication to the supplier	See 7.4.1		See 7.4.1		See 7.4.1		See 7.4.1	

7.4.3 Verification of purchased products									
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Acceptance criteria o Verification plans o Test regulations o Regulations re approval under concession o Test records of suppliers or of organization's own incoming inspection o Certifications o incoming inspection		In this context inspection/other activities must be established and implemented which verify product conformity with requirements. For verification measures conducted at the supplier's premises, the intended verification measures and methods must be defined.	See 7.4.1		See 7.4.1		See 7.4.1		See 7.4.1	

7.5 Production and service provision

7.5.1 Control of production and service provision

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Acceptance criteria o Work instructions o Test plans o drawings o Maintenance plans o Installation plans o Service contracts o Operating instructions o Process flow charts		In this context: (s.a. 7.1) - product characteristics must be defined, - work instructions, as necessary, must be made available, - suitable equipment must be used, - monitoring and measuring devices must be made available, - activities must be monitored and measured - release and delivery of products/services must be ensured • post-delivery activities must be implemented		1 1 1 1 1 1		1 1 1 1 1 1		1 1 1 1 1 1		1 1 1 1 1 1

7.5.2 Validation of processes for production and service provision											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua		
o Evidence of machinery and process capability o Process descriptions o data of process control o Skills documentation and training certificates o Qualification certificates o Validation specifications		Validation must demonstrate process capability. In this context, the following must be taken into account: validation of all production processes where the resulting output cannot be verified by subsequent monitoring or measurement. This includes all processes where deficiencies become apparent only after the product has been delivered. Validation must include (where appropriate): - criteria for review and approval - approval of equipment and personnel qualification - use of specific methods and procedures - requirements pertaining to quality records (s. 4.2.4) - possible necessity of renewed validation		1 1 1 1 1		1 1 1 1 1		1 1 1 1 1		1 1 1 1 1

7.5.3 Identification and traceability											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Work instructions o Accompanying documents, e.g. routing slips o production plans o IT records o Product identification o Test certificates o Segregation slips o Approvals		- Where appropriate, the product must be identified throughout product realization - The product status must be identified with respect to monitoring and measurement requirements. - .Identification must be controlled and recorded, if traceability is required		1 1 1		1 1 1		1 1 1		1 1 1

7.5.4 Customer property											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Inventory of customer property o Identification (e.g. labels, stickers) o Correspondence with customers o Records on verification and maintenance conducted o Incoming inspection		In this context, the following must be observed: • careful handling (also where intellectual property is concerned) - identification, verification, protection and maintenance - procedure and documentation in cases involving damage or loss (notification of customer)		1 1		1 1		1 1		1 1

7.5.5 Preservation of product								
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Regulations on packing, storage, preservation and delivery o Piece lists o Inventory lists o Stock-replenishment and –withdrawal plans o Regulations on storage periods and segregation (where appropriate) o delivery labels o Assembly / operating instructions		This refers to both internal processing and delivery and must include: - preservation of product conformity - identification - handling - packaging - storage - protection • This also applies to the constituent parts of products.		1		1		1		1

7.6 Control of monitoring and measuring devices

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Test certificates including acceptance criteria o Evidence of capability of monitoring and measuring devices o List or use of EDP for monitoring and measuring devices o Calibration instructions o Calibration records o Gauging records o Calibration standards o Calibration certificates o Records on comparative measurements and inter-laboratory tests o Records on software qualification testing		- Determination of required monitoring and measuring devices	There is no available description regarding control of monitoring and measuring devices. If there are no monitoring and measuring devices there has to be a written exclusion in the QM-documentation.	3	There is no available description regarding control of monitoring and measuring devices. If there are no monitoring and measuring devices there has to be a written exclusion in the QM-documentation.	3	There is no available description regarding control of monitoring and measuring devices. If there are no monitoring and measuring devices there has to be a written exclusion in the QM-documentation.	3	There is no available description regarding control of monitoring and measuring devices. If there are no monitoring and measuring devices there has to be a written exclusion in the QM-documentation.	3
		- Determination of monitoring and measuring device ability		3		3		3		3
		- Calibration and adjustment at regular intervals		3		3		3		3
		- Identification of measuring equipment		3		3		3		3
		- Identification of calibration status		3		3		3		3
		- Steps to ensure protection and handling		3		3		3		3
		- Documentation of calibration results		3		3		3		3
		- Definition of corrective action		3		3		3		3
		- Documentation		3		3		3		3
		- If the equipment is found not to conform to calibration requirements, previous measuring results must be reassessed and documented.		3		3		3		3
		- The capability of computer software must be confirmed. Capability must be confirmed prior to initial use and reconfirmed as necessary.		3		3		3		3

Chapter of standard: 8. Measurement, analysis and improvement

8.1 General

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Design and development flow charts o Design and development test plans o company data system o objectives and the actualisation o Improvement schemes o Statistics o Progress reports o Information boards o inputs for continual improvements		• Monitoring, measurement, analysis and continuous improvement processes must be - defined - planned - implemented (s.a. 4.1) to demonstrate conformity of the product and the quality system and improvement of quality system effectiveness. • Determination of applicable requirements must include the use of suitable statistical techniques.	The process of continuous improvement is not implemented effectively and consistent.	 3 2 2 3	The process of continuous improvement is not implemented effectively and consistent.	 2 2 2 3	The process of continuous improvement is not implemented effectively and consistent.	 2 3 2 3	The process of continuous improvement is not implemented effectively and consistent.	 2 2 2 3

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
• Action catalogs • Customer-satisfaction analyses • Benchmarking • Checklists • Evaluation of mailing and telephone initiatives • Evaluation records (general) • Records of target requirement review		Customer perception must be monitored. Methods of obtaining and using this information must be determined. (s.a. 5.2)	Monitoring of customer perception has not been established in all relevant parts.	3	Monitoring of customer perception has not been established in all relevant parts.	3	Monitoring of customer perception has not been established in all relevant parts.	3	Monitoring of customer perception has not been established in all relevant parts.	3

