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Förderung der regionalen Qualitätsinfrastruktur in Lateinamerika (SIM / IAAC)

Report
IAAC 2008 - 2

IAAC – PTB - Peer Evaluator Workshop
ECA – San José - Costa Rica
12th - 15th February 2008

im Auftrag der
Physikalisch-Technischen Bundesanstalt
Bundesallee 100, 38116 Braunschweig

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Report

IAAC – PTB - Peer Evaluator Workshop

Introduction

In 2005, it was planned to demonstrate the results of PTB long-term monitored accreditation bodies to experienced peer evaluators, using simulations in an IAAC-recognized accreditation body, to give a demonstration about the limits of the existing peer evaluation procedures. It was announced to IAAC as an exchange of experience about:

1. Accreditation in the context of a National MSTQ (Metrology – Standardisation – Testing – Quality Assurance) System and the limitations of MSTQ in developing countries (for example in traceability)
2. The 30 Milestones (30 MS) Program as a Roadmap to international recognition. (This program is a long-term project planning and monitoring software tool of PTB, established in more than 25 countries to support the international recognition via ILAC – IAF MRA. It analyses periodically 30 necessary components of the ISO 17011 implementation with a ten-graded scale and monitors the impact of project activities with different key indicators and relations.
3. Peer evaluation tools for National Accreditation Bodies as ISO 17011 and KPI and their implementation in the 30 Milestones Program. Weak points detected during peer evaluations in accreditation bodies of developing countries, where 30 MS Program was used to monitor implementation:
   - political influences
   - financial stability
   - work overload
   - conflicts of interests
   - corruption and bribery
   - access to expertise
   - evaluation of consultancy results
   - structure – process – outcome deficiencies
   - corrective and preventive actions
4. Scenarios, based on real cases:
   How to detect and how to deal with following situations:
   - top management depends on political party
   - poor salaries of staff in environments of susceptible to corruption
   - conflicting tasks of main shareholder
   - insufficient availability of expertise in the country
   - a lot of evaluated results (quality documentation, assessment reports, etc) are based on dominant influence of foreign consultants
   - exponential growth of applications (volume and scope) vs. existing capacity of staff in AB
   - unexpected economical crisis in countries
   - main technical experts lost to private sector
   - political pressure to grant “VIP”-accreditations via “fast track” or other preferential treatment

5. Presentation of tools, discussion of solutions and consequences for the peer evaluation training

In 2008 the modified IAAC-PTB workshop at the National Accreditation Body ECA of Costa Rica defined following objectives of the exchange of experiences:

1. Evaluation of detected Nonconformities with their sources,
2. Development and evaluation of adequate Corrective Actions
3. Estimation of the limits of peer evaluation methods and procedures
4. Presentation of PTB developed tools for long-term monitoring of accreditation bodies,
5. Discussion of the findings and consequences for the improvement of the peer evaluation training

A complete set of an IAAC Application package for the peer evaluation with all documents in Spanish was prepared by the staff of ECA Costa Rica:

- Acreditación de Laboratorios de Calibración
- Acreditación de Organismos de Inspección
- Acreditación de Certificación de Sistemas de Gestión de Calidad (QMS)
- Acreditación de Certificación de Sistemas de Gestión Ambiental (EMS)
- Acreditación de Certificación de Producto (Producto)

with application form and 29 attached documents including the self-assessment report of Key Performance Indicators. All the documents were given on 23rd January 2008 on a CD to IAAC Secretary.

For the participants following rules and hints were given:

IMPORTANT:

The review of documents should be finished till 13th February 2008. For clarifications contact the ECA quality manager Catalina Barquero Ulloa. The on-site peer evaluation takes 8 hours and includes only some parts of a total peer evaluation procedure:

• Only one accreditation case of each field (calibration, inspection, system and product certification), first accreditation procedure and surveillance visits
• Only the responsible case manager, but interviews with the head of AB and quality manager
• Only the involved ECA assessors and technical experts (no interviews)
• Only the related committees and decision-makers (no interviews)
• Not any witnessing of assessments

The peer evaluation team should be concentrated to the major and critical nonconformities and quality relevant observations.

The workshop started on 13th February 2008 with 4 experienced peer evaluators of Brazil, Ecuador and Mexico under the supervision of Fabian Hernandez, chairman of IAAC- MRA Committee. Moderator was Manfred Kindler, freelanced expert on accreditation of PTB.

The workshop started with an overview about the background and the history of peer evaluation.

History and Background

1974 PTB founded the first accreditation body of Germany: DKD Deutscher Kalibrierdienst. In 2007 DKD was separated from PTB as an independent body. At this time, a lot of PTB Technical Assistance Projects started. Today DKD has accredited 396 calibration laboratories including 25 labs in 15 foreign countries.

1975 DKD is the founding member of WECC Western European Calibration Cooperation. For the mutual recognition first Peer Evaluation activities were started.

1991 DKD is founding member of DAR German Accreditation Council.

1994 WECC merged together with the WELAC (western European Laboratory Accreditation Cooperation) to EAL (European Accreditation of Laboratories) which was later merged together with EAC to EA (European cooperation of Accreditation)

1994 The Governmental accreditation body BAM-Accreditation System was transferred to the private body DAP (Deutsches Akkreditierungssystem Prüfwesen – German Accreditation System for Testing), which has accredited till today 1059 testing labs, 23 medical labs, 108 inspection bodies and 100 certification bodies in more than 20 countries. DAP was peer evaluated in 1995/1996 by EAL, EAC, EA and NIST.

1995 Start of PHARE Project of European Union: The Peer Evaluation of the MSTQ System (Metrology – Standardisation – Testing – Quality Assurance) for 12 Easter European Countries. In the field of accreditation requirements were listed as **30 Milestones**. 5 years of peer monitoring of the development and progress of accreditation bodies followed based on 30 Milestones reports of experienced peers in accreditation.

1997 Analysis of all Peer Evaluation reports of EA were done by DAR / DAP (Mittmann / Kindler)

1998 First drafts of Key Performance Indicators were developed, based on the evaluation results of the EA reports

2001 The first Peer Evaluator Training was arranged in Pretoria with Key Performance Indicators included.

2003 The Review of the New Approach (COM(2003) 240 final) of EU stated: **"***The use of accreditation in this context is an important step towards greater comparability in the assessment and surveillance of notifies bodies, in particular due to the co-ordinating function of the Multi-Lateral Agreement (MLA) established by the European co-operation for Accreditation (EA).* ***However, the MLA has not solved all problems"***

2005 The first common ILAC / IAF Guidance A3: Key Performance Indicators (KPIs) was published.

2006 The EA General Assembly at Riga established a new project "Enhancing European Accreditation" with 5 Subprojects and 3 Project Teams, especially subproject # 5 "Enhancing the peer evaluation process"

2006 The IAF General Assembly at Cancun established the new IAF Task Force „Re-engineering of Accreditation" with Lorenzo Thione, Chairman of EA as convener. The final report was presented on Oct 2007 at ILAC/IAF GA Open Forum Sydney.

2007 The new revision ILAC / IAF A3: KPIs was issued.

2007 At the ILAC General Assembly at Sydney new drafts about „Effective tools for evaluating accreditation bodies“ were presented.

2007 EA General Assembly Nicosia presented the first results:
- Best Practice Guide (Mandatory Area)
- Revision of MLA Procedure EA -2/02
- DANAK, UKAS, SIT will be peer evaluated by risk-based approach (pilot process)

2008 The PTB – IAAC Workshop „Peer Evaluation“ for awareness building and exchange of experience is organised at ECA Costa Rica.

Program

Improvement of Peer Evaluation Procedures – Exchange of Experience

Wednesday, 13th Feb	09.00 – 13.00	Welcome Introduction to the workshop News from EA and ILAC about Peer Evaluation
	14.00 – 18.00	Opening meeting (Simulation) ECA Onsite evaluation Part I
Thursday, 14th Feb	09.00 – 13.00	ECA Onsite evaluation Part II Final meeting (Simulation)
	14.00 – 18.00	Report writing and classification of findings Presentation of the report
Friday, 15th Feb	09.00 – 13.00	Evaluation of the results Exchange of experiences
	14.00 – 17.00	Exchange of experiences Recommendations for improvement

Participants:

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Fabián Hernandez	EMA	fhernandez@ema.org.mx as IAAC-Observer

Peer Evaluation Procedure

After the opening meeting, the participants started the “classical” peer evaluation procedure by using the application package of ECA. Review of documents, analysis of records and interviews of the accreditation body staff were done for a reduced scope during the next 8 hours.

At least the findings were discussed and described on a peer evaluation report and presented to ECA staff at the final meeting on the second workshop day.

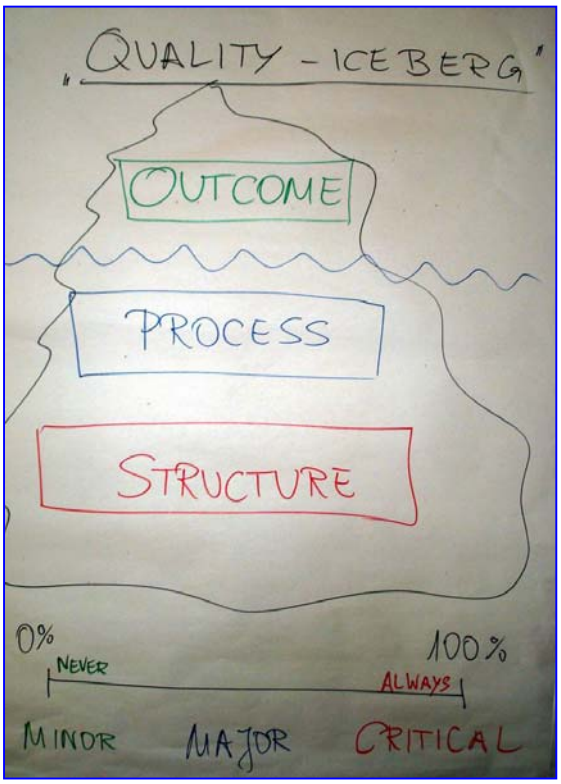
For detailed information see the confidential peer evaluation report about ECA Costa Rica.

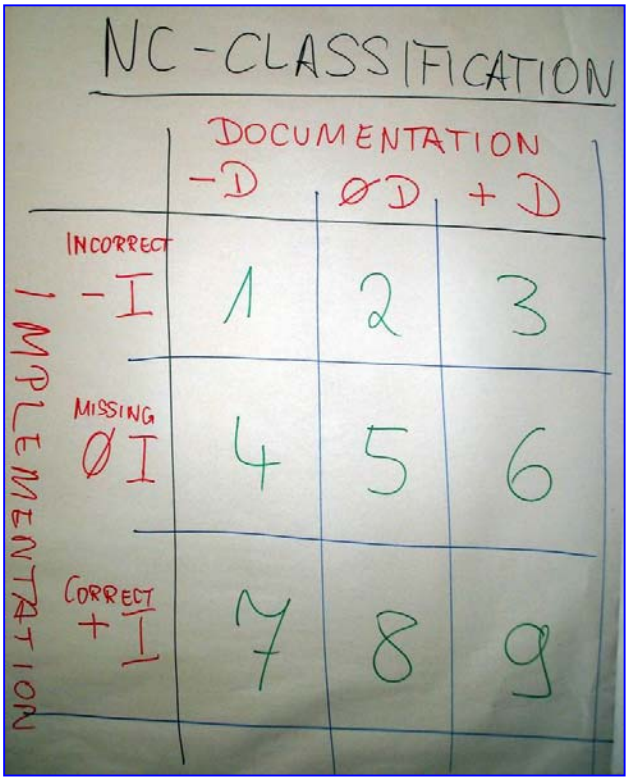
The participants demonstrated a high performance in peer evaluation mainly based on intensive training and long-term experiences in these activities.

