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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

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# 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/lfU, 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

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	Requirement / subject	- 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	nse	- 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		
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4.2.3 Control of document	Documents reviewed	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						·										

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o Manpower-		statutory and			available.		system effectiveness	-		
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o Records of defined		- Establishing of quality		~		6	Recause there is no   2			۰
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o Investment plans	-	5.4)		2		1-				
o Plant agreements		- Conduct of		ო		~	<u> </u>			ç
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		(s. 5.6)				•				
		- Steps taken to		_		_			,	-
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Documents reviewed Obc.         Requirement / subject         Costa Rica         El Salvador         Guatemala         Nicaragua           • Evaluation of customer surveys customer surveys customer surveys customer surveys half ensure the customer surveys customer surveys half ensure the customer analyses of customer analyses of customer analyses of customer analyses expectation (s.a. Product validation records customer satisfaction analyses of customer satisfaction analyses of customer surveys and surveys analyses of customer satisfaction analyses of customer satisfaction analyses of customer satisfaction analyses of expectation (s.a. Standards of customer satisfaction analyses of expectation (s.a. Standards of customer satisfaction analyses of expectation analyses of customer satisfaction analyses of expectation analyses of customer satisfaction analyses of expectation analyses of expectation analyses of expectation analyses of customer satisfaction analyses of expectation an	5.2 Customer focus	sno								
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	Guatemala	specific sion. The ssues see	"(this issues are obligatory)		
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	El Salvador	There is no specific model or vision. The necessary issues see below "Requirement/subject	"(this issues are obligatory)	•	
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	Costa Rica	There is no specific model or vision. The necessary issues see below "Requirement/subject" (this issues are obligatory)			
	Requirement / subject	- 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
	Doc.				
5.3 Quality policy	Documents reviewed	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	,

5.4 Planning										
5.4.1 Quality objectives	2									
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala	N	Nicaradua	
o Quality Manual o Internal/external		Determination on the basis of data and	Agreements/ Goals should be harmonized with the	2	Agreements/ Goals should be	2	There is no approved 2	+ -	Agreements/ Goals	2
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	Requirement / subject	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		1		•
	Doc.				,		•								
ir	Documents reviewed	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	

5.5.1 Responsibility and authority         Requirement / subject         Costa Rica         El Salvador         El Salvador         Guatemala         Nicaragua           Documents reviewed         Doc.         - Definition and communication of person of responsibilities and authorities         The overall responsible person of person of the QMS has to be responsibilities and authorities         The overall responsible person of the QMS has to be responsibilities and authorities         The overall responsible person of the QMS has to be defined. Function authorities         The overall responsible person of the QMS has to be responsibilities and authorities         The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be available or to be available or to be adjusted         The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be available or to be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be available or to be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should be available or to be adjusted         Approximation of the QMS has to be defined. Function descriptions should available or to b	плиту, аптиоги	5.5 Responsibility, authority and communication	ion						1	
Requirement / subject Costa Rica	thority									
The overall responsible 3 The overall 3 The owerall 3 The owerall 3 The overall 3 The owerall 3 The overall 3 The owerall 4 The	Ċ.	Requirement / subject	Costa Rica		El Salvador		Guatemala	ž	aragua	
		- Definition and communication of responsibilities and authorities	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	က	The overall responsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	6	The overall sesponsible person of the QMS has to be defined. Function descriptions should be available or to be adjusted	The permanent of the pe	soverall responsible son of the QMS has be defined. Function criptions should be lilable or to be usted	<u>က</u>

5.5.2 Management representative	esentative						
Documents reviewed	Doc.	Requirement / subject   Costa Rica	Costa Rica	El Salvador	Guatemala	Nicaracita	
o Quality Manual o Organizational chart and organizational structure o QMR appointment letter o QMR function profile o QMR job 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 3 person of the QMS has to be defined and documented.	The overall responsible person of the QMS has to be defined and documented.	The overall responsible person of the QMS has to be defined and documented.	The overall responsible person of the QMS has to be defined and documented.	m
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		<u>8</u>	N	•
	,	Quality Management has to be an action issue within every meeting		
	Nicaragua	Quality Management to be an action issue within every meeting		
		8	8	
	ala	Quality Management 2 has to be an action issue within every meeting		
	Guatemala	Quality National August Control of the Control of t		
1		-	Ν.	•
	El Salvador	Quality Management has to be an action issue within every meeting		,
	F	<del> </del>		`
	Costa Rica	Quality Management has to 2 be an action issue within every meeting		
	Requirement / subject Costa Rica	Establishment of suitable communication processes within the organization (s. a. 7.2.3)	Communication     regarding quality     system effectiveness	
ication	Doc.			
5.5.3 Internal communication		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	

5.6 Management review	review									Γ
5.6.1 General										
Documents reviewed	Doc.	Requirement / subject	Costa Rica	F	El Salvador		Guatemala		Nicaragua	
o Management-review		- Regular review of		3	The management-	3	The management-	3	gement-review	8
o monthly		quality system - Assessment of	not avaitable and has to be established	<u> </u>	review is not available and has to	~	review is not available and bas to	ď	is not available and has	,
management reports		opportunities for			be established	. ,	be established	· ·		,
o controlling reports		improvements to	,						,	
o finance reports	•	quality policy and					•			,
o G-reports		quality objectives								
o supplier evaluations	<u>.</u>	- Recording of the		က		က		က	,	<u>س</u>
o logistic reports		need for changes to			-					
		ire quality system								
-					7	],				
5.6.2 Review input									•	<u></u>
Documents reviewed	Doc.	Requirement / subject	Costa Rica	۳	El Salvador		Guatemala		Niceracita	T
o Management-review		Management review	The management-review is		The management-		The management.		The management review	T
report		must include:	not available and has to be		rovious is not		me management		ing management eview	
o Customer-		• audit results			review is not	ŗ	review is not		nd has	
satisfaction analyses		customer feedback	1	) e	avaliable and lids to he established	o ~	available and has to	2 0	to be established	· ·
o Process analyses		• process performance			no le compos de	י כ	De established	,		· ·
o Evidence of		and product-			•	2		2		77
corrective and		conformity					•			•
preventive action		<ul> <li>status of preventive</li> </ul>		.e		m		er.		~
o Resource		and corrective action	•			)		·		<u> </u>
deployment and		<ul> <li>follow-up action from</li> </ul>	,	က		ന		က		63
		previous							•	
o Benchmarking		management reviews								
		changes that could								
o Cuality analyses		affect the quality		<del>ر</del>	•	က		ო		~
o Risk analyses	<u>.</u>	system			-					,
(technical/economic)		recommendations for					,			
o Internal audit reports		improvement (s.		9	,	က	•	n		ري
		8.1+8.2+8.4+8.5)								
o Product audits /										
reports						,	-			•
o Action reports										
o myesunem piananing			1			`	,	`		