8.2.2 Internal audit

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o DP internal audits o Audit plans o Audit reports o Nonconformance reports o Action catalogs for the establishment of corrective action o Test records etc. o Management reviews o Reports on effectiveness of corrective action o Evidence of auditor qualification		- Conducting of internal audits to the planed arrangements (s.7.1) at planned intervals - planning - execution - documentation - evaluation - definition and implementation of corrective action - surveillance - The results of previous audits must be taken into account. - The objectivity and impartiality of auditors must be ensured.	The process of internal audit does not exist yet.	3	The process of internal audit does not exist yet.	3	The process of internal audit does not exist yet.	3	The process of internal audit does not exist yet.	3

8.2.3 Monitoring and measurement of processes											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o company data o Process data o controlling data o statistic analysis o Quality data o SPC-data and evaluations o Work instructions o Risk analysis records (FMEA) o Maintenance and servicing plans and implementation measures o Q records o Test plans o Test records		Suitable methods for monitoring and measurement of quality system processes must be determined, applied, reviewed and corrective and preventive action implemented, where appropriate. (s. 7.1+5.1)	There are defined key indicators but the method of measurement and general coordination has not been implemented yet.	2	There are defined key indicators but the method of measurement and general coordination has not been implemented yet.	2	There are defined key indicators but the method of measurement and general coordination has not been implemented yet.	2	There are defined key indicators but the method of measurement and general coordination has not been implemented yet.	2

8.2.4 Monitoring and measurement of product										
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Test plans o Test instructions o Test records o Sampling plans (attributive und variable) o Checklists o Comparative samples o Q records o Approval under concession by the customer or an authority (where appropriate)		- Product characteristics: - monitoring - measuring - verification - documentation - at appropriate stages of product realization.(s. 7.1) - Products or service may only be approved after conformity has been established. - The responsible person for release must be identified in each case.	See 8.2.3	2 3 2 2	See 8.2.3	2 3 2 2	See 8.2.3	2 3 2 2	See 8.2.3	2 3 2 2

8.3 Control of nonconforming product

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o DP control of nonconforming product o Nonconformance records o Test regulations o Test certificates o Customer information o Additional test plans, where appropriate o Approval records o Expert opinions o Approval under concession o Identification requirements		- Nonconforming products must be: - identified - separated - controlled - corrected - re-verified - documented	The handling of non-conforming Services and products has not been established in all relevant parts.	2	The handling of non-conforming Services and products has not been established in all relevant parts.	2	The handling of non-conforming Services and products has not been established in all relevant parts.	2	The handling of non-conforming Services and products has not been established in all relevant parts.	2
		- corrected nonconforming products must be: - re-verified,		2		2		2		2
		- approval by customer under concession, where appropriate		2		2		2		2
		• Consequences of nonconformances, also for products in use must be: - determined and - action taken		2		2		2		2
		- records of concessions shall be maintained		2		2		2		2

8.4 Analysis of data

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Measurement and test records o Nonconformance records o Records of customer complaints o Customer-satisfaction analyses o Audit reports o Q reports o Records relating to field experience o Target/performance comparison reports		• Appropriate data to demonstrate quality system suitability and effectiveness must be: o determined o collected o analyzed • to provide information relating to o customer satisfaction/dissatisfaction (s. 8.2.1) o conformity of product requirements (s. 7.2.1 o process and product characteristics (s. 8.2.3 + 8.2.4) o suppliers (s. 7.4.1) for the purpose of continuous improvement of the effectiveness of the quality management system	There is no process data analysis and client satisfaction.	2	There is no process data analysis and client satisfaction.	2	There is no process data analysis and client satisfaction.	2	There is no process data analysis and client satisfaction.	2

8.5 Improvement

8.5.1 Continuous improvement

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o Quality management plans o Project plans o Documentation of target requirements o Progress reports o Management reviews o Corrective-action catalogs o Preventive-action catalogs o inputs for continual improvements		Continuous improvement must be made possible through the use of - the quality policy - quality objectives - audit results - data analysis - corrective and preventive action - management review. (s. 4.1)	There are some relevant elements missing	2 3 3 2 2 3	There are some relevant elements missing	2 3 2 2 2 3	There are some relevant elements missing	2 3 2 2 2 3	There are some relevant elements missing	2 3 3 2 2 3

8.5.2 Corrective action

Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o DP Control of corrective action o Nonconformance records o 8-D-reports o Statistical evaluations o Test / result records o Instructions re corrective action o Training plans o Training certificates o Complaints analyses o Amended delivery contracts (where appropriate), o Q agreements o Investment plans o Documentation of reviews		To prevent the recurrence of nonconformances, the documented procedure must cover the following aspects: - reviewing nonconformities (incl. Customer complaints) - determination of the causes of nonconformities - required measures to prevent recurrence - action / corrective action - monitoring and evaluation of corrective action - documentation	The process to prevent the recurrence of nonconformances is not established appropriate.	2 2 3 2 3 2	The process to prevent the recurrence of nonconformances is not established appropriate.	2 2 3 2 3 2	The process to prevent the recurrence of nonconformances is not established appropriate.	2 3 3 2 3 2	The process to prevent the recurrence of nonconformances is not established appropriate.	2 2 3 2 3 2

8.5.3 Preventive action											
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o DP Control of preventive action o Risk analyses (economic / technical) o Nonconformance records o 8-D-reports o Analyses records o Test records o Action catalogs o Training plans o Training certificates o Amended delivery contracts o Q agreements o Investment plans o Trend analysis o cost evaluations o inputs for continous improvement		To eliminate the causes of potential nonconformances, the documented procedure must cover the following aspects: - determination of potential nonconformances - planning of preventive action - implementation of preventive action - evaluation of preventive action taken - documentation	There is no process established to eliminate the causes of potential nonconformances.	3 3 3 3 3	There is no process established to eliminate the causes of potential nonconformances.	3 3 3 3 3	There is no process established to eliminate the causes of potential nonconformances.	3 3 3 3 3	There is no process established to eliminate the causes of potential nonconformances.	3 3 3 3 3

3 Progress of QM-documentation

3.1 Interpretation of the "process progress template"

The following template was used during the 2nd mission to evaluate the process progress. Each process was evaluated based on the rating listed below. The evaluation has got a subjective character but can be used as a general surveyor's rod and to compare the different centers. The progress graph of each center is linked with the individual process architecture also provided as graph.