Evaluation of the findings

After the official peer evaluation procedure additional evaluations of the findings against several parameters were done using special PTB-tools:

1. Documentation and Implementation of ISO 17011 requirements
2. Classification of Nonconformities from Type 1 to 9
3. Definition of Severity: minor, major or critical
4. Detection of NC-Sources: outcome, process or structure
5. Analysis of connected deficiencies
6. Discussion of appropriate corrective actions
7. Statistical evaluation of all nonconformities





Classification of Findings:

Example:
A obsolete English version of the accreditation procedure is published on the Webpage of Accreditation Body

Statement 1:
It is a nonconformity on the outcome level, because a written document is not correct.

Question: What about the severity, the consequences of this NC?

Statement 2:
Minor: if NC does not influence the process result. In this case, the Spanish version of the accreditation procedure is up-to-date.
CRITICAL: if the English version is used by foreign applicants in English speaking countries. In this case, all applicants will get the wrong information.
Major: if NC is not minor nor critical, there is a potential probability that the NC will defect the procedure.

Question: Does exist a correct version of accreditation procedure in English in the quality manual?

Statement 3: (see 3x3 Matrix last page!)
If yes, than we have the case +D -I (positive = correct documentation, but negative = incorrect implementation), this is a NC of Type 3
If no, because no English version exists, it is a NC of Type 2 (0 D = missing documentation and –I = incorrect implementation)
If the obsolete version is part of the quality manual, than it is a NC of Type 1 (-D = incorrect documentation and –I = incorrect implementation)

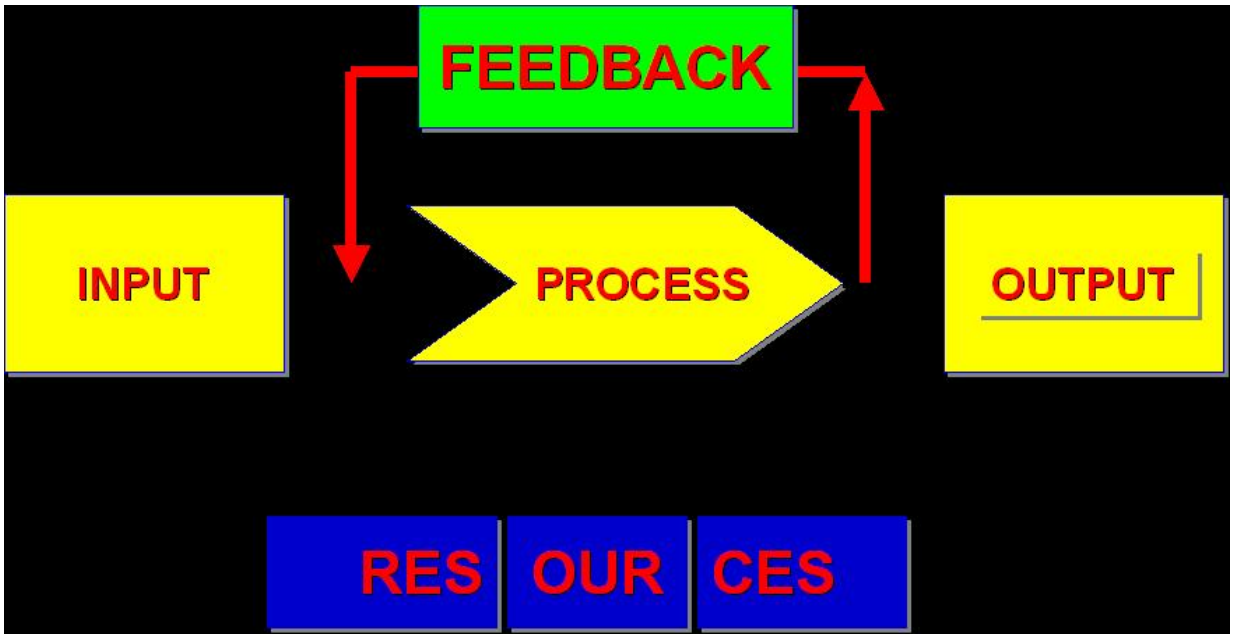
Question: Does exist a procedure in the quality system to update regularly the webpage content?

Statement 4:
If no, it is a NC on process level.
If yes, is the procedure understandable, complete and practical? Is the update period adequate? etc.
In this case, only a correction of the webpage as a corrective action would not be accepted, necessary is a corrective action on process level.

Question: What about the responsible person? Does he / she exists? With appropriate language skills? With necessary tools to modify webpages? With sufficient time resources?

Statement 5:
If no, it is a NC on structure level.
If yes, why the responsible person has not yet changed the English version?
In this case, corrective actions on outcome an process levels would not be accepted. The responsible person has to assure the appropriate performance to this task.

Questions:
Process*: What about the written procedures about Webpage-Updating activities? What about the implementation, the reality, how many updates were done?*
Input: *What about the original text of the procedure? (is it correct in the Spanish version? Is it correct in the English translation? Is it the uptodate version?)*
Resources*: What about the responsible person? Qualification, experience, necessary tools, time resources, etc?*
Feedback: *What about the supervision? Why the NC was not detected by the responsible person? By the quality manager, by the head of department, by the internal auditor, by the top management (management review), by other external auditors, by clients? Does exist any feedback about the English version?*



Additional questions:
Were other nonconformities of the similar type detected? Was the same person responsible? Was it detected / detectable by internal audits? Does it happened only one time or several times (random error or systematic error)? Is this NC connected to other NC and/or observations?

Summary:

A potential result at the end of the investigation by interviewing the staff could be:
The institution has severe structural problems, because

- the quality manager is overloaded with work,
- the internal auditor is only qualified about ISO 9001,
- the top management is not aware about the work load and adjacent lack of resources,
- the English language skills are insufficient for foreign accreditations
- the responsible person for the webpage has not enough knowledge about handling the webserver and related software
- information about this problems by clients were ignored in the past.

The “classical” peer evaluation has no priorities in assessment topics: all requirements of ISO 17011 and all parameter of Key Performance Indicators will be evaluated completely.

The risk-based approach, which was established in 2007 by European cooperation for Accreditation (EA) in a pilot study, analyses only critical points by deep investigation.

Pre-condition of using this method is the knowledge of all critical points of accreditation bodies. The PTB analysis and project monitoring tools of the 30 Milestones are not oriented directly to ISO 17011 and KPI, because the root of this approach is based in 1993 and the scope covers not only the requirements for accreditation bodies.

The 30 Milestones evaluate and monitor for example the National Policy, including National coordination with all ministries, financial stability for 5 years based on a business plan, the stakeholder infrastructure of all relevant associations in quality management, industry, trade, research and development, consumer protection, metrology and standardization.

All activities were described by a Structure-Process-Outcome-Analyse (SPO), which defines activities, involved persons and produced outcomes. A ten-level scaled rating is based on a catalogue of criteria for each milestone, where the most important factor is sustainability of the “construction”.

A lot of specialized key parameters monitor continuously the characteristics of the project progress, the results are visualized by dashboard diagrams.

Based on the implementation of 30 Milestones program in more than 25 countries and 4 regions since the year 2000, nearly all critical points of accreditation bodies were identified and analysed by regular visits onsite (2 –4 times per year for one week).

In the following, basic tools of risk analysis by reducing risk with “error-filtering methods” (as document review, on-site assessments, technical and accreditation committees etc) and by using a simplified 3x3 risk matrix will be introduced.

At least the Key Performance Indicators and the standard ISO 17011 were analysed against inherent risk factors for accreditation bodies.

The list contents also information about the used PTB tools in project management and experiences in practice about observed worst cases.

Finally a statistical tool for fast evaluation of peer evaluation reports is presented. Based on comparisons of more than a dozen 30 milestones programs and pre peer and peer evaluation reports, some findings about typical problems and recommendations for improvement of peer evaluation techniques were given.

Tools of Risk Analysis

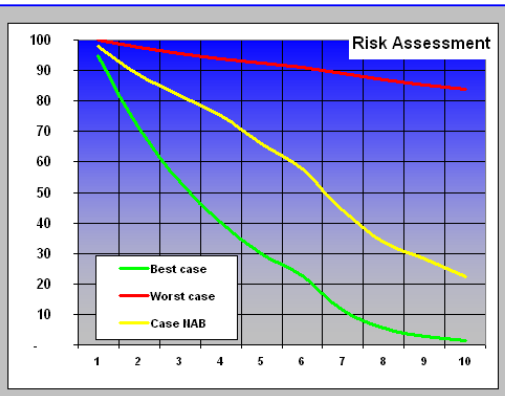
The risk-based assessment approach was introduced by some basic tools of risk analysis, demonstrated by a systematic SPO-analysis (Structure – Process-Outcome) of the simplified initial accreditation procedure.

SPO-Analysis: First Accreditation Procedure

	P Participation / Support E Execution / Decision	STRUCTURE Responsible Persons / Groups								
#	PROCESS Activity	A Public Relation	B Consultant	C Case Manager	D Technical Expert	E Assessor Team	F Pool of Experts	G Technical Committee	H Decision Committee	OUTCOME Visible Results
1	Information	E	P		P		P	P		Brochures, Guides, Seminars
2	Preparation		E		P		P			Quality Manual, Quality Policies
3	Application		P	E						Application Package, Check record
4	Pre-Assessment		P	P	E	P	P	P		Notes, Records, Pre-Assessment Report
5	Review of Docs			P	P	E	P	P		Assessment Report Part I
6	CA Documentation			P		E				CA Report to Part I, Check record
7	Onsite Assessment			P	P	E	P	P		Assessment Report Part II
8	CA Implementation			P		E		P		CA Report to Part II, Check record
9	Report Evaluation			P			P	E		Minutes, Evaluation Report, Recommend.
10	Decision Finding			P	P	P	P	P	E	Minutes, Decision, Certificate

Risk Assessment of Accreditation Bodies

	Structure	Best case		Case NAB		Worst case	
A	Public Relation	5	100%	2	40%	0	0%
B	Quality System	5	100%	3	60%	1	20%
C	Case Officer	5	100%	2	40%	1	20%
D	Technical Expert	5	100%	1	20%	0	0%
E	Assessor Team	5	100%	3	60%	0	0%
F	Pool of Experts	5	100%	2	40%	0	0%
G	Technical Committee	5	100%	1	20%	0	0%
H	Decision Committee	5	100%	3	60%	0	0%