Requirement / subject Costa Rica Decisions and actions The management-review is shall include: Improvement of the established effectiveness of the QMS and its processes  product improvements  resource needs	El Salvador			
<i>(</i> 2		Guatemala	Nicaragua	Τ
AS and its cesses duct or verments ource needs	and has to be review is not a available and has to be be satablished	The management-review is not available and has to	The management-review is not available and has to be established	
ovements urce needs	8	3	m	
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Chapter of stan	dard: 6. K	Chapter of standard: 6. Resource management	ment						
6.1 Provision of resources	esources						;		
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador	Ĺ	Guatemala	Nicaragua	
o Quality Manual		- Determination and	The determination and		The determination	Ĺ	The determination	The determination and	ation and
o Investment plans		provision of	provision of resources		and provision of		and provision of	provision of resources	esources
o relating to personnel		resources required	required for implementing,		resources required	_	resources required	required for	
o relating to equipment		for:	maintaining and continually		for implementing,	: -	for implementing,	implementing	
o relating to real estate		- implementing,	improving the quality	က	maintaining and	~	maintaining and 3	maintaining and	nud 3
o Staffing schedules		maintaining and	system is implemented.		continually improving		continually improving	continually improving the	proving the
o Other target plans		DG.	•		the quality system is		the quality system is	quality system is	n is
		the quality system	systematically destination		implemented.		implemented.	implemented.	
		- ensuring customer	of the client satisfaction in	2	There is just one	7	There is just one 2	There is just one	one 2
		satistaction	training.		systematically		systematically	systematically	
,	•				destination of the		destination of the	destination of the client	f the client
			,		client satisfaction in	-	client satisfaction in	satisfaction in training.	training.
		•	,		training.	-	training.		
						7			

Documents reviewed Doc. o Quality Manual o Job / function profiles o Employment contracts o Manpower- development plans o Qualification	WILL S O O I I I I	ement / subject nel performing fecting product must be tent based on: ttion	Costa Rica See 6.2.2	2						
o Quality Manual o Job / function profiles o Employment contracts o Manpower- development plans o Qualification	T > GO 1 1 1 1		See 6.2.2	2	El Salvador		Guatemala		Nicaragua	
o Job / function profiles o Employment contracts o Manpower- development plans o Qualification	<u> </u>	work affecting product quality must be competent based on: - education - training			See 6.2.2	2	See 6.2.2	2	See 6.2.2	2
profiles o Employment contracts o Manpower- development plans o Qualification	001111	quality must be competent based on: - education - training			,					i
o Employment contracts o Manpower- development plans o Qualification	0 1 1 1 1	competent based on: - education - training			•		1			
contracts o Manpower- development plans o Qualification		education - training								
o Manpower- development plans o Qualification	1 1 1	- training			-				-	
development plans o Qualification	1 1	1 1 1 1 1 1 1					r			
o Qualification		- SKIIIS	•							<b></b>
		- experience.	•		•					•
documentation							•			•
o Records of										-
employee interviews										
o Employee				_						
certificates										
o qualification matrix		•								
						-				
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				<del>,</del>	,				•	

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	Nicaragua	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	``.
		က	
	Guatemala	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	
		N .	
	El Salvador	The following needs are missing or incomplete - Job / function plans - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evafuation	:
		m	
	Costa Rica	The following needs are missing or incomplete - Job / function profiles - Induction plans - Records of employee interviews - Training schedules - Training certificates - Records on the evaluation	
ining	Requirement / subject	- Determination of training needs - Provision of appropriate training effectiveness - actions of awarenessbuilding measures for the relevant activities and for the achievements of the objectives - Maintaining of relevant records	
areness and tra	Doc.		
6.2.2 Competence, awareness and training	Documents reviewed	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	

6.3 Infrastructure						
eviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaragua
o Workniace		• Determination	+			,
			-			`
Investigations		provision and				
o Investment plans		maintenance of				
o Maintenance and		infrastructure, e.g.:				
servícing plans and		• buildings, workplace			. ,	
records		and associated				
o Records of process	*	utilities	:			
capability studies		• process equipment				,
o Records of		hardware and	-			
o supplier evaluation		software	•	-		
o (including service	,	• ellonord services			•	-
providers)		(such as transport or	•	•		
		communication)		•		
6.4 Work environment	ment					
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Oilogacily Gillogacily
o Evidence of		- Dofinition and accept				and and
instruction in		· Desiliation and control		<u> </u>	_	
illastiucuoji ili		or work-environment				
		ractors needed to				
o Evidence of the		achieve product		-		-
Saustacuori Oi	•	conformity.		,		
statutory and		,				
regulatory						
requirements or						
conditions						
o Maintenance /				,		
servicing plans		•		-	Α.	,
(records)						,
o workplace						
Investigations						`
o benchmarking re						
work environment	•					
o Employee -				,		
satisfaction analyses	:		8	,		
o Analyses re labor						•
turnover /	١		•			
absenteeism						

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MISSION ICPOIL QUAINTY MANAGEMENT 10/2003