Audit regarding completeness of the QMS documentation

o Costa Rica o Guatemala o El Salvador o Nicaragua

process	0%	25%	50%	75%	100%
1100					
1200					
1300					
1400					
1500					
1600					
1700					
2100					
2200					
2300					
2400					
2500					
2600					
2700					
2800					
2900					
3100					
3200					
3300					
3400					
3500					
3600					
3700					
3800					
3900					

0%... No documents at all

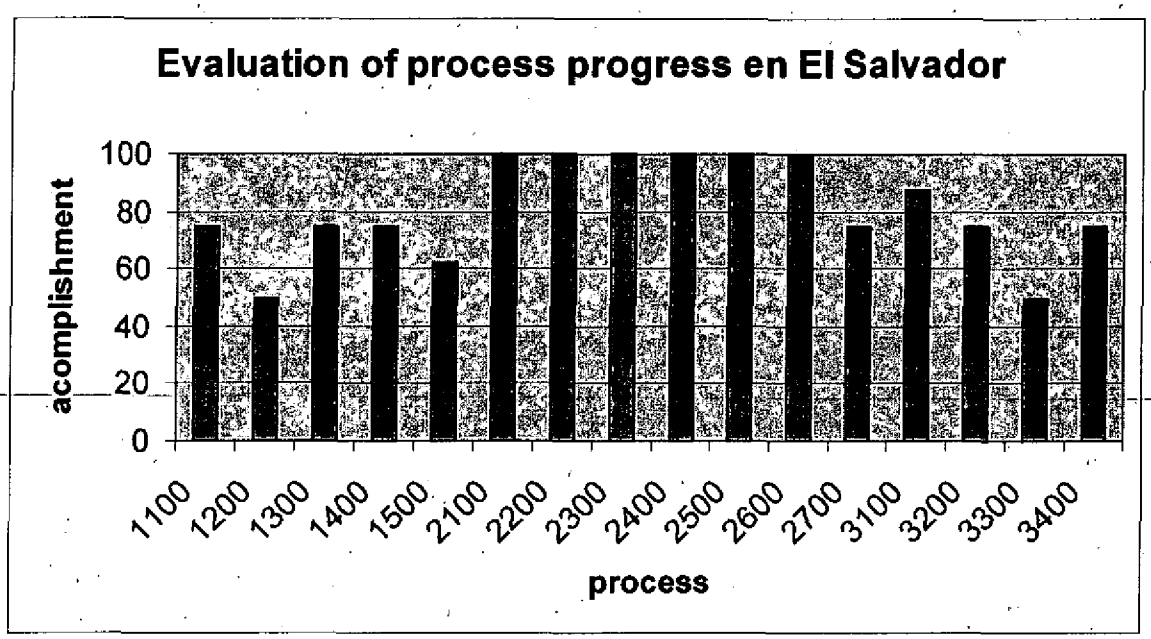
25%... half of process description finished, few appended documents

50%... process description finished, few appended documents

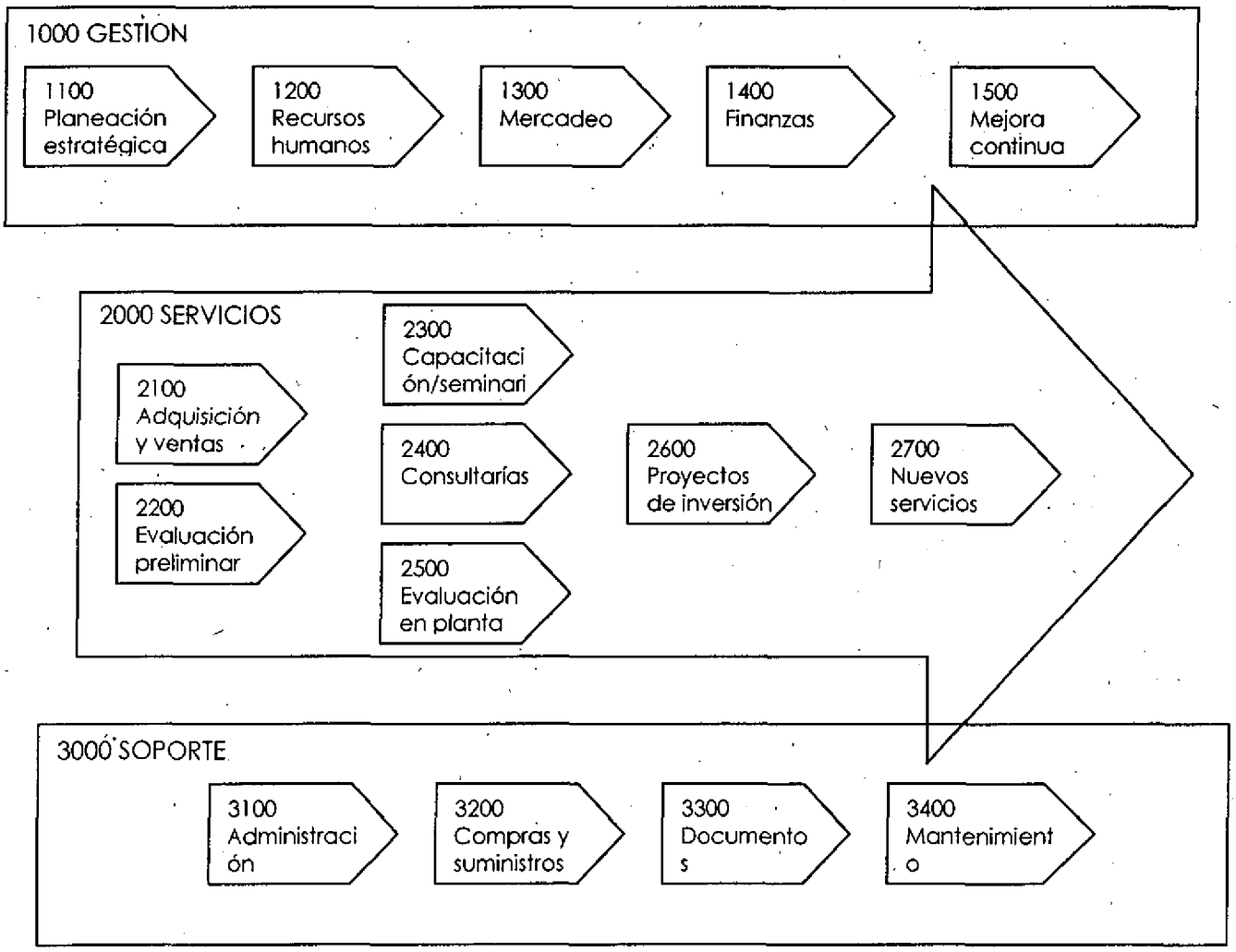
75%... process description finished, half of appended documents finished