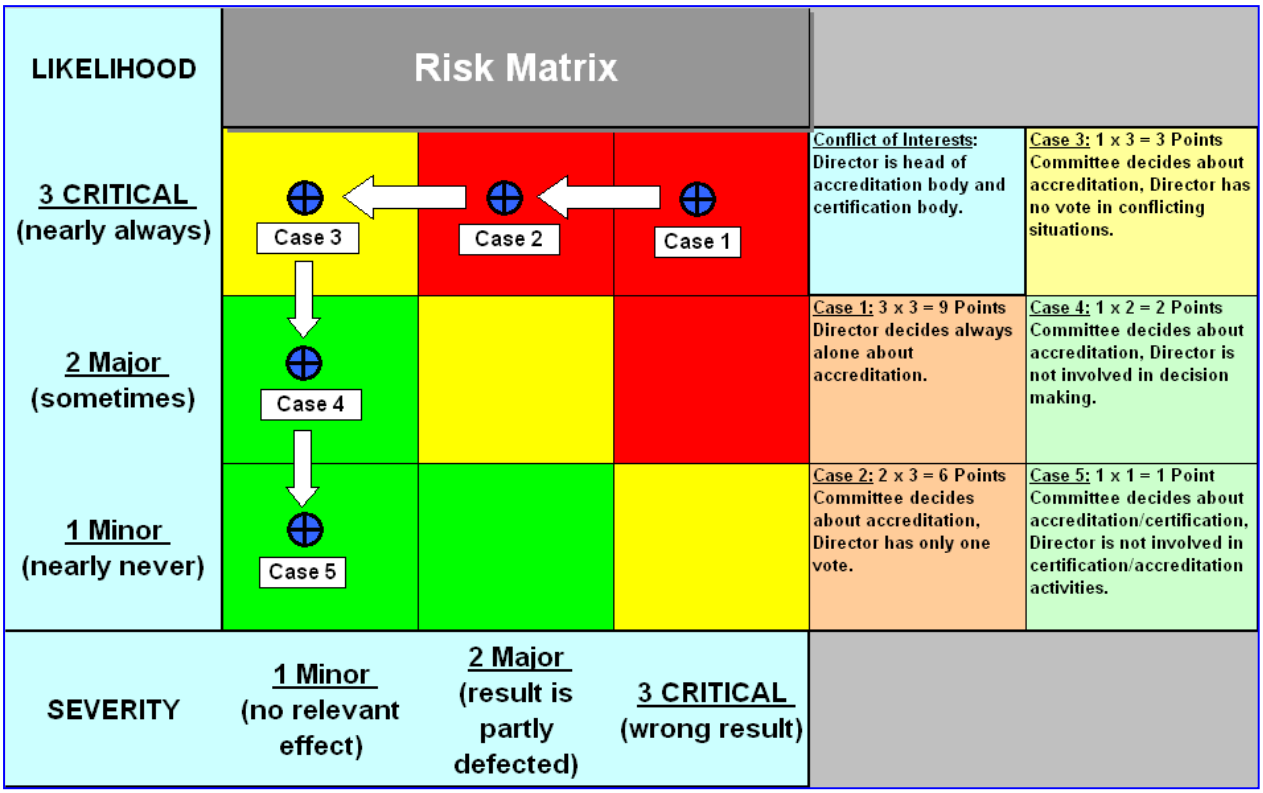
Nonconformities	25	x	CABs	4	=	100

	Process	Best case		Case NAB		Worst case	
1	Pre-Information	5%	95	2%	98	0%	100
2	Pre-Visit	25%	71	9%	89	2%	98
3	Check of Application	25%	53	8%	82	2%	96
4	Pre-Audit	25%	40	8%	75	2%	94
5	Check of Documents	25%	30	12%	66	1%	92
6	Corrective Actions	25%	23	12%	58	1%	91
7	Onsite-Audit	50%	11	24%	44	3%	89
8	Corrective Actions	50%	6	23%	34	2%	87
9	TC-Examination	50%	3	17%	28	2%	85
10	DC-Evaluation	50%	1	21%	22	2%	84
Reduction of Nonconformities		98,6%		77,7%		16,0%	

	A	B	C	D	E	F	G	H	Sum
1	5	1				1			7
2	3	1	5	3		1			13
3		1	3	5		1			10
4		1	3	5		1			10
5		1	2		5	2	1		11
6		1	2		5	2	1		11
7		1	2		5	3	1		12
8		1	2		5	3	2		13
9		1	1			5	5		12
10		1	1				5	5	12
Sum	8	10	21	13	20	19	15	5	111

Based on experience-based values a weighting matrix of influences of structure elements to process components the reduction of risks in worst, normal and best case was demonstrated.

A case study (conflicts of interests of a director who heads accreditation and certification services at the same time) was analysed by a risk matrix (see ISO 1441).



Severity and Likelihood of risk factors based on poor fulfillment (worst case in practice) of 11 ILAC-IAF Key Performance Indicators were analysed.

Risk Analysis Key Performance Indicators (Examples)

KPI	Key Performance Indicator	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
1	The AB has established effective ways to communicate with organisations and institutes which will provide the necessary expertise	Interviews with interested and involved parties	Barriers of communication, no peer-to-peer relation, access to politicals instead of technicians	2	3	6
2	The AB should have ... a policy how to extend into new areas or into technical fields of accreditation	Interviews with interested and involved parties	No pro-active view, no design procedures, poor access to expertise in new areas	2	3	6
3	The competence of the AB is essentially based on its staff, assessors, experts and committees. (training and monitoring)	Competence profiles and Monitoring system	No sufficient access to external expertise, poor training resources, no systematic monitoring	2	3	6
4	The assessment team must have sufficient competence.	Competence profiles and Monitoring system	Lack of work experience, "certification approach" instead of CAB competence evaluation	3	2	6
5	The market place and MLA members must have full confidence that accreditation is granted on the basis of full impartiality of the AB, its committees, assessors, experts and decision making bodies	Interviews with interested and involved parties	Longterm high corruption without any progress, poor economical power, insufficient salaries	3	3	9
6	Decision-making depends on the AB's judgement regarding the NCs and CAs. Adequate separation of the assessment from the decision-making process.	NC Classification Good Decision Practice	Decider depends totally on opinion of single assessors / experts, no competence in decider group	3	2	6
7	Internal audits and management reviews give good indication about the capability of an AB to identify elements for improvement, in which way it develops and how it does learn.	Pre Peer Evaluation by PTB	Unprofessional management review, poor structure analysis, no pro-active view, poor strategies	3	2	6
8	Successful participation in PTs and ILCs demonstrate the ability of a laboratory to produce credible results. AB's competence to properly analyse PT results.	Statistical Evaluation	Poor competence to evaluate PT results. No or bad PTs available, no CA for poor results	3	2	6
9	Calibration, traceability and use of RMs are fundamental means for acheiving consistency in testing and measurement results, for proper function of technical equipment and for validation	Pre Peer Evaluation by PTB	Only formal traceability, no competence of NMI, RM and calibration services too expensive	3	2	6
10	Surveillance and reassessment activities must provide confidence that accredited CABs continue to provide reliable results over their full scope of accreditation and continue to operate an effective QMS.	Pre Peer Evaluation by PTB	Depth of surveillance insufficient, no trendanalysis, market reactions and capacity limits not evaluated	2	3	6
11	Abs have the opportunity to provide supplementary service that benefits the AB, its clients, its stakeholders and other interested parties.	Pre Peer Evaluation by PTB	Poor customer-focused services, no resources available, poor access to client parties, market	3	2	6

Risk Analysis ISO 17011 Examples 4 Accreditation body						
Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
4.2.1	The structure and operation of an AB shall be such as give confidence in its accreditations	Interviews with interested parties	Missing anticorruption actions in high corrupted countries	2	2	4
4.2.2	The AB shall have authority and shall be responsible for its decisions ...	SPO Analysis	Responsibility for decisions not transparent in governmental ABs	2	3	6
4.2.5	The AB shall identify the top management ... d) decisions on accreditation	Good Decision Practice	Decider is a person / board outside of AB quality system	2	2	4
4.2.6	The AB shall have access to necessary expertise for advising...	Interviews with interested parties	No access to important parties, no technical competence in TCs	3	2	6
4.2.7	The AB shall ... identify the parties participating (in committees)	Interviews with interested parties	Important representatives are missing in committees	2	2	4
4.2.8	The AB shall document its entire structure, showing lines of authority and responsibility	SPO Analysis	The head of AB decides about everything, no delegation of tasks	2	2	4
4.3.1	The AB shall be organized and operated so as to safeguard the objectivity and impartiality of its activities	Interviews with interested parties	Corrupted staff caused by poor salaries / economy / mentality	3	2	6
4.3.2	The AB shall have ... implemented a structure to provide opportunity for effective involvement by interested parties.	Interviews with interested parties	Interested parties have no effective representation, no motivation	2	2	4
4.3.2	The AB shall ensure a balanced representation of interested parties with no single party predominating	Interviews with interested parties	In practice governmental dominance by hidden relations	2	3	6
4.3.3	The ABs policies and procedures shall be non-discriminatory and shall be administered in a non-discriminatory way.	Statistical Evaluation	Hidden political, religious, financial, gender discrimination	3	2	6
4.3.4	All AB personnel and committees... shall be free from any undue ... pressures that could compromise impartiality.	Statistical Evaluation	Multiple pressure by financial, personal, political, other sources	2	3	6
4.3.5	The AB shall ensure that each decision on accreditation is taken by competent persons or committees.	Good Decision Practice	Decider is not competent, TCs are not involved, 1 expert decides	3	3	9
4.3 5	The deciders shall be different from those who carried out the assessment.	Good Decision Practice	Decider depends 100% on opinion of assessor team	3	3	9
4.3.6	The AB shall not offer or provide any services that affects its impartiality, such as b) consultancy	SPO and Risk Analysis	No competent consultancy available in the country	3	3	9
4.3.7	The AB shall ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality...	SPO and Risk Analysis	Related body has multiple access to acc data, in practice	2	3	6
4.3.7	The AB, with the participation of interested parties .. shall identify, analyse and document the relationships with related bodies	SPO and Risk Analysis	No analysis with interested par-ties, no transparency of relations	2	2	4
4.3.7	Where potential conflicts of interests are identified, appropriate action shall be taken.	Risk Management	Conflicts are still active in the background, no measures taken	2	3	6
4.5.2	The AB shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities	Financial 5 y Plan, Business Plan	no financial stability by shareholders, national economy	3	3	9
4.6.3	The AB shall establish procedures for extending its activities and to react to demands of interested parties.	Interviews with interested parties	no design scheme for new areas, no access to market demands	3	3	9
4.6.3	Possible elements to be included in the procedures are: a) analysis of its present competence, suitability of extension, resources...	AB Capacity Analysis	No capacity available: no time, money, experts, training	3	3	9

The same analysis was done with some relevant requirements of ISO 17011. Observed problems in practice and used PTB tools were presented for each deficiency.