7.1 Planning of product realization	oduct rea	lization								
Documents reviewed	Doc.	Requirement / subject	Costa Rica	EIS	El Salvador		Guatemala	Γ	Nicaragua	
o Project-strategy		Planning and	General the requirements	Gen	General the		General the		General the	
approaches o Sperifications		development of	are met - some specific	redn	requirements are met	•	requirements are met		requirements are met -	
o chedilloris		product-realization	steps like client needs,	OS –	<ul> <li>some specific</li> </ul>		<ul> <li>some specific</li> </ul>		some specific stens like	
o Quality plans		processes.	project plan, verification	step	steps like client		steps like client		client needs omject	1
o Project-development		Such planning must	and validation have to	neec	needs, project plan.		needs, project plan		men verification and	
plans		take the following	describe more specific and	Verifi	verification and		verification and		well-define hour to	,
o Milestone plans		points into account:	in more detail	rila >	validation baye to		volidation have to		Validadoli liave (O	
o Feasibility records		<ul> <li>quality objectives and</li> </ul>		200	describe more	•	describe more		describe more specific	
o Measurement and		product requirements	,	1 Spec	specific and in more	_	coording and in more	-		_
test strategies		- the need to establish	-	of of the control of			appendict and in more		•	-
o Logistic strategies		or provide product-		-	•	_	במנפון. 	-		
o Records relating to		specific processes,		-				-		_
risk assessment and		documents and							,	
process evaluation		resources								,
(technical,		- product-specific					,			
economic)		verification,	1							
o FMEA		validation,								
o criteria for process		monitoring,		7		7		N		2
release		inspection and test		,			•			
		activities and criteria								
		for product								
		acceptance								
		appropriate records								
		to provide								
		documented evidence for the	-			_	,	_		_
		realization of product			, -					
		source of second pure				-				٠,
		4.2.4)								
			•						•	
		•				•				
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7.2 Customer-related processes	ated proce	sess								
7.2.1 Determination of requirements related to the product	requirements	related to the product								
Documents reviewed	Doc.	Requirement / subject	Costa Rica	-	El Salvador		Guatemala		Nicaragua	
o Order letter		Determination of:	The corresponding	Ė	The corresponding		The corresponding	L	The corresponding	_
o Customer inquiries		product requirements	determination of client-	<u>، د</u>	determination of	°	determination of	٥	determination of client-	ç
o Records of	ı	including delivery	needs should be improved		client-needs should	ı	client-needs should	_	needs should be	1
consultations with		and post-delivery			be improved		be improved		imnroved	
customers		support					·		5	
o specifications		requirements not		. (	-	,				,
o drawings		stated by the		2		N		ر د		7
o Trend analyses		customer but						_	-	
o Competitor analyses		necessary for the								
o Research re		nse								
standards and		<ul> <li>statutory and</li> </ul>		-						
statutory		regulatory	•	က		2	-	٥		٥
requirements		requirements	è			ı .		J	•	<u>.</u>
		- all additional		0		٥		ç	,	Ç
		requirements laid		1	- J	1		1		V.
		down by the					,			•
	. •	organization								

	l	0 0 0 0 0	
	Nicaragua	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	
		0 0 00 0	
	Guatemala	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fuffill this issue	•
	El Salvador	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	
	Γ	0 0 00 0	
	Costa Rica	The employee reviews the product requirements during the corresponding projects. There is no specific process defined to fulfill this issue	
to the product	Requirement / subject	Review of product requirements prior to commitment to supply product to customer.  The following must be ensured:  - definition of product requirements - elimination of contract review - teasibility - technical - commercial - commercial - commercial - qualitative - documentation and	understanding of amendments
ements related	Doc.		·
7.2.2 Review of requirements related to the product	Documents reviewed	o Evidence of quotations, contracts, contract review o Documentation of amendments o Feasibility analysis records o Confirmations of orders o calculations o price lists o delivery schedules	

	El Salvador Guatemala Nicaragua				:															
,	Salvador	:				1							,					,		
		-	,			``				,		•	 _	-					,	
	Costa Rica													-			,	•		
	Requirement / subject   C	Determination and	communication with	customers concerning:	product information	inquiries, contracts or	order handling.	including	amendments	<ul> <li>customer feedback.</li> </ul>	including customer	complaints								
7.2.3 Customer communication	Doc.	-							. —		_				_	_	_			
15	Documents reviewed	o process description		o Customers' product		o Inquiry documents		o Confirmation of		o Advertising material	o Customer surveys	-	Customer- satisfaction analyses	o Queries, complaints	o Complaint analyses	o Customer requests				

7.3 Design and development	levelopmer	ıt		,						
7.3.1 Design and development planning	lopment plann	iing				-				T
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	J.C	Guatemala	8	Z	Nicaragua	
o Project plans	•	Planning and	The environmental project	The environmental	onmental	There is no clear	o clear	F	The environmental	L
o Design and		controlling of design	should be planned in a	project should be	onld be	delimitation to the	n to the		project should be	
development plans		and development; in	more effective way. The	planned in a more	a more	marketing process	Drocess	<u> </u>	planned in a more	
and flow charts		this context, the	documentation of client	effective way. The	vav. The	The environmental	nmental	<u>. a</u>	effective way. The	
o Milestone plans		following aspects must	needs is incomplete.	documentation of	ation of	project should be	onld be	<del>-</del>	documentation of client	
o Measurement and		be defined:			ds is	planned in a more	a more	-	needs is incomplete	
test plans		- design and		incomplete		effective way The	av The	<u>.</u> ო		2
o Verification and		development stages		,		documentation of	ation of			•
validation		- review, verification			•	client needs is				
specifications		and validation			<i>i</i> .	incomplete	2		*	
o Approval provisions		process	÷				<u> </u>		-	
o Responsibility matrix		- responsibilities and								
o Risk assessment		authorities			1 6			1 6		
		- actualization of plans			•			) c		٠ -
		• interfaces and				<u>-</u>				_
	í	communication								
		between the various	,	*					,	3
		groups involved							=	
					•			<u>.                                      </u>		
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	Nicaraona	The determination and	recording or Input	relating to produce	requirements has to be	Davoidin	,					,	•			,		,	,				• ,
	Γ						7		2	i I		·	7					2			•	1	
	Guatemala	The determination	innut relation to	product requirements	has to be improved	neas to be suited as the second					-	-											
							7		2		,	٥	Į.					2	•		0	1	
	El Salvador	The determination	relating to product	requirements has to	he improved								ı				•			,	•		
						,	2		~							-		2			7		
	Costa Rica	The determination and recording of input relation	to product requirements	has to be improved		1				1													
	Requirement / subject	Determination and recording of input	relating to product	requirements.	This includes	- functional and	performance	requirements	<ul> <li>applicable statutory</li> </ul>	and regulatory	requirements	<ul> <li>previous design and</li> </ul>	development results	obtained in	connection with	similar products	- other requirements	(price, service life,	recyclables)	- adequate, clear-cut	requirements		
lopment input	Doc.																						
1.3.2 Design and development inputs	Documents reviewed	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