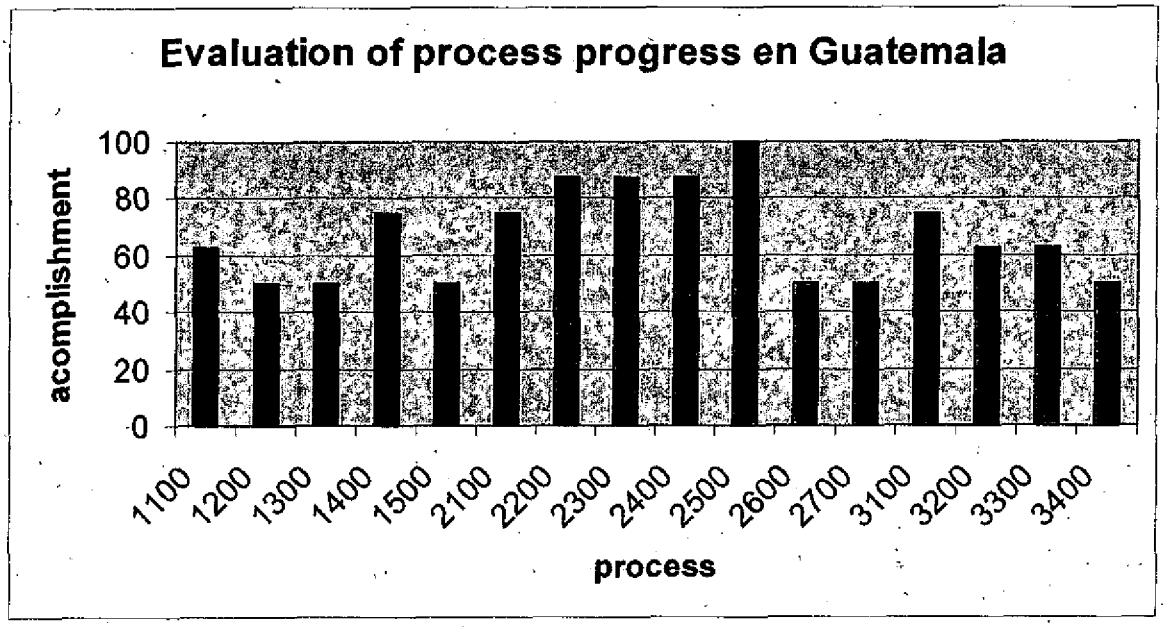
100%... process description finished, all appended documents finished