The risk classes are:

- Red condition: risk is not acceptable
- Yellow condition: ALARP region (as low as reasonable possible), risk management is needed
- Green condition: remaining risk is acceptable

Risk Analysis ISO 17011 Examples 5 Management

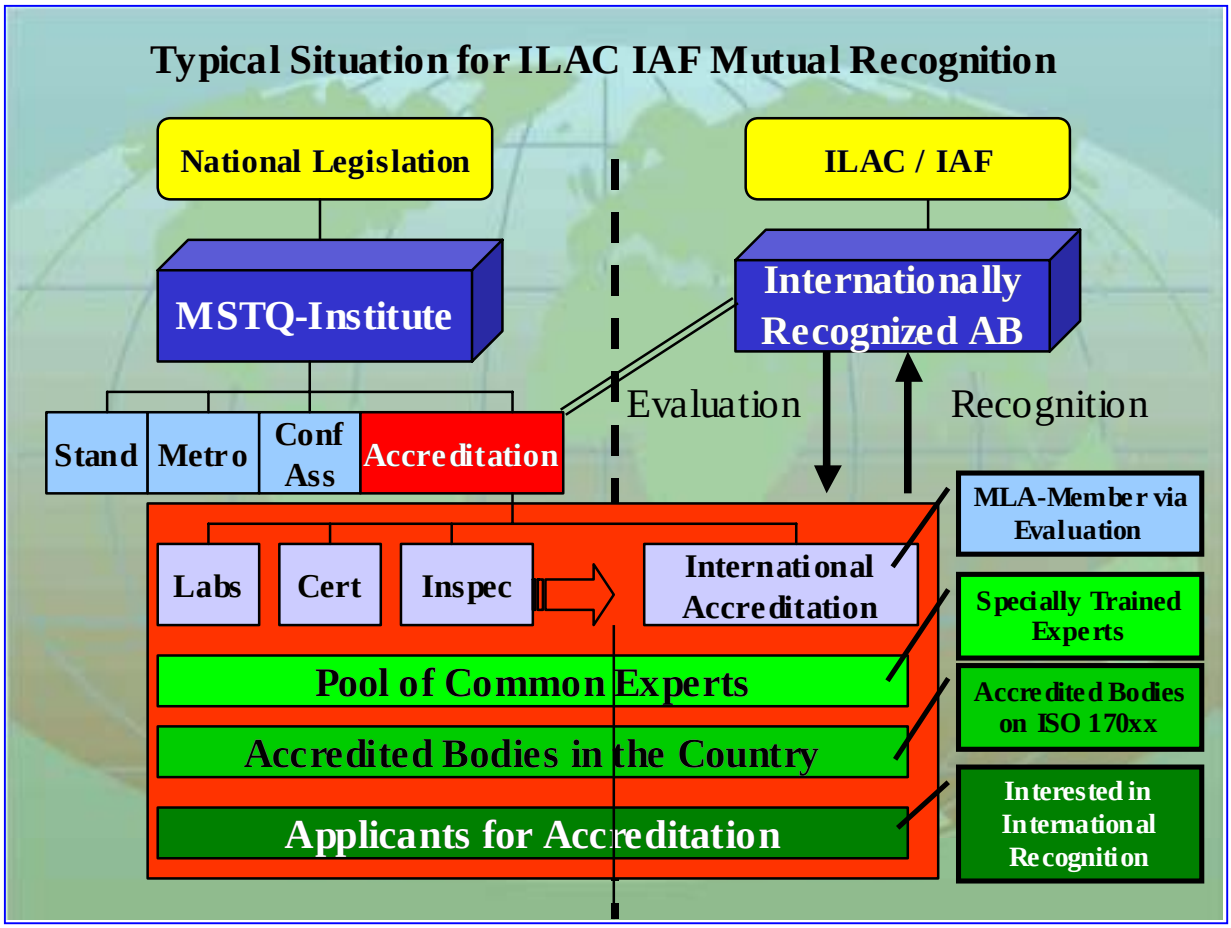
Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
5.2.1	The AB top management shall ensure effective communication of the needs of the interested parties.	Interviews with interested parties	No feedback by interested parties, no sustainable effects	3	2	6
5.2.2	The AB shall operate a management system appropriate to the type, range and volume of work performed	AB Capacity Analysis	AB totally overloaded with work, expon. Growth, linear planning	3	3	9
5.5	The AB shall establish procedures for the identification and management of nonconformities in its own operations	Pre Peer Evaluations	no permanent internal quality control, no four- eyes check	2	3	6
5.5	The AB shall also .. take actions to eliminate the causes of NCs.. The procedures shall cover: b) determining the causes of NC	NC Classification Scheme	No professional cause analysis, only surface effects detected	2	3	6
5.5	The AB procedures shall cover: g) reviewing the effectiveness of corrective actions	NC Classification Scheme	no effective CAs, no structure analysis, indicators and measures	2	3	6
5.6	The AB shall establish procedures to identify opportunities for improvement and to take preventive actions to eliminate causes of potential NCs.	NC Classification Scheme	no tools for preventive actions, only reacting quality instruments	2	3	6
5.6	The AB procedures shall define requirements for a) identifying potential NCs and their causes	NC Classification Scheme	No professional cause analysis, only surface effects detected	2	3	6
5.6	The AB procedures shall define requirements for d) reviewing the effectiveness of the preventive actions taken.	NC Classification Scheme	no effective PAs, no structure based analysis and measures	2	3	6
5.8.1	The AB top management shall establish procedures to review its management system to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements	Pre Peer Evaluations	No benchmarking, no measurable quality goals, no indicators, only formal check	2	3	6
5.8.2	Inputs to management reviews shall include....: e) new areas of accreditation, j) changes that could affect the management system	AB Capacity Analysis	No market knowledge, no pro-active view of analysis, only formal check	2	3	6
5.8.3	The outputs from the management reviews shall include actions related to c) need for resources	AB Capacity Analysis	Linear planning, but exponential growth	2	3	6
5.9	The Ab shall establish procedures for dealing with complaints.	Interviews with interested parties	No professional complaint manage-ment, suppressed complaints	2	2	4

Risk Analysis ISO 17011 Examples 6 Human Resources

Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
6.1.1	The AB shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time)..	AB Capacity Analysis	Staff overloaded with work, insufficient financial resources, poor work conditions	3	3	9
6.1.1	... Having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed	Competence profiles	Insufficient work experience for complex scopes, no external support	3	3	9
6.1.2	The AB shall have access to a sufficient number of assessors, including lead assessors, and experts to cover all its activities	AB Capacity Analysis	No sufficient experts available on competiting market	3	3	9
6.2.2	The AB shall establish procedures for selecting, training and formally approving assessors and experts used in the assessment process	Train the Trainer Program	AB uses only standard training offers, no check of effectiveness, no selection because lack of experts on the market	2	3	6
6.2.3	The AB shall identify the specific scopes in which each assessor and expert has demonstrated competence to assess	Competence profiles	No detailed scope description, only general classification	2	2	4
6.3.1	The AB shall review the performance and competence of its personnel in order to identify training needs.	Competence profiles	Insufficient tools for measuring performance and competence	2	2	4
6.3.2	Each assessor shall be observed on-site regularly..	Trainee Concept	Practice: Mostly one assessor in surveillance assessments	2	2	4

Risk Analysis ISO 17011 Examples 7 Accreditation Process

Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
7.3.1	The AB shall review its ability to carry out the assessment of the applicant CAB, in terms of its own policy, competence and ability of suitable assessors and experts.	Competence profiles	No "contract review", AB accepts always all applications	2	2	4
7.5.1	Before the initial assessment, a preliminary visit may be conducted with the agreement of the CAB.	Train the Trainer Program	No pre-assessments offered, no resources available	2	2	4
7.5.3	The AB shall ensure that team members act in an impartial and non-discriminatory manner.	Risk Analysis, Statistical analysis	In practice: optimists, pessimists, extremists, doubtists active	2	2	4
7.5.3	In particular: b) any existing, former or envisaged link or competitive position	Risk Analysis	In practice in small countries multiple links by competition	2	2	4
7.5.7	For initial assessments, in addition to visiting the main or head office, visits shall be made to all other premises of the CAB	"SGS - Model"	Global CABs have only "mailbox-offices" in smaller countries	3	1	3
7.8.6	The information provided to the accreditation decision-maker shall include the following as a minimum: f) the assessment report h) information on the resolution of all NCs i) any further information ... the competence of the CAB	Good Decision Practice	NC-Information for deciders insufficient, complete assessment report not available, never deviations to team opinion appeared	2	3	6
7.11.3	The interval between on-site assessments,.. depends on the proven stability that the services of the CAB has reached.	CAB Capacity Analysis	Market situation after accreditation changed drastically, CAB instabile	3	1	3



Tools for the Analysis of Peer Evaluation Reports

The statistical evaluation and visualization of nonconformities allows the identification of typical profiles and main deficiencies concerning the type (documentation, implementation or both), level of severity (minor, major, critical), location of source (structure, process, outcome) and related chapter of the standard.

A comparison of the findings with the results of the 30 milestones analysis of the same accreditation body and the related infrastructure allows the identification of typical deficient areas of the peer evaluation procedure.

In the following slides the statistical analysis of peer evaluation results was demonstrated by a report about a pre peer evaluation. The peer evaluator Philippe Delmas formerly COFRAC detected during such activity at an accreditation body 128 nonconformities, which were classified against PTB criteria.

During the workshop also the findings of the peer evaluation team about the ECA situation were partly classified against the PTB criteria. The analysis was not completed because the participants requested the demonstration of principles of the 30 milestones analysis.

The volume of a 30 milestones analysis contents normally about 50 pages. The first analysis is done during a 4 - 5 days workshop. So a sample of such a report with some examples of irregular results is attached as an annex to this report.

NAB Non Conformities against ISO 17011
Results of Pre Peer Evaluation Philippe DELMAS

NC #	Type 1 - 9	Level: small M C	Location: S P O	ISC 17011 Chapter	Description of NC
1	4	C	S	4.2	CEO
2	6	C	S	4.2	Boardmember
3	6	C	S	4.2	CEO
4	4	s	S	4.2	Art 10
5	4	M	S	4.2	RAC or Board
6	4	s	S	4.2	Art 9
7	4	s	P	4.2	Art 9
8	6	s	S	4.2	QRC
9	5	s	S	4.2	TC
10	4	s	S	4.2	TC
11	4	s	S	4.2	TC
12	4	s	S	4.2	TC Med
13	4	s	S	4.2	TC Med
14	6	s	S	4.2	Committees
15	4	s	S	4.2	Pool Assessor
16	5	C	S	4.3	CSI
17	5	C	S	4.3	CSI Member
18	5	M	P	4.3	Decision
19	1	M	S	4.3	Training

Non Conformities against ISO 17011
Statistical Evaluation Pre Peer Evaluation NAB

Non-Conformity Type 1 - 9 Documentation versus Implementation				Summaries
1	6	wrong Impl	wrong Doc	Type I: 1+2+4
2	5	wrong Impl	no Doc	31 NCs
3	0	wrong Impl	correct Doc	Type II: 3+5+6
4	20	no Impl	wrong Doc	42 NCs
5	35	no Impl	no Doc	Type III: 7+8+9
6	7	no Impl	correct Doc	55 NCs
7	26	correct Impl	wrong Doc	All Types: 1-9
8	29	correct Impl	no Doc	128 NCs
9	0	correct Impl	correct Doc	

minor	95 m	x 1 =	95 Points	Level
Major	16 M	x 3 =	48 Points	
CRITICAL	17 C	x 5 =	85 Points	228 NC Points
128 Nonconformities				