7.3.3 Design and development outputs	lopment outpu	ıts							
Documents reviewed	Doc.	equirement / subject	Costa Rica	El Salvador		Guatemala		Nicaragua	
o drawings o FF-calculations	. 7	Design and	The design- and	The design- and		The design- and		The design- and	
o QM-plans		must:	should be established more	development outputs   should be established		development outputs		development outputs	
o Acceptance		- meet input	consequent.		ç	established more	٠	more consequent	c
certificates		requirements for		•		Consequent	4	Nischaelle College	<b>y</b>
o Order documents		design and							
containing		development							
specifications		provide information	6	•	•		٠,		
o Risk analyses (e.g.		for purchasing,			4		<u>v</u>		7
FMEA)		production and		•					
o Test records (for		service provision	-		. •	,			
production,		- reference product			Ç		Ç		
verification and	,	acceptance criteria	<u> </u>		٧	•	<u>'</u>		?
validation)	_	- specify product	6 .		(				
o Approval documents		characteristics			۷		N		~
o sample test		essential for its safe							
		and proper use							
			,	`					
	٠.,		•	-		-			
		,						•	

7.3.4 Design and development review	opment reviev	*								
Documents reviewed	Doc.	Requirement / subject   Costa Rica	Costa Rica		El Salvador		Guatemala		Nicaradua	
o Intermediate / final		- Systematic review of	Sensible mile-stones	3	Sensible mile-stones	-	Sensible mile-etones	~	Sensible mile-stones	9
design and		design and	should be introduced	_	Should be introduced		should be introduced	>	should be introduced	4
development reports		development at			9		200000000000000000000000000000000000000			
o Appropriate test		suitable stages (s.	, ,					Ĺ		
records, e.g. of		7.3.1)					-			
laboratory or field		- to assess their ability	•		•				•	
testing		to fulfill requirements								
o Minutes of meetings	,	to identify problems	-						•	
o Milestone and phase		and propose					•			
reviews		necessary action								,
o FMEA		- The results of the								
o Models and		review and the					-		,	
simulations		necessary action								
o Approval documents		must be						,		
		documented. (s.								
		4.2.4)	- N		-					
	ı	•	,							-
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		7 00
		The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation
	GHO	The terms of validation and verification do not exist in the vocabulary the Management-syste Documentation
	Nicaraoua	The te and ve exist in the Ms Docur
		0 00
	Guatemala	The terms of validation and verification do not exist in the exocabulary of the Management-system Documentation
	Γ	0 00
	El Salvador	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation
	,	2 2 2
	Costa Rica	The terms of validation and verification do not exist in the vocabulary of the Management-system Documentation
ation	Requirement / subject	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)
lopment verific	Doc.	1
7.3.5 Design and development verification	Documents reviewed	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

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	Nicaragua	The terms of validation	exist in the vocabulary of	the Management-system	Documentation		•				-	•	•				•			
					c	4 c	7		က		2									
	Guatemala	The terms of	validation and	exist in the	vocabulary of the	Management-system	Documentation			,		٠					-	·		
					٥	١,	4		က		N									
	El Salvador	The terms of	varidation do not	exist in the	vocabulary of the	Management-system	Documentation			,		;								
					~	1 0	າ າ		က		~									_
	Costa Rica	The terms of validation and	the vocabulary of the	Management-system	Documentation	. ;					F						-			
tion	quirement / subject	Design and development validation	must ensure: (s. 7.3.1)	- fitness for use	- partial validation, if	applicable	<ul> <li>validation prior to</li> </ul>	product delivery, if	possible	- documentation (s.	4.2.4)		ı							
opment valida	Doc.	,	-												*		_		_	
7.3.6 Design and development validation	Documents reviewed	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			

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ړي	t/sn	s revi 3 aspe on an	documentation of	review, verification,	and	approval prior to	tation	<b>ect</b>	changes in design	and development	and of follow-up	action on product	documentation of	review results (s.											•	
ange	emer	ivolve Iowing ificatig	ment	¥,∨e	validation and	oval	implementation	¥of€	iges i	devel	of fo⊪	no no	ment	w res	<del>+</del>						*					ļ
בֿן בּן	Requirement / subject	This involves review of the following aspects:	documer	revie d	valid	appr	imp	<ul> <li>review of effects of</li> </ul>	char	and	and	actio	noop.	revie	4.2.4)								,			
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.3.7 Control of design and development changes	Documents reviewed	o Documented requests for changes (e.g. by the	customer,	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	,		