3.2 Results regarding process progress at each CPC

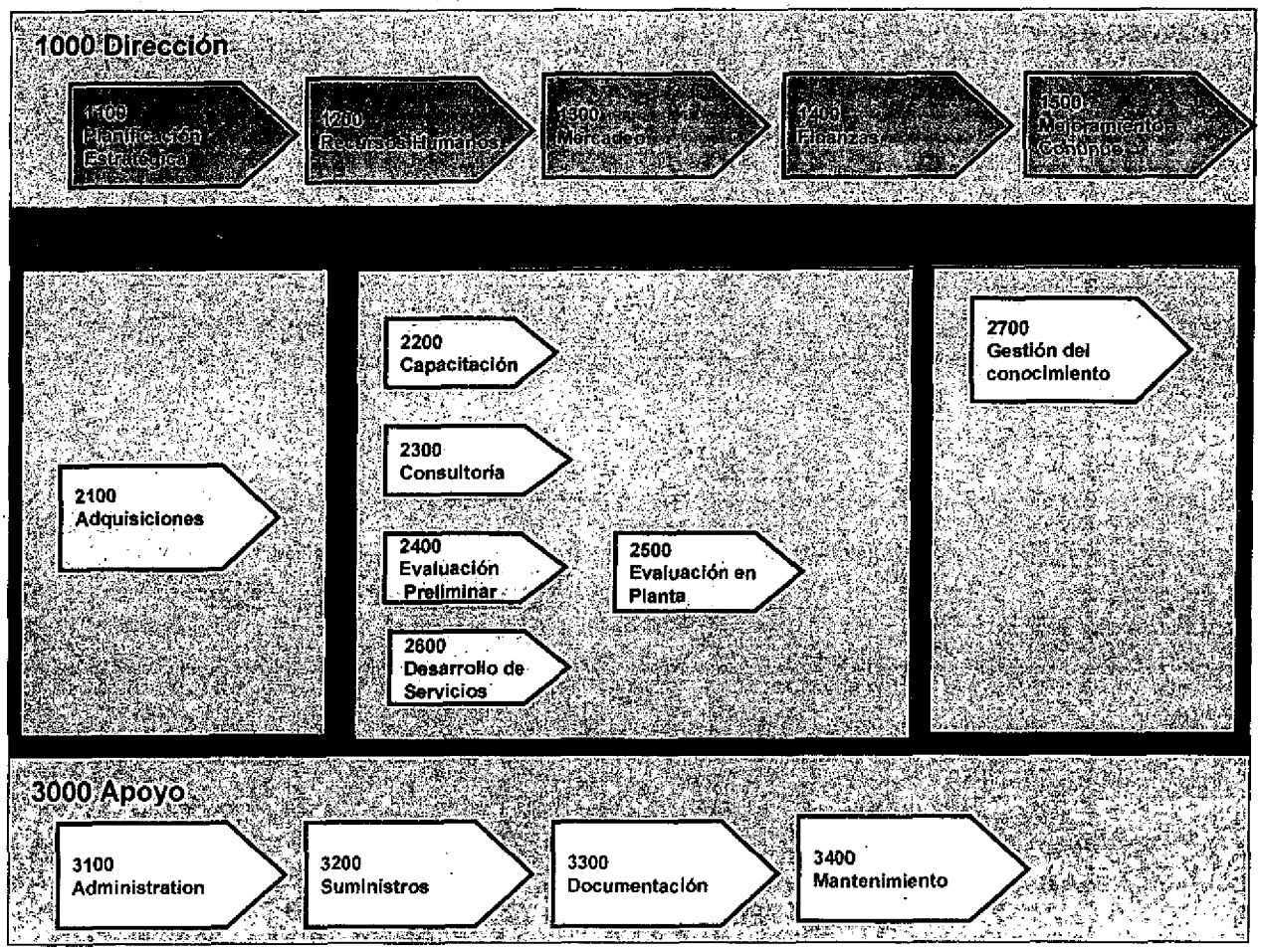


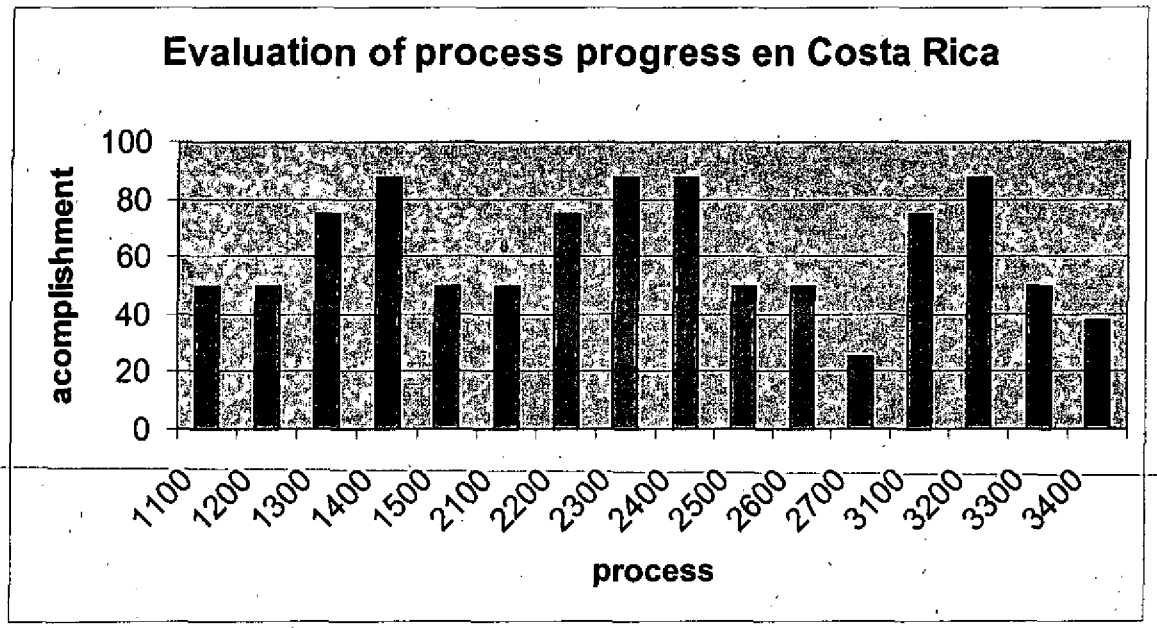
Process architecture NCPC El Salvador



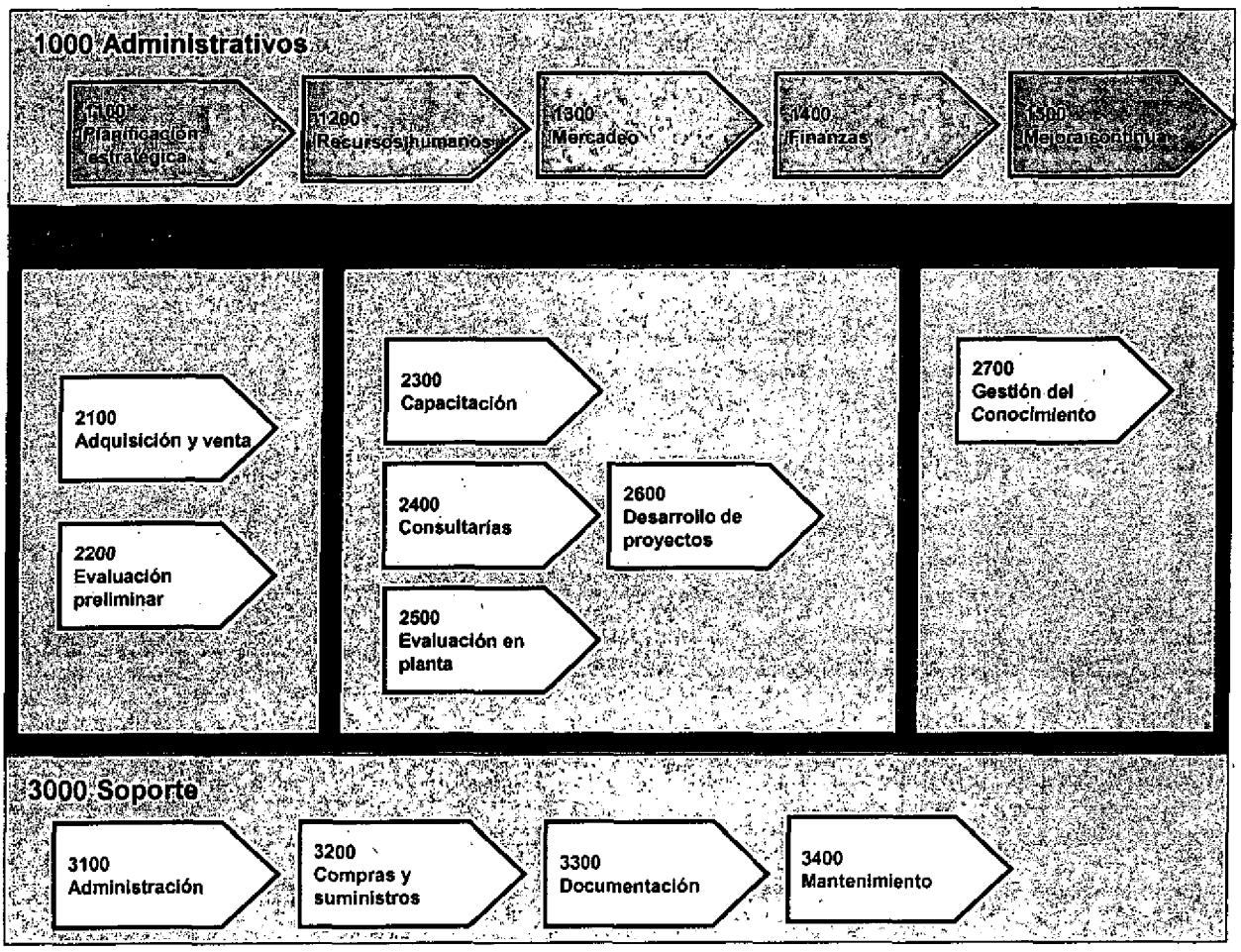


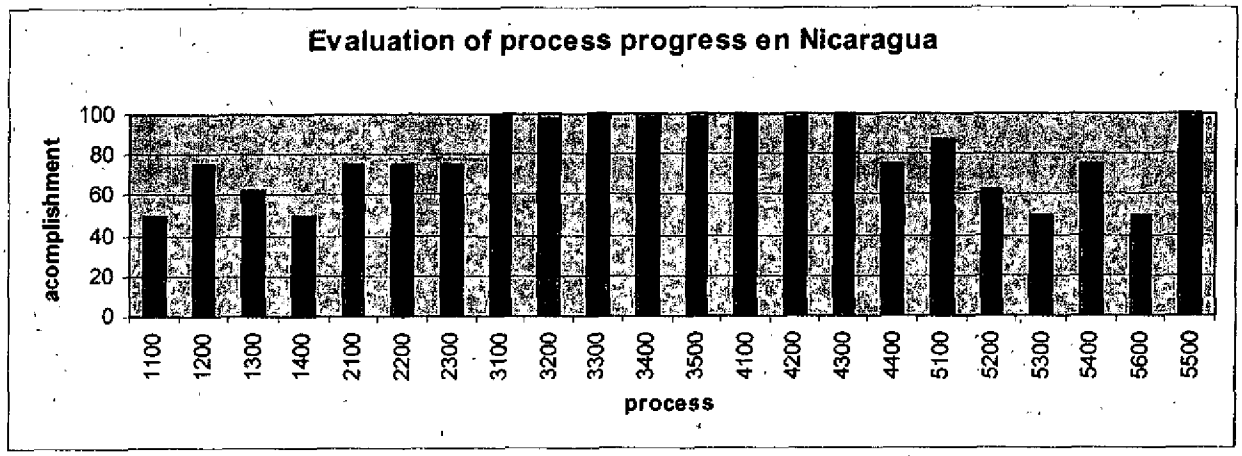
Process architecture NCPC Guatemala



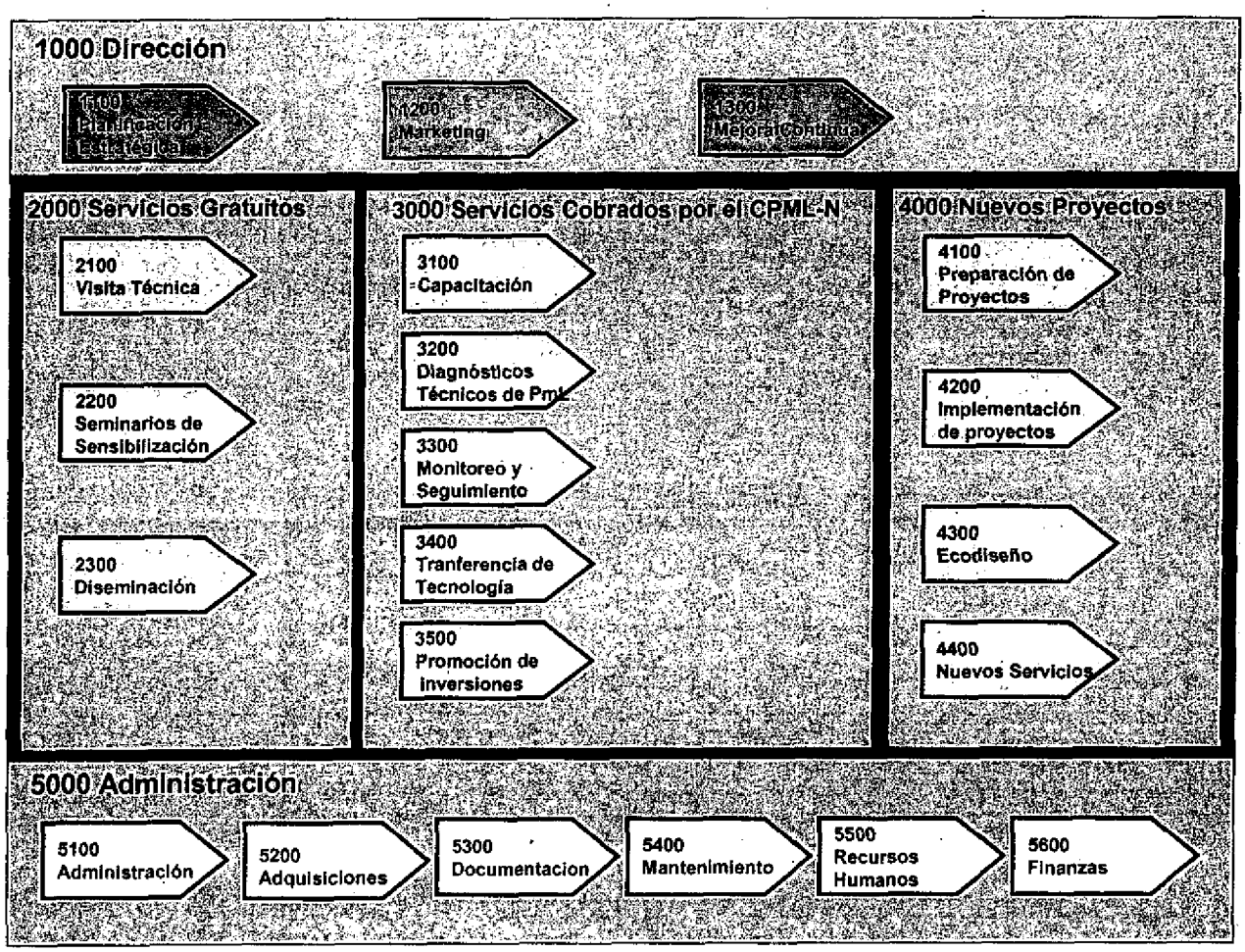


Process architecture NCPC Costa Rica





Process architecture NCPC Nicaragua



4 Examination of Quality Managers

All quality responsible of the different NCPC were invited to do an examination in order to get the certificate as Quality Manager EOQ. All participants of the QM-training held in Guatemala in May 2005 applied for the examination. The European diploma is internationally recognised and a proof for the knowledge of the subject. For that reason before the mission the expert together with FHBB organised an English version of the test questionnaires the participants had to fill in. In addition an oral examination was conducted by the expert during the workshops at each NCPC to verify the know-how.

The examination will be passed by reaching 60% of the maximum points. Fortunately, every participant reached the necessary sum of points; a result that shows sufficient know-how for the new role as quality manager at an NCPC. Following candidates were successful:

- Ms. Ana Victoria Rodriguez (Guatemala)
- Mr. Carlos Perera Heinrich (Costa Rica)
- Ms. Carla Isabel Romero Garcia (UNIDO Guatemala)
- Mr. Nelson Mauricio Vaquero Andrade (El Salvador)
- Mr. César Vallejo Bolanos (Guatemala)
- Ms. Tania Urbina (Nicaragua)
- Ms. Akira Hidalgo Segura (Costa Rica)

The participants will get the official certificates soon from FHBB that were covered by SAQ. The title is valid for five years and expires in 2010. In Switzerland this international certification can only be obtained by SAQ. An example for the certificate is listed in Annex 2 of this report.

5 Review and conclusion