S Structure	35	Relations	Location
P Process	50	Relations	
O Outcome	43	Relations	

Classification of NAB NCs

		S	P	O	m	M	C	NC Pts	Class	Events
Type I: System NCs (Combined NCs in Documentation and Implementation)	I	15	10	6	22	3	6	61	C I S	31
Type II: Implementation NCs (No NCs in Documentation, but incorrect Implementation)	II	15	18	9	23	9	10	100	M II P	38
Type III: Documentation NCs (No NCs in Implementation, but incorrect Documentation)	III	5	22	28	50	4	1	67	m III O	119
minor NC: Nonconformity is not able to affect the process result	m	22	32	41				228		188
Major NC: Nonconformity could affect the process result	M	3	11	2						
CRITICAL NC: Nonconformity will always affect the process result	C	10	7							

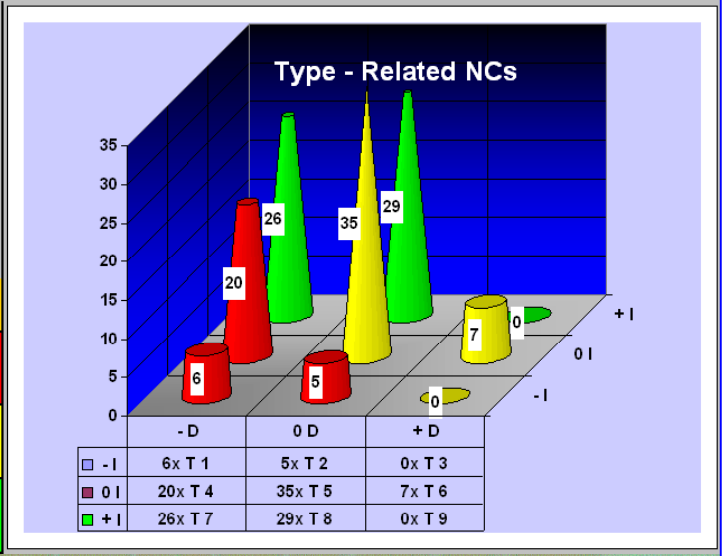
ISO 17011 Chapter

		S	P	O	m	M	C	I	II	III	All
4 Accreditation Body	4	22	6	6	20	7	7	15	14	5	34
5 Management	5	6	15	23	32	7	5	8	18	18	44
6 Human Resources	6	1	6	6	12		1	2	3	8	13
7 Accreditati											
8 Responsibi											

Classification Accreditation Body ISO 17011			Main Problems:	Documen- tation	of Processes		Class C I = 10%	Profile m III O
NAB	Year	Delmas	S	P	O	Type I	Type II	Type III	228
	Class	Degree	Structure	Process	Outcome	System-NCs	Implement.	Document.	NC-Points
		0%	No Quality System						
17	C I	10%	4	2		6			30
CRITICAL	C II	20%	6	4			10		50
NCs	C III	30%		1				1	5
16	M I	40%	2		1	3			9
Major	M II	50%	1	7	1		9		27
NCs	M III	60%		4				4	12
95	m I	70%	9	8	5	22			22
minor	m II	80%	8	7	8		23		23
NCs	m III	90%	5	17	28			50	50
perfect		100%	No Nonconformities in Quality System						Sum
Summary	128	NCs	35	50	43	31	42	55	228
			Structure	Process	Outcome	System-NCs	Implement.	Document.	

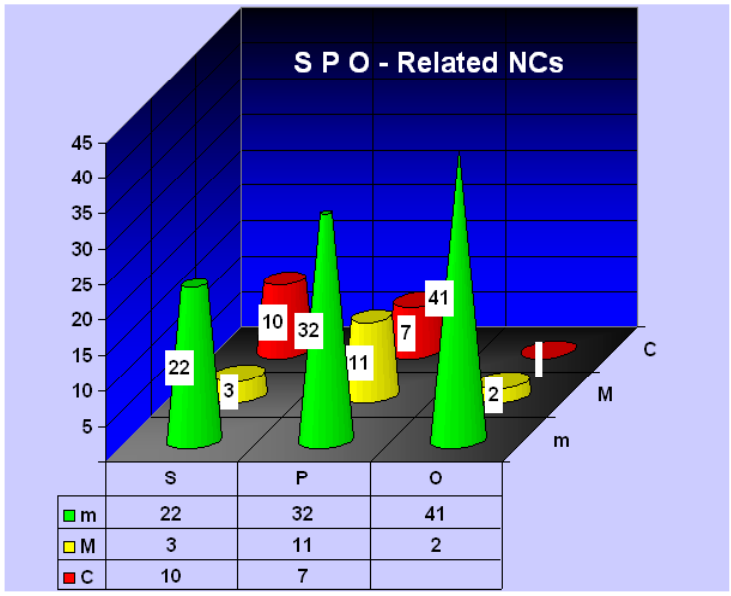
	- D	0 D	+ D	
- I	6x T 1	5x T 2	0x T 3	11
0 I	20x T 4	35x T 5	7x T 6	62
+ I	26x T 7	29x T 8	0x T 9	55
	52	69	7	128

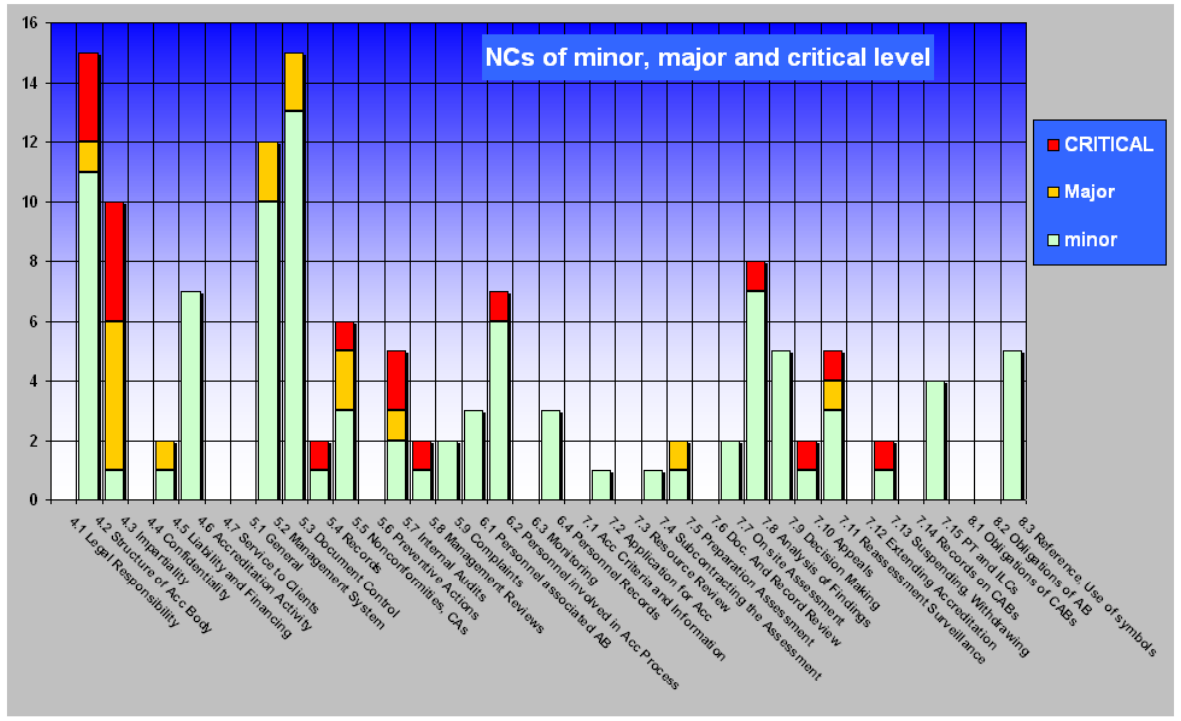
Type I:	System-NCs: Combined NCs in Documentation and Implementation	31
Type II:	Implementation: No NCs in Documentation, but incorrect Implementation	42
Type III:	Documentation: No NCs in Implementation, but incorrect Documentation	55

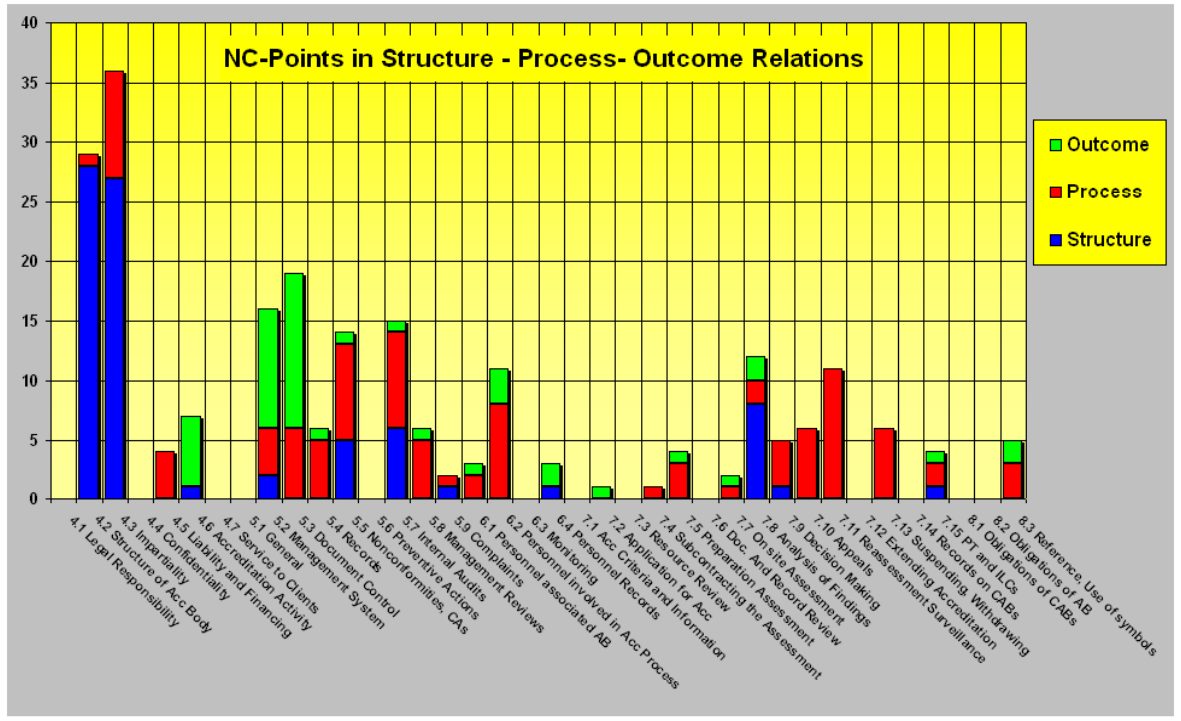


	S	P	O	
m	22	32	41	95
M	3	11	2	16
C	10	7		17
	35	50	43	128

minor	Nonconformity is not able to affect the process result
Major	Nonconformity could affect the process result
CRITICAL	Nonconformity will always affect the process result