7.4 Purchasing							
7.4.1 Purchasing process	SS						T
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaragua	Τ
o Product		The purchased product	There is a described	There is a described	There are lists of	There is a described	T
specifications		must conform to	purchasing-process. Some	purchasing-process.	suppliers.	ourchasing-process	
o Supplier's quality		product requirements.	issues have to be added	Some issues have to	There is a described	Some issues have to be	
system		The supplier must be	within the process-	be added within the	nurchasing-process	added within the	
documentation		evaluated and criteria	documentation. There has	Drocess-	Some issues have to	process-documentation	
o Checklist		for such evaluation	to be a difference between	documentation	he added within the		
o Evidence of supplier		established. The	existing and new clients.		DIDUCESS-		
evaluation		following aspects must			documentation		
o List / database of		be considered in the					
approved suppliers		purchasing process,					
o Evaluation criteria	,		,		,		
o complaints		- external product					•
o statistics		quality			1		_
o specifications		- factors of influence	,		•	`	
		- supplier capability					
	-	criteria for supplier		. '	•		
		selection, regular		-			
		evaluation and re		8	2		~
		evaluation					
		- documentation of		,			
	•	evaluation (s. 4.2.4)	2	2	2		2
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	•	,		1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		:	
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7.4.2 Purchasing information	nation						
ts reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaraoua	
o Product		- Purchasing	See 7.4.1	See 7.4.1	Soo 7.4.1	Soc 7.4.4	
specifications	?	information must			- · · · · · · · · · · · · · · · · · · ·	Ode 7.4.1	
o Order forms	,	describe the product		,			
o purchasing		to be purchased					
specifications in		Such information					
			,			•	
	,	must include, where					
o Older Rots, piece		appropriate, a		•			
lists		description of the		1			
o Performance /		requirements					
delivery contracts		pertaining to:					
o Quality assurance		- product annroval					
		proceed approved,		-	-		
agreements		procedures,					
o Order approval		processes, facilities		•			
documents		and equipment					
		- personnel			`		
	•	oualification					
		44 Alloway					
	•	- ine quality system.				,	
		- The adequacy of					
		requirements must	,				
		be ensured prior to		•			
		their communication					
		to the supplier					
					-		
7.4.3 Verification of purchased products	rchased prod	lucts					
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Gratemala	Nicaracito	
o Acceptance criteria		In this context	Spp 7 4 1	Sec 7.4.1	00-744	anical sales	T
o Verification plans		inspection/other		Odd: 1.4.	See 7.4.1	See 7.4.1	
lo Test regulations	i	activities must be		,			
o Regulations re		octoblished and					
approvol inder		implemental and					
מאלים מוומכו		implemented winch	<u> </u>	•	-		
		verify product					
o lest records of		conformity with					,
suppliers or of		requirements. For		-			
organization's own	-	verification measures				-	
incoming inspection		conducted at the			ı	,	
OPATIBOSTIONS		Contraction at the					
o Certifications		supplier's premises,	-			-	
nonzedsui di usbection		the intended					
		verification measures					
		and methods must be				•	
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		Requirement / subject	ro.		characteristics must		- work instructions, as	st be	made available,	ent			ces			G			<ul> <li>release and delivery</li> </ul>	of products/services	ğ		æ			- *	ļ
		t/su	xt: (s		tics		ction	mű	lable	uipm	g.	and	devi	ade		ustb	and	•	del	s/ser	Sure	≥	ustl	장			İ
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vis	rovi	quire	In this context: (s.a. 7.1)	oduc	Jara(	be defined,	Ä×	eces	ade	suitable equipment	must be used,	- monitoring and	measuring devices	must be made	available,	activities must be	monitored and	measured	leas	pro	must be ensured	post-delivery	activities must be	implemented			
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7.5 Production and service provision	7.5.1 Control of production and service provision	Documents reviewed	o Acceptance criteria o Work instructions	o Test plans	o drawings	o Maintenance plans	o Installation plans	o Service contracts	o Operating	inst	o Process flow charts																

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quirement / subject Cos		pability. In this	ntext, the following st be taken into	count:	idation of all	ere the resulting	tput cannot be	nited by subsequent initioning or	asurement.	IS Includes all	ficiencies become	parent only after the	livered.	lidation must include	where approphate): riteria for review and	pproval	pproval of	ersonnel	jualification	nethods and	nocedures	equirements ertaining to quality	ecords (s. 4.2.4)	ossible necessity of enewed validation	
Requirement / subject Cos		capability. In this	context, the following must be taken into	account:	validation of all	where the resulting	output cannot be	verified by subsequent monitoring or	measurement.	I nis includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	
Requirement / subject Cos		capability. In this	context, the tollowing must be taken into	account:	validation of all	where the resulting	output cannot be	verified by subsequent monitoring or	measurement.	I his includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of equipment and	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity or renewed validation	
Requirement / subject Cos		capability. In this	context, the following must be taken into	account:	validation of all	where the resulting	output cannot be	verned by subsequent monitoring or	measurement.	Ins includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of equipment and	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	
Doc. Requirement / subject Cos		capability. In this	context, the following must be taken into	account:	validation of all	where the resulting	output cannot be	verified by subsequent monitoring or	measurement.	Ins includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of equipment and	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	
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ewed Doc. Requirement / subject Cos	Validation must		tions			where the resulting	output cannot be	verified by subsequent monitoring or	measurement.	I his includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of equipment and	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	
reviewed Doc. Requirement / subject Cos	Validation must		tions							I his includes all	deficiencies become	apparent only after the	delivered.	Validation must include	(where appropriate): - criteria for review and	approval	- approval of equipment and	personnel	qualification	methods and	procedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	
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Documents reviewed Doc. Requirement / subject Cos	Validation must		o Process descriptions context, the following o data of process		o Skills documentation and training and training		<u> </u>	certificates verified by subsequent o Validation monitoring or	specifications measurement.	Ins includes all	deficiencies become	apparent only after the	delivered	Validation must include	(where appropriate):	approval	- approval of	bersonnel	qualification	methods and	brocedures	- requirements pertaining to quality	records (s. 4.2.4)	- possible necessity of renewed validation	

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Documents reviewed	COC.	Reduirement / subject	Costa Rica	El Salvador	Guatemala	Nicaragua
o Work instructions	Ţ	- Where appropriate,				-
o Accompanying		the product must be				
documents, e.g.		identified throughout			,	
routing slips		product realization				,
o production plans		- The product status			_	i
o IT records		must be identified	. /		-	
o Product identification		with respect to	·			
o Test certificates		monitoring and				
o Segregation slips		measurement				
o Approvals		requirements.		-		
	-	- Identification must	•			
	-	be controlled and				*
•	_	recorded if				-
		traceability is	, ,			
		required	-			
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7.5.4 Customer property	4					
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaragua
o Inventory of		In this context, the				
customer property	Parties de	following must be				
o Identification (e.g.	-	observed				
labels, stickers)		· careful handling (also		•		
	_	D	_		_	

7.5.4 Customer property	ty						Γ
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaragua	1
o Inventory of		In this context, the					
customer property		following must be					
o Identification (e.g.	-	observed:		•	,		
labels, stickers)	· 	careful handling (also					
o Correspondence		where intellectual					
with customers		property is	-	,			
o Records on		concerned)					
verification and		- identification,	ing-				·
maintenance		verification,		•	-		_
conducted		protection and	,				
o Incoming inspection		maintenance					
		- procedure and	-				
		documentation in					
		cases involving					
	•	damage or loss					
	•	(notification of					
		customer)	3				
	,					,	-