Although the time for the 2nd QM-mission was very limited, it was possible to go trough all *process-descriptions of the Quality Management System with the responsibles.* However, to discuss all process descriptions and appended documents was not possible. It was agreed with the involved QM-managers that from the first QM-training in May 2005 and the internal audit of October 2005 a selected regional coordinator should be responsible for the elaborated QMS documentation. This task included collection and distribution of the QMS documentation from and to each NCPC, which has not been satisfactory performed. Therefore FHBB took over and acted as a platform for the NCPC. Nevertheless, not all of the process descriptions were elaborated by the NCPC and available before the expert's mission as foreseen.

Some of the quality managers expected a clearer statement about the correctness of the process descriptions contents from the expert Mr. P. Schönenberger. It is obvious that the structure and complexity of the QMS is a core task of the NCPC and the external auditor is not in the position to define the structure in detail from outside. To build a client-oriented QMS needs internal know-how and creativity. A structure dictated from outside would never be a tailor-made system and therefore would not be accepted by the employee. Probably this perception has also been an experience of the people involved in this project. The main task of the expert during this mission was to check the conformity acc. to ISO 9001.

Non-conformities with the standard have been discussed during the internal audits and the project members were advised to add missing parts or to correct non-conformities immediately and not only after receiving the final audit-report. For the detailed list of the audit results see chapter 2.2. From the expert's point of view it is possible to get the ISO 9001 certification for *each centre by April 2006 if the project plan is followed (see chapter 6). Generally, each centre* made a big effort and the QMS documentation is on a good level. The expert Mr. Peter Schönenberger offered the NCPC to review the final QMS documentation regarding conformity