NCs of minor, major and critical level
CRITICAL
Major
minor
16
14
12
10
8
6
4
2
0
4.1 Legal Responsibility
4.2 Structure of Acc Body
4.3 Impartiality
4.4 Confidentiality
4.5 Liability and Financing
4.6 Accreditation Activity
4.7 Service to Clients
5.1 General
5.2 Management System
5.3 Document Control
5.4 Records
5.5 Nonconformities, CAs
5.6 Preventive Actions
5.7 Internal Audits
5.8 Management Reviews
5.9 Complaints
6.1 Personnel associated AB
6.2 Personnel involved in Acc Process
6.3 Monitoring
6.4 Personnel Records
7.1 Acc Criteria and Information
7.2 Application for Acc
7.3 Resource Review
7.4 Subcontracting the Assessment
7.5 Preparation Assessment
7.6 Doc. And Record Review
7.7 On site Assessment
7.8 Analysis of Findings
7.9 Decision Making
7.10 Appeals
7.11 Reassessment Surveillance
7.12 Extending Accreditation
7.13 Suspending, Withdrawing
7.14 Records on CABs
7.15 PT and ILCs
8.1 Obligations of AB
8.2 Obligations of CABs
8.3 Reference, Use of symbols


NC-Points in Structure - Process- Outcome Relations
Outcome
Process
Structure
40
35
30
25
20
15
10
5
0
4.1 Legal Responsibility
4.2 Structure of Acc Body
4.3 Impartiality
4.4 Confidentiality
4.5 Liability and Financing
4.6 Accreditation Activity
4.7 Service to Clients
5.1 General
5.2 Management System
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5.4 Records
5.5 Nonconformities, CAs
5.6 Preventive Actions
5.7 Internal Audits
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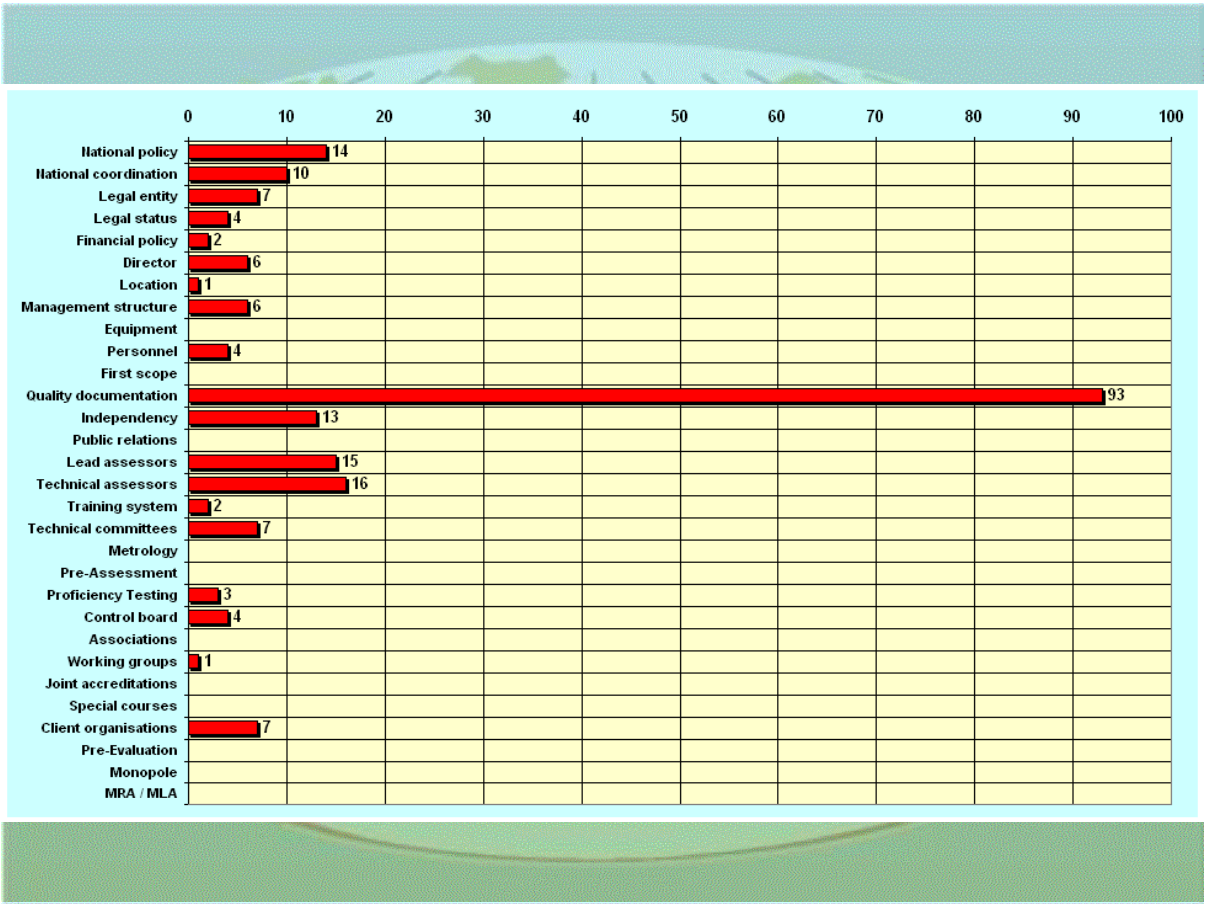
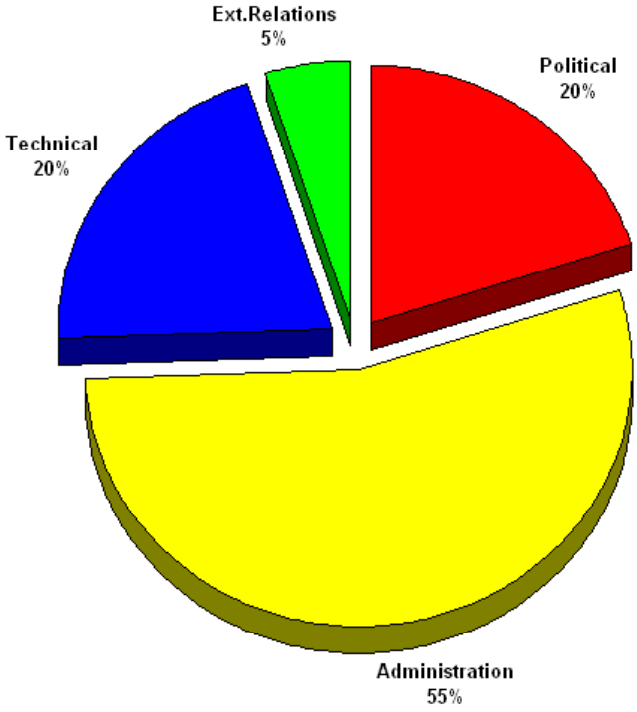

0
10
20
30
40
50
60
70
80
90
100
National policy 14
National coordination 10
Legal entity 7
Legal status 4
Financial policy 2
Director 6
Location 1
Management structure 6
Equipment
Personnel 4
First scope
Quality documentation 93
Independency 13
Public relations
Lead assessors 15
Technical assessors 16
Training system 2
Technical committees 7
Metrology
Pre-Assessment
Proficiency Testing 3
Control board 4
Associations
Working groups 1
Joint accreditations
Special courses
Client organisations 7
Pre-Evaluation
Monopole
MRA / MLA


Ext.Relations
5%
Political
20%
Technical
20%
Administration
55%

Summary

At the end of the workshop, a summary was given about the experiences during the peer evaluation. The detected deficiency areas, which were normally not covered by, peer assessment activities were listed and some recommendations for improvement of the peer evaluation training and procedure were listed.

Most Critical Points

- Political influence, mostly hidden
- "unprepared" market, no quality culture in industry and trade
- Lack of local expertise, too much competition
- Poor access to relevant parties, especially powerful global players
- Exponential growth of work volume
- Insufficient finances, no "critical mass" of clients
- Poor decision finding base
- "certification mentality", no evaluation of competence
- No orientation to risk-based assessments
- Poor monitoring of markets for innovations, new branches, etc
- Poor protection against corruption, low paid staff and assessors
- Subjective assessor profiles (optimist, pessimist, extremist, doubtist)
- Staff overloaded with work or demotivated
- "Mafia-CABs", high rate of counterfeiters

Additional tools for Peer Evaluations

- Knowledge base about country situation: history, culture, politics, economy, special conditions
- Interviews with assessors, solving case studies
- Interviews with accreditation body staff, using worst-case scenarios
- Interviews with interested parties: members and non-members (!)
- Risk analysis with worst-case scenarios
- Measurable performance indicators (for example 30 Milestones)
- Effective surveillance-tools and feedback lines
- Statistical analysis of trends and distributions

IAAC-PTB Workshop:

Improvement of Peer Evaluation Procedures – Exchange of Experience

ECA Costa Rica

13th – 15th February 2008

Manfred Kindler

PTB Germany

Peer Evaluation Workshop

Wednesday, 13th Feb 2008

09.00 – 13.00	Welcome Introduction to the workshop News from EA and ILAC about Peer Evaluation
14.00 – 18.00	Opening meeting (Simulation) ECA Onsite evaluation Part I

Peer Evaluation Workshop

Thursday, 14th Feb 2008

09.00 – 13.00	ECA Onsite evaluation Part II Final meeting (Simulation)
14.00 – 18.00	Report writing and classification of findings Presentation of the report

Peer Evaluation Workshop

Friday, 15th Feb 2008

09.00 – 13.00	Evaluation of the results Exchange of experiences
14.00 – 17.00	Exchange of experiences Recommendations for improvement

Peer Evaluation Workshop

Objectives of the exchange of experiences

1. Evaluation of detected NCs with their sources,
2. Development and evaluation of adequate CAs
3. Estimation of the limits of peer evaluation methods and procedures
4. Presentation of PTB developed tools for long-term monitoring of accreditation bodies,
5. Discussion of the findings and consequences for the improvement of the peer evaluation training

Peer Evaluation Workshop

Used training material

- Complete set of an IAAC Application package for the peer evaluation (all documents in Spanish):

- Acreditación de Laboratorios de Calibración
- Acreditación de Organismos de Inspección
- Acreditación de Certificación de Sistemas de Gestión de Calidad (QMS)
- Acreditación de Certificación de Sistemas de Gestión Ambiental (EMS)
- Acreditación de Certificación de Producto (Producto)

- with application form and 29 attached documents including the self-assessment report of Key Performance Indicators (Annexo 23)
- given on a CD at 23th January 2008 to the IAAC Secretary.

Peer Evaluation Workshop

IMPORTANT:

The review of documents should be finished till 13th February 2008. For clarifications contact the ECA quality manager Catalina Barquero Ulloa.

The on-site peer evaluation takes 8 hours and includes only some parts of a total peer evaluation procedure:

- Only one accreditation case of each field (calibration, inspection, system and product certification), first accreditation procedure and surveillance visits
- Only the responsible case manager, but interviews with the head of AB and quality manager
- Only the involved ECA assessors and technical experts (no interviews)
- Only the related committees and decision-makers (no interviews)
- Not any witnessing of assessments.

The peer evaluation team should be concentrated to the major and critical nonconformities and quality relevant observations.