7.5.5 Preservation of product	product						
Documents reviewed Doc.	Doc.	Requirement / subject Costa Rica	Costa Rica	El Salvador	Guatemala	Nicaracata	
o Regulations on		This refers to both	•	*	+	nivaraña an an a	
packing, storage,	_	internal processing	•		_		-
preservation and		and delivery and must	•	,			
delivery		include:		,			
o Piece lists	,	- preservation of					
o Inventory lists		product conformity					•
o Stock-replenishment		- identification				,	
and -withdrawal		- handling					
plans	,	- packaging	,			·	
o Regulations on		- storage			•	<del>,</del>	
storage periods and		- protection			-		_
segregation (where		This also applies to		,			
appropriate)		the constituent parts	•	•			
o delivery labels		of products.		,			
o Assembly / operating	-	•			•	٠	
instructions				•	•		
					v	•	
			*	-			
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Dogument of commend	,					
Cocuments leviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Guatemala	Nicaraoua
o Design and		Monitoring,	The process of continuous	The process of	The process of	The process of
development flow		measurement,	improvement is not	continuous	continuous	continuous improvem
charts		analysis and	implemented effectively	improvement is not	improvement is not	is not implemented.
o Design and		continuous	and consistent.	implemented	implemented	effectively and
development test		improvement		effectively and	effectively and	consistent
plans		processes must be		consistent	consistent	CONSISTENT.
o company data		- defined			Corsional.	· ·
system		- planned	<u>e</u>	, ,		7
o objectives and the		- implemented (s.a.	2	2	•	· ·
actualisation		4.1)				
o Improvement		to demonstrate				
schemes		conformity of the				
o Statistics	,	product and the				
o Progress reports		quality system and				
o Information boards		improvement of		,		
o inputs for continual		quality system				
improvements		effectiveness.		•		
		Determination of				
		applicable	3	<u> </u>		· ·
-	•	requirements must			•	
	,	include the use of				•
		suitable statistical		r		
		techniques.				

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8.2 Monitoring and measurement	surement							
8.2.1 Customer satisfaction								
Documents reviewed Doc.	Requirement / subject Costa Rica	Costa Rica	El Salvador	tor	Guatemala		Nicaraqua	
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 percept has not been established in all relevant parts.	Monitoring of 3 customer perception has not been established in all relevant parts.	Monitoring of customer perception has not been established in all relevant parts.	m	Monitoring of customer perception has not been established in all relevant parts.	e
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8.2.2 Internal audit										
Documents reviewed	Doc.	Requirement / subject	Costa Rica		El Salvador		Guatemala		Nicaragua	
o DP internal audits o Audit plans		- Conducting of internal audits to the	The process of internal 3	<u>= .5</u>	The process of	က_	The process of	က	The process of internal	3
o Audit reports		planed arrangements	106 1000 1000 1000	È	internal about opes		not exist yet		audit does not exist yet.	
o Nonconformance		(s.7.1) at planned		<u>-</u>	or chief yet.		ווטו כאופו אבו.	•		
reports		intervals		•	<b>3</b>		•			`
o Action catalogs for		- planning	.,							<del></del>
the establishment	•	- execution								
of corrective action		- documentation					•			
o Test records etc.		- evaluation					-		,	
o Management		- definition and			-					
reviews		implementation of								
o Reports on	1	corrective action	,							
effectiveness of		- surveillance	•						-	
corrective action		- The results of								
o Evidence of auditor		previous audits must			:					
qualification		be taken into					,			•
		account.			-					
		- The objectivity and	• .							
		impartiality of								
•	•	auditors must be								
		ensured.								

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	Nicaradina	- model against	There are defined key	indicators but the	Harcarols but tile	method of measurement	and general coordination	has not been	implemental con	implemented yet.						,					
		1	<u>-</u>	ı			,									-					
	Guatemala	5.5	There are defined	key indicators but the	mothed of	illeanod of	measurement and	general coordination	has not been	ings not been	Implemented yet.		-		-						,
			2					,											• •		
	El Salvador		There are defined	key indicators his the	method of			general coordination	has not heen	implemented vet	mpenenten yer.	-		•	,	•					
		,	~																		
	Costa Rica		I here are defined key	indicators but the method of	measurement and general	coordination has not been	the feet of the fe	Implemented yet.	•					·		,				1	
processes	Requirement / subject	Suitable mothade for		monitoring and	measurement of	quality system	processes mist be	An reputation of	determined, applied,	reviewed and	corrective and	preventive action	implemented, where	appropriate. (s.	7.1+5.1)						
neasurement of	Doc.																•				
8.2.3 Monitoring and measurement of processes	Documents reviewed	o company data	and friedly of	o Process data	o controlling data	o statistic analysis	o Ouality data	man diament	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	

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	Nicaracus	See 8.2.3										,				,		••
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	Guatemala	See 8.2.3	-			,	,	:										
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	El Salvador	See 8.2.3	4					,										
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	Costa Rica	See 8.2.3						,		,					'			
f product	Requirement / subject	- Product	- 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.
neasurement o	Doc.															,	,	
8.2.4 Monitoring and measurement of product	eviewed	o Test plans	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)			-