to ISO 9001. For that reason the responsible are requested to finalize the descriptions and to send the last version to the backstopping manager, Mr Jürg Walder at FHBB with a respective note.

It has been agreed with the QM-responsible that the release of the whole documentation of the Management-System (going "live") has to be on 1st January 2006 at the latest (every NCPC agreed).

Unfortunately, the directors of all centres were not or shortly present during the workshops although they were informed and invited several months in advance. Of course we do not see this as representative for the priority of the Quality Management System within the Centres as the directors backed FHBB's initiative to implement a QM-system according to ISO 9001:2000. However, it has to be emphasised at this point, that the successful ISO 9001-certification is very much dependent on the involvement and commitment of the centres' management. No involvement may lead to failure of the certification audit.

The expert recommends choosing Swiss TS (TÜV) for the certification in spring 2006. Swiss TS (TÜV) is internationally present and well known by the expert. This certification body conducts audits on a very professional level to fair conditions and has a representative in Mexico that could continue with the mandatory surveillance audits. The presence of the coach Mr. P. Schönenberger, SAQ-Qualicon during the certification audit is not compelling but might have a decisive influence to pass the external certification-audit. Sometimes the auditors tend to ask about issues which are not required by the standard ISO 9001. To discuss and deal within those particular situations an ISO-expert could help the NCPC to get a better position.