Peer Evaluation Workshop

History and Background of this workshop (I)

1974 PTB founded the first accreditation body of Germany: DKD Deutscher Kalibrierdienst, after 2007 separated body, now 396 accred. CLs including 25 CLs in 15 foreign countries.
Start of PTB Technical Assistance Projects

1975 DKD is Founding Member of WECC Western European Calibration Cooperation
Start of Peer Evaluation Activities

1991 DKD is Founding Member of DAR German Accreditation Council

Peer Evaluation Workshop

History and Background of this workshop (II)

1994 Merge WECC with WELAC to EAL, European Accreditation of Laboratories, later EA

1994 Transfer from BAM-Accreditation to DAP
Now 1059 TLs, 23 MLs, 108 IB, 100 CBs in >20 countries
In 1995/1996 peer evaluated by EAL, EAC, EA and NIST

1995 Start of PHARE Project of European Union: MSTQ-Peer Evaluation, Birth of **30 Milestones** for 12 Easter European Countries, 5 years of peer monitoring of development and progress of ABs

History of 30 Milestones

1995 - 2000 Eastern European Countries			
EAK	Estonia	ILAC	IAF
LA	Lithuania	ILAC	IAF
LATAK	Latvia	ILAC	IAF
PCA	Poland	ILAC	IAF
CAI	Czech Rep	ILAC	IAF
NAT	Hungary		
SNAS	Slovakia	ILAC	IAF
SA	Slovenia	ILAC	IAF
IARM	Macedonia		
DPS	Albania		
RENAR	Romania	ILAC	
BAS	Bulgaria	ILAC	IAF

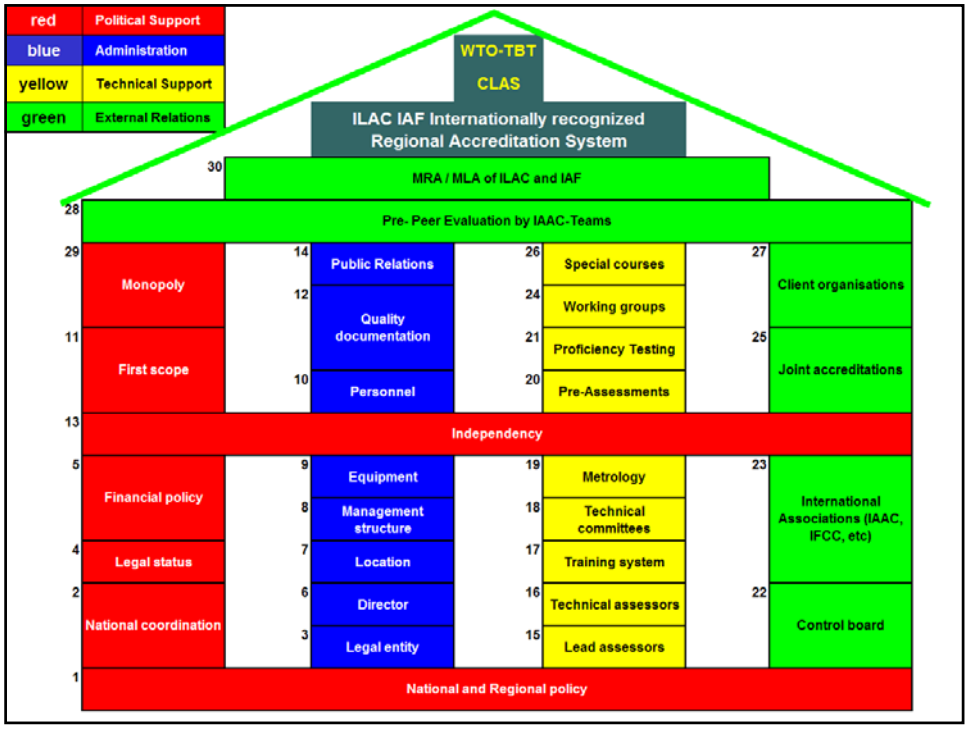
2000 - 2005 Asia			
TURKAK	Turkey	ILAC	IAF
TISI	Thailand	ILAC	IAF
BPSLAS	Philippines	ILAC	IAF

2000 - 2010 Southamerica			
OAA	Argentina	ILAC	
INN	Chile		
ONA	Paraguay		
INDECOPI	Peru		IAF
OAE	Ecuador		
SIC	Colombia		
SENCAMER	Venezuela		
OBA DTA	Bolivia		

2005 - 2010	Centroamerica	
ECA	Costa Rica	ILAC
OHA	Honduras	
ONA	Nicaragua	
OGA	Guatemala	
CNA	Panama	
FOCA	FOCA Region	

2005 - 2010	Caribbean Region	
TTLABS	Trinidad & Tobago	
JANAS	Jamaica	
CLAS	CLAS Region	
ONARC	Cuba	ILAC

2005 - 2010	African Countries
KENAS	Kenya
UNAS	Uganda
TANAS	Tanzania
MCI	Morroco
TUNAC	Tunisia
ALGERAC	Algeria
EGAC	Egypt
EACAS	EAC Region



Peer Evaluation Workshop

History and Background of this workshop (III)

1997 Analysis of all Peer Evaluation reports of EA by DAR / DAP (Mittmann / Kindler)

1998 First drafts of Key Performance Indicators by Mittmann, based on EA report evaluation

2001 First Peer Evaluator Training in Pretoria with Key Performance Indicators

2005 Common ILAC / IAF Guidance A3: Key Performance Indicators (KPIs)

2007 New Revision ILAC / IAF A3: KPIs

Peer Evaluation Workshop

History and Background of this workshop (IV)

2003 Review of New Approach **COM(2003) 240 final**

The use of accreditation in this context is an important step towards greater comparability in the assessment and surveillance of notifies bodies, in particular due to the co-ordinating function of the Multi-Lateral Agreement (MLA) established by the European co-operation for Accreditation (EA).
However, the MLA has not solved all problems.

Peer Evaluation Workshop

History and Background of this workshop (IV)

2003 Review of New Approach **COM(2003) 240 final**

The Commission considers that in order to improve this situation, more comprehensive guidance for the use of accreditation should be developed with the aim of increasing coherence and structure for accreditation services within the Community, especially regarding the independence of accreditation bodies from commercial activities and competition between different bodies....

Peer Evaluation Workshop

History and Background of this workshop (V)

2006 EA General Assembly Riga: New Project
"Enhancing European Accreditation"
- with 5 Subprojects and 3 Project Teams
 # 5 "Enhancing the peer evaluation process"

2006 IAF Cancun: New IAF Task Force
„Re-engineering of Accreditation"
- Convener: Lorenzo Thione, Chairman of EA
- Final report presented on Oct 2007
at ILAC/IAF GA Open Forum Sydney

Peer Evaluation Workshop

History and Background of this workshop (VI)

2007 ILAC General Assembly Sydney: New Drafts
„Effective tools for evaluating accreditation bodies".
2007 EA General Assembly Nicosia: First results
- Best Practice Guide (Mandatory Area)
- Revision of MLA Procedure EA -2/02
- DANAK, UKAS, SIT peer evaluated by risk-based approach (pilot process)

2008 PTB – IAAC Workshop **„Peer Evaluation"**
- Awareness building, Exchange of experience

Peer Evaluation Workshop

European co-operation for Accreditation

EA ACTIVITY REPORT

May to July 2007 ILAC ARC (07) 51 Ag. 1.4

Another major project supporting the EA development strategy is the EA Development Project on "Enhancing European Accreditation" that started at the General Assembly in Riga in June 2006. All its five sub-project groups have made significant headway in one year.

Sub-project 1: Harmonisation of assessment procedures for accred.
Sub-project 2: Information and Knowledge Database
Sub-project 3: A Best Practice guide related to communications between ABs and national regulators,
Sub-project 4: Relations between EA and the Commission
Sub-project 5: Enhancing the peer evaluation process focuses on
1) opening more to the National Authorities whose representatives could be invited to peer evaluation visits as observers and
2) developing the risk-based approach for surveillance activities.

Peer Evaluation Workshop

European co-operation for Accreditation

EA ACTIVITY REPORT

May to July 2007 ILAC ARC (07) 51 Ag. 1.4

The Multilateral Agreement Committee (MAC)

The MAC had completed a revision of EA-2/02 Policy & Procedures for the Multilateral Agreement which was endorsed by the General Assembly in May.

The MAC will also have to come up with a detailed proposal on how to enhance the surveillance process for MLA signatories based on the risk-based approach, which was well received by the General Assembly.

A process for providing technical training for evaluators will be worked out; a proposal will be submitted to the GA in Nov 2007

IAAC-PTB Workshop:

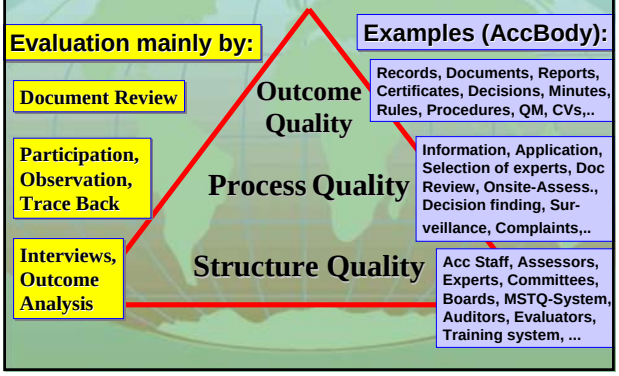
Improvement of Peer Evaluation Procedures – Exchange of Experience
Part II
ECA Costa Rica

13th – 15th February 2008

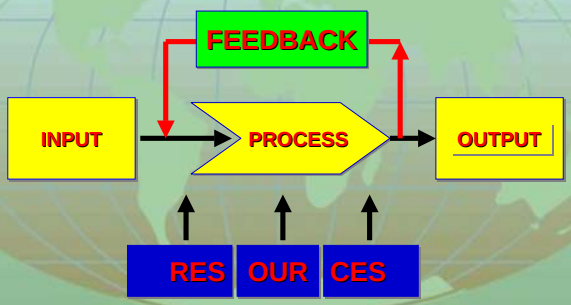
Manfred Kindler
PTB Germany

Basic Quality Tools (not only) for Accreditation Bodies

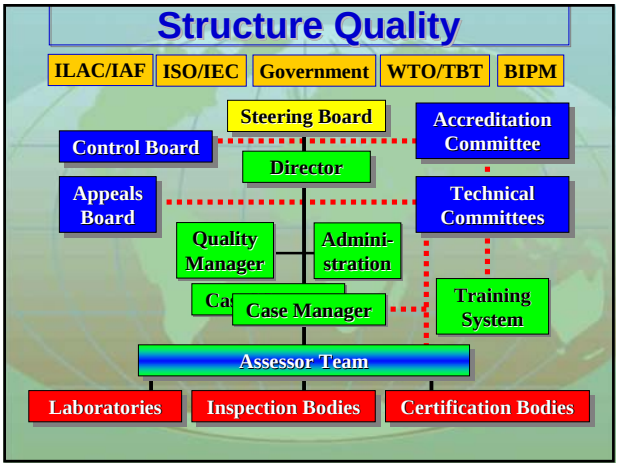
Pyramid of Qualities

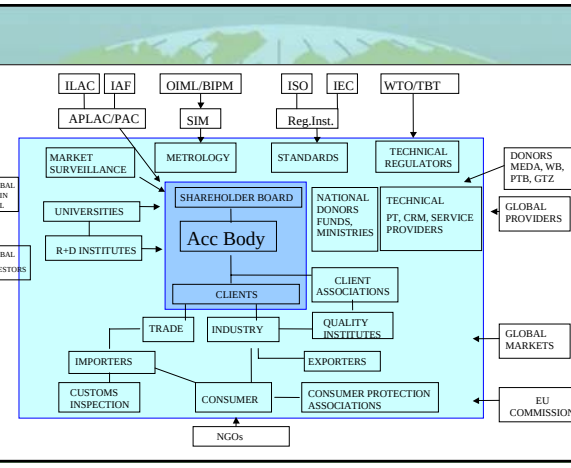


Principle of Quality Management



Structure Quality





Risk-Based Audits

First steps

Peer Evaluation Workshop

European co-operation for Accreditation

EA ACTIVITY REPORT

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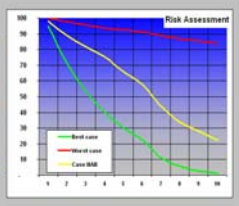
A process for providing technical training for evaluators will be worked out; a proposal will be submitted to the GA in Nov 2007