Documents reviewed Doc. Requirement subject Costa Rica Decuration of the process	8.4 Analysis of data	ıta					-				
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system suitability analysis and client data analysis and client satisfaction.  effectiveness must be:  o determined o collected o analyzed o collected o analyzed o collected o collected o collected o collected o collected o conformity of provide information relating to o customer satisfaction (s. 8.2.1)  o conformity of product requirements (s. 7.2.1 o product characteristics (s. 8.2.4)  o suppliers (s. 7.4.1)	o Measurement and		Appropriate data to	There is no process data	2	There is no process	<del> </del> -	SS	Ť	process data	2
effectiveness must be:     odetermined     o collected     o collected     o collected     o construct     satisfaction(satis     faction (s. 8.2.1)     o conformity of     product     requirements (s. 7.2.1     o process and     product     conformity of     product     requirements (s. 7.2.1     o process and     product     conformity of the product     requirements (s. 7.2.1     o process of the effectiveness of the effec	o Nonconformance			analysis and client satisfaction		data analysis and	<del>ರ</del> 7	ata analysis and	10	analysis and client	
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8.5 Improvement								
8.5.1 Continuous improvement	ovement							
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	Ö	Guatemala	Nicaragua	T
o Quality management plans o Project plans		Continuous improvement must be made possible through	There are some relevant elements missing	There are some relevant elements missing	F 2 E	There are some relevant elements missing	There are some relevant elements missing	
target requirements o Progress reports o Management		une use or the quality policy quality objectives	<u> </u>		000	232		200
reviews o Corrective-action		- data analysis - corrective and	0.0		2 2	8 8		~ ~ ~
catalogs o Preventive-action	,	preventive action - management review.		-	<del></del>			က
o inputs for continual improvements		Î.	,					
Documents reviewed	Doc.	Requirement / subject	Costa Rica	El Salvador	0	olomoto		
o DP Control of		To prevent the	The process to prevent the	The process to	PF	The process to	The process to process	,
corrective action o Nonconformance		recurrence of nonconformances, the	recurrence of	prevent the	<u>a</u>	prevent the	the process to prevent	
records		documented procedure	established appropriate.	nonconformances is	5.5	recurrence or nonconformances is	nonconformances is not established appropriate.	
o Statistical		must cover the following aspects:		not established		-		
evaluations o Test / result records		- reviewing			<u>.</u> د	.2	-	7
o Instructions re		Customer			•		-	
corrective action		complaints)		;	•			
o Training plans o Training certificates		- determination of the causes of	<u> </u>		7	<u>e</u>	-	7
o Complaints analyses		nonconformities						
		- 40 COST COCCOS BOOK COCK	_		-	_		

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	Nicaragua	There is no process established to eliminate	nonconformances.				,				•				,	-11			
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	Guatemala	There is no process established to	of potential	nonconformances.	· ·			,	,								•		
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Cl Colt.odes	Ei Salvador	There is no process established to eliminate the causes	of potential	noncomonnances.		•		,											١
						က	•	က		ď	_	ŕ	,			က			
Costs Dies	Costa INCA	There is no process established to eliminate the causes of potential			, .		,	:				·	-			•		-	
Requirement / cubiact	To all all all all all all all all all al	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	•		•	
Doc					-							,						,	
Documents reviewed	O Control of	o Dr. 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

### 3 Progress of QM-documentation

## 3.1 Interpretation of the "process progress template"

The following template was used during the 2<sup>nd</sup> 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%
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0%... No documents at all

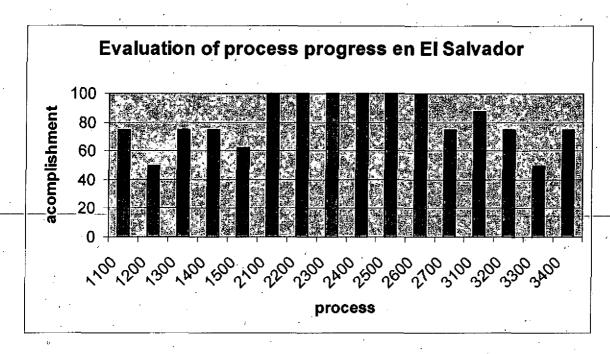
25%... half of process description finished, few appended documents

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

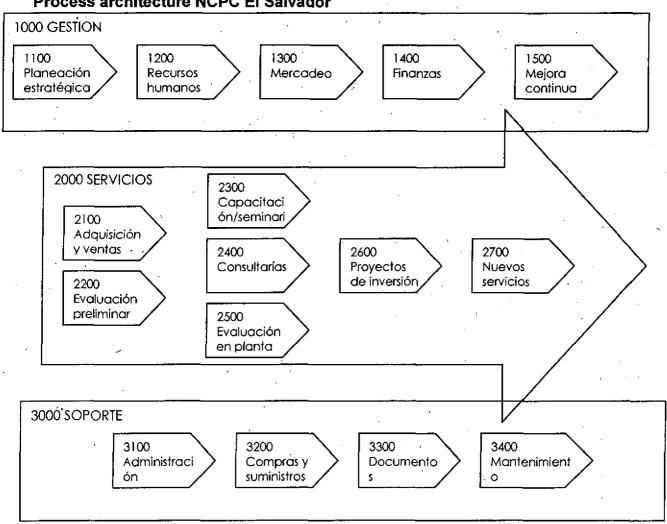
75%... process description finished, half of appended documents finished

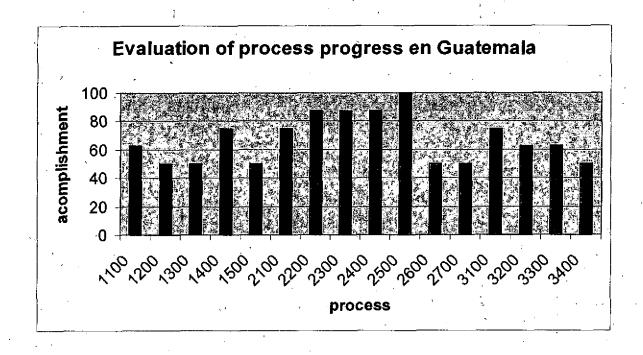
100%... process description finished, all appended documents finished

## 3.2 Results regarding process progress at each CPC

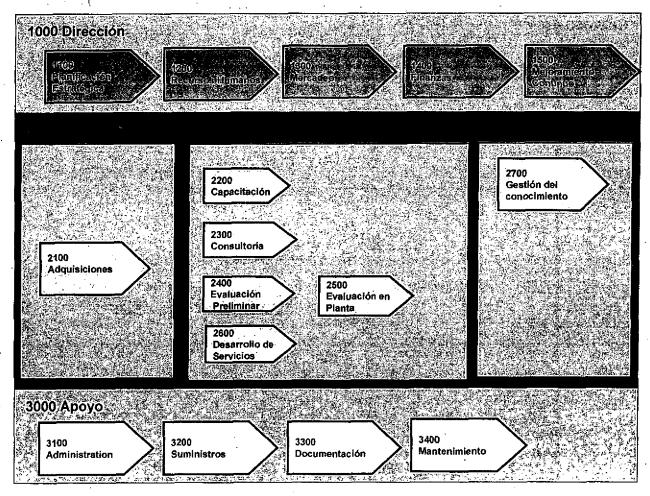


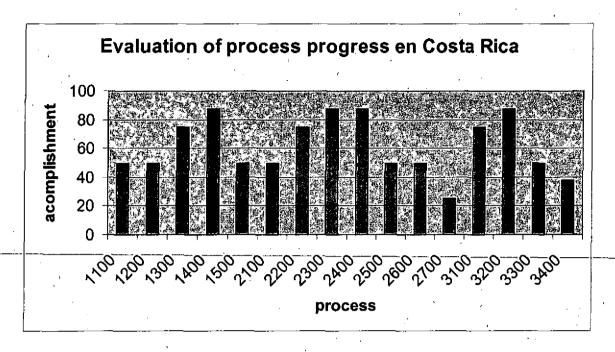
#### Process architecture NCPC El Salvador