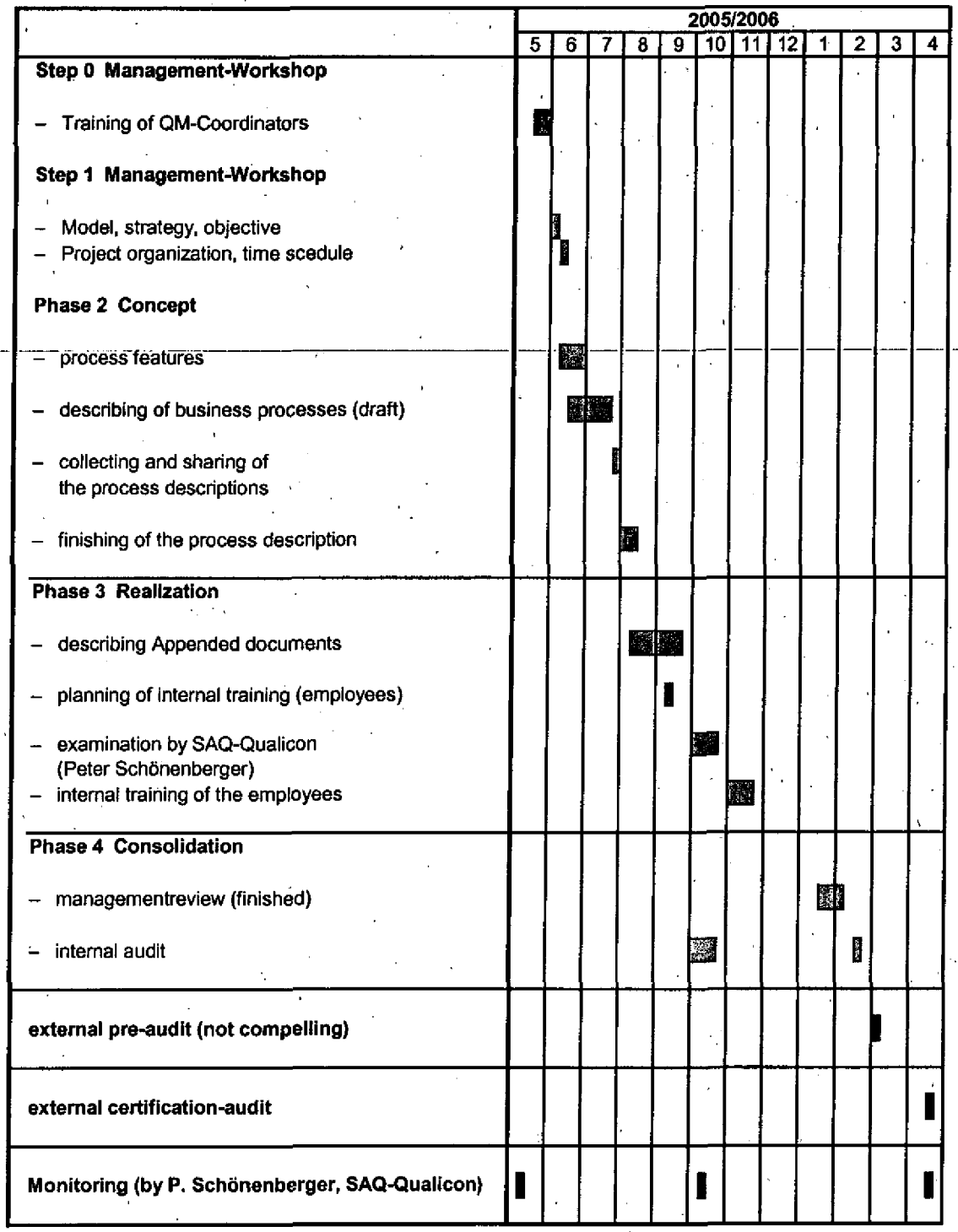
6 "To do – list" until Certification (April 2006)

This "to do- list" corresponds with the project plan and the defined process owners

To do	Responsibility	Deadline
Definition of individual model, strategy, objectives. Planning of necessary time resources to fulfil the objectives of the project	Each project leader together with the top management within the corresponding center	15th June 2005
Draft of process description	Each process owners (name is defined in the process architecture, figure 3) In a first step the following processes will be drafted by P. Schönenberger: 1100 Strategic planning 1300 Marketing 1500 Continuous Improvement 3300 Documentation	15th July 2005
Collecting of the drafts of process description	Carlos Perera (CNP+L) Costa Rica	25th July 2005
Distributing of the drafts of process description (to each centre and P. Schönenberger)	Carlos Perera (CNP+L) Costa Rica	30th July 2005
Finishing the process description individual (related to the centre),	Each process owner	15th August 2005
Creating of a draft of the management review	Each project leader together with the top management within the corresponding centre	15th September 2005
Creating of an internal training plan for the employees		15th September 2005
Creating of an internal training plan for the employees		15th September 2005
Preparation of the Examination regarding EOQ certification (Quality Systems Manager)	Participants of the training	30th September 2005
Creating of the appended documents (each centre on its own)	Each process owner	20th September 2005

To do	Responsibility	Deadline
Finishing and completing the Quality-Management Documentation (by considering the suggestions and nonconformities of the external audit, 2nd mission from SAQ-Qualicon AG, October 05)	Each process owner	30th November 2005
Creating of an internal training plan for each employee – realization of this training until end of January	Project-leader / each process owner	31st December 2005
Going "live" with the Management-System. Release of the whole documentation of the Management-System by the director of the NCPC.	Each project leader together with the top management within the corresponding center	1st January 2006
Creating of the management review. All defined and available key indicator figures have to be included		28th February 2006
External certification-audit	Every employee	25th April 06

Annex 1 Adjusted project plan



Annex 2 EOQ Certificate (example)

European Organization for Quality

This is to certify that

Tania Urbina

born in Nicaragua, on 22-06-1982

has fulfilled the requirements of the
EOQ Personnel Registration Scheme as

EOQ Quality Systems Manager

The holder of the certificate has proven the knowledge and practice in accordance with the EOQ Harmonized Scheme in front of the EOQ Full Member Organization of Switzerland: SAQ

This certificate is valid for 5 years and **expires on 15-12-2010**

For the SAQ

Head of Certification

For the EOQ

Secretary General

Registration No.: CH05QSM-1643
Date: 28-11-2005

This certificate is property of the European Organization for Quality (EOQ)