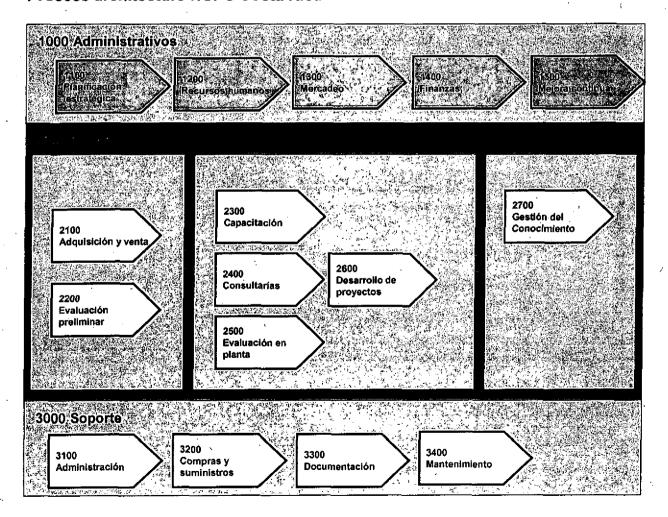


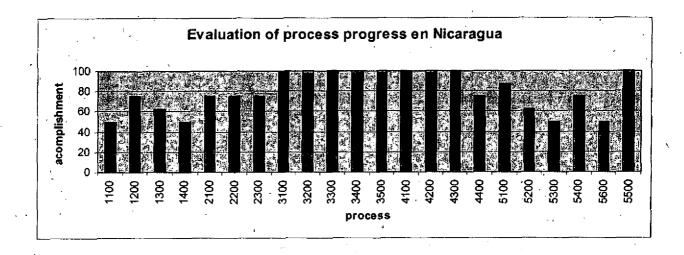
## Process architecture NCPC Guatemala



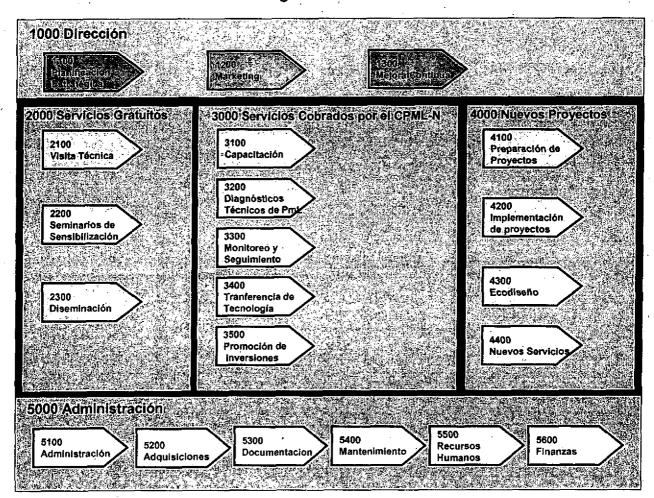


#### **Process architecture NCPC Costa Rica**





#### 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 2<sup>nd</sup> 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 <u>and</u> 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 1<sup>st</sup> 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	15 <sup>th</sup> June 2005
,	Draft of process description	Each process owners	15 <sup>th</sup> July 2005
- -	1	—(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	
	Collecting of the drafts of process description	Carlos Perera (CNP+L) Costa Rica	25 <sup>th</sup> July 2005
	Distributing of the drafts of process description (to each centre and P. Schönenberger)	Carlos Perera (CNP+L) Costa Rica	30 <sup>th</sup> July 2005
1	Finishing the process description individual (related to the centre),	Each process owner	15 <sup>th</sup> August 2005
	Creating of a draft of the management review	Each project leader	15 <sup>th</sup> September 2005
	Creating of an internal training plan for the employees	together with the top management within the	15 <sup>th</sup> September 2005
	Creating of an internal training plan for the employees	corresponding centre	15 <sup>th</sup> September 2005
	Preparation of the Examination regarding EOQ certification (Quality Systems Manager)	Participants of the training	30 <sup>th</sup> September 2005
	Creating of the appended documents (each centre on its own)	Each process owner	20 <sup>th</sup> September 2005

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

# Annex 1 Adjusted project plan

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	5	6	7	8	9	10	11	12	1	2	3	4
Step 0 Management-Workshop					· '	1				•		
- Training of QM-Coordinators												
Step 1 Management-Workshop		ľ										
- Model, strategy, objective	ı	4		1		ļ	ł	ĺ				
- Project organization, time scedule			-			ł						
Phase 2 Concept												
- process features	-		-		-		-	_	-	_		_
- describing of business processes (draft)	•	200										
- collecting and sharing of						•				Ì		
the process descriptions												
- finishing of the process description												
Phase 3 Realization	<u> </u>		T		T	_						
<ul> <li>describing Appended documents</li> </ul>				1500				•				٠.
<ul> <li>planning of internal training (employees)</li> </ul>		İ										,
- examination by SAQ-Qualicon			l		l				,			
(Peter Schönenberger)						Ţ.		٠. ا				
internal training of the employees					·				•			
Phase 4 Consolidation			Г									\
- managementreview (finished)									N.			
- internal audit							'		•			
external pre-audit (not compelling)												
external certification-audit												Í
Monitoring (by P. Schönenberger, SAQ-Qualicon)								`				

## **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 EOO Personnel Registration Scheme as

# **EOQ Quality Systems Manager**

The holder of the certificate has proven the knowledge and practice in accordance with the EOO/Harmonized Scheme in front of the EOO/Full Member Organization of Switzerland SAO

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

or the SAOT LICENT APPRECIATION

Registration No.: CH05QSM-1643

This cartificate is property of the Engages of School Constitution Quality (EOC)