SPO-Analysis: First Accreditation Procedure

#	PROCESS Activity	A Public Relation	B Consultant	C Case Manager	D Technical Expert	E Assessor Team	F Pool of Experts	G Technical Committee	H Decision Committee	OUTCOME Visible Results
	P Participation / Support E Execution / Decision	STRUCTURE Responsible Persons / Groups								
1	Information	E	P		P		P	P		Brochures, Guides, Seminars
2	Preparation		E		P		P			Quality Manual, Quality Policies
3	Application		P	E						Application Package, Check record
4	Pre-Assessment		P	P	E	P	P	P		Notes, Records, Pre-Assessment Report
5	Review of Docs			P	P	E	P	P		Assessment Report Part I
6	CA Documentation			P		E				CA Report to Part I, Check record
7	Onsite Assessment			P	P	E	P	P		Assessment Report Part II
8	CA Implementation			P		E		P		CA Report to Part II, Check record
9	Report Evaluation			P			P	E		Minutes, Evaluation Report, Recommend.
10	Decision Finding			P	P	P	P	P	E	Minutes, Decision, Certificate

Risk Assessment of Accreditation Bodies

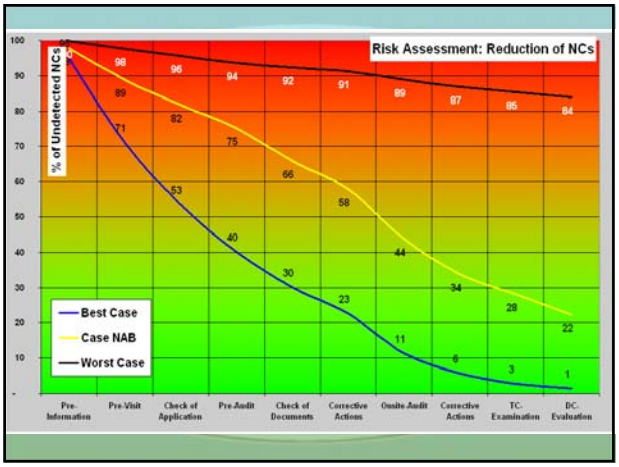


	Structure	Best case		Case NAB		Worst case	
A	Public Relation	5	100%	2	40%	0	0%
B	Quality System	5	100%	3	60%	1	20%
C	Case Officer	5	100%	2	40%	1	20%
D	Technical Expert	5	100%	1	20%	0	0%
E	Assessor Team	5	100%	3	60%	0	0%
F	Pool of Experts	5	100%	2	40%	0	0%
G	Technical Committee	5	100%	1	20%	0	0%
H	Decision Committee	5	100%	3	60%	0	0%

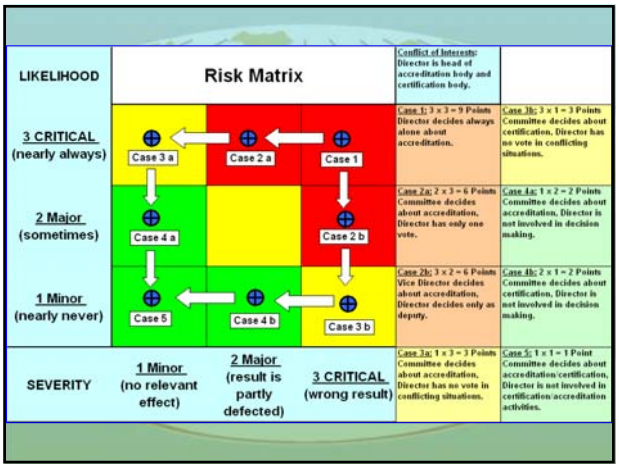
Nonconformities	25	x	CABs	4	=	100

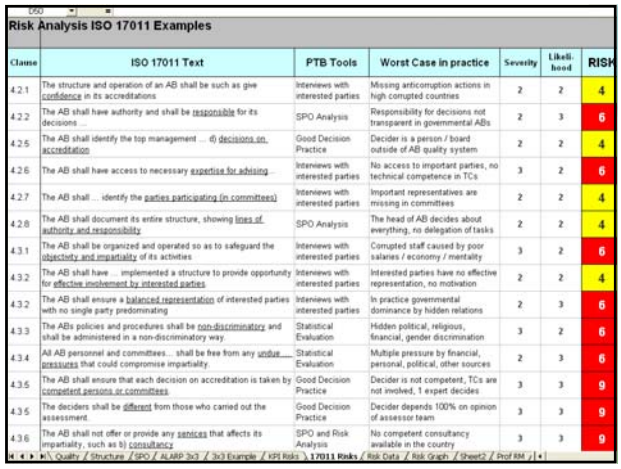
	Process	Best case		Case NAB		Worst case	
1	Pre-Information	5%	95	2%	98	0%	100
2	Pre-Visit	25%	71	9%	89	2%	98
3	Check of Application	25%	53	8%	82	2%	96
4	Pre-Audit	25%	40	8%	75	2%	94
5	Check of Documents	25%	30	12%	66	1%	92
6	Corrective Actions	25%	23	12%	58	1%	91
7	Onsite-Audit	50%	11	24%	44	3%	89
8	Corrective Actions	50%	6	23%	34	2%	87
9	TC-Examination	50%	3	17%	28	2%	85
10	DC-Evaluation	50%	1	21%	22	2%	84
	Reduction of Nonconformities	98,6%		77,7%		16,0%	

	A	B	C	D	E	F	G	H	Sum
1	5	1				1			7
2	3	1	5	3		1			13
3		1	3	5		1			10
4		1	3	5		1			10
5		1	2		5	2	1		11
6		1	2		5	2	1		11
7		1	2		5	3	1		12
8		1	2		5	3	2		13
9		1	1			5	5		12
10		1	1				5	5	12
Sum	8	10	21	13	20	19	15	5	111



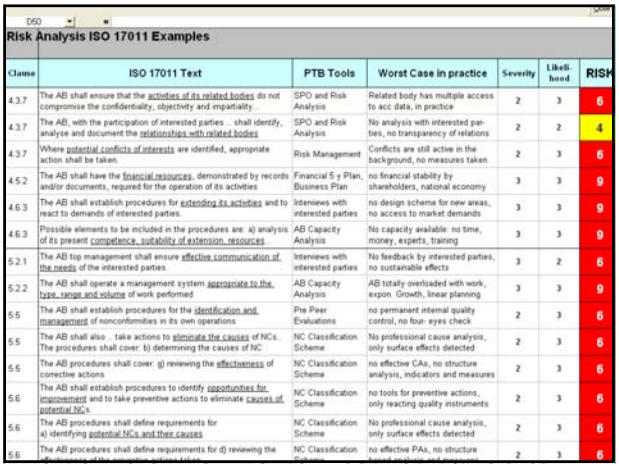
LIKELIHOOD	3 x 3 Risk Matrix		
3 CRITICAL (nearly always)	ALARP (as low as reasonable possible)	not acceptable risk	not acceptable risk
2 Major (sometimes)	acceptable risk	ALARP (as low as reasonable possible)	not acceptable risk
1 Minor (nearly never)	acceptable risk	acceptable risk	ALARP (as low as reasonable possible)
SEVERITY	1 Minor (no relevant effect)	2 Major (result is partly defected)	3 CRITICAL (wrong result)





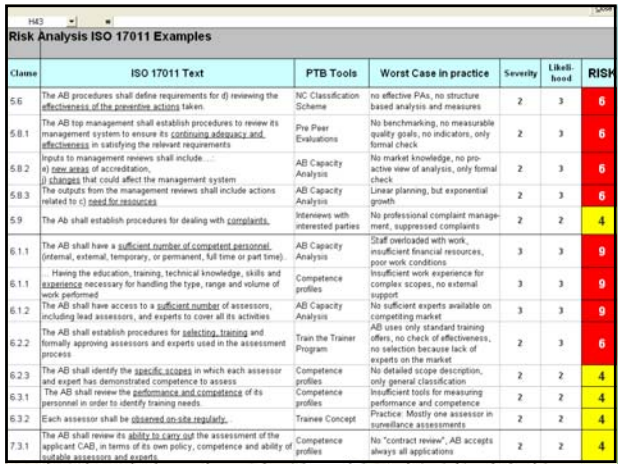
Risk Analysis ISO 17011 Examples

Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
4.2.1	The structure and operation of an AB shall be such as give confidence in its accreditations	Interviews with interested parties	Missing anticorruption actions in high corrupted countries	2	2	4
4.2.2	The AB shall have authority and shall be responsible for its decisions ...	SPO Analysis	Responsibility for decisions not transparent in governmental ABs	2	3	6
4.2.5	The AB shall identify the top management ... d) decisions on accreditation	Good Decision Practice	Decider is a person / board outside of AB quality system	2	2	4
4.2.6	The AB shall have access to necessary expertise for advising ...	Interviews with interested parties	No access to important parties, no technical competence in TCs	3	2	6
4.2.7	The AB shall ... identify the parties participating (in committees)	Interviews with interested parties	Important representatives are missing in committees	2	2	4
4.2.8	The AB shall document its entire structure, showing lines of authority and responsibility	SPO Analysis	The head of AB decides about everything, no delegation of tasks	2	2	4
4.3.1	The AB shall be organized and operated so as to safeguard the objectivity and impartiality of its activities	Interviews with interested parties	Corrupted staff caused by poor salaries / economy / mentality	3	2	6
4.3.2	The AB shall have ... implemented a structure to provide opportunity for effective involvement by interested parties	Interviews with interested parties	Interested parties have no effective representation, no motivation	2	2	4
4.3.2	The AB shall ensure a balanced representation of interested parties with no single party predominating	Interviews with interested parties	In practice governmental dominance by hidden relations	2	3	6
4.3.3	The ABs policies and procedures shall be non-discriminatory and shall be administered in a non-discriminatory way.	Statistical Evaluation	Hidden political, religious, financial, gender discrimination	3	2	6
4.3.4	All AB personnel and committees... shall be free from any undue ... pressures that could compromise impartiality.	Statistical Evaluation	Multiple pressure by financial, personal, political, other sources	2	3	6
4.3.5	The AB shall ensure that each decision on accreditation is taken by competent persons or committees.	Good Decision Practice	Decider is not competent, TCs are not involved, 1 expert decides	3	3	9
4.3.5	The deciders shall be different from those who carried out the assessment.	Good Decision Practice	Decider depends 100% on opinion of assessor team	3	3	9
4.3.6	The AB shall not offer or provide any services that affects its impartiality, such as b) consultancy	SPO and Risk Analysis	No competent consultancy available in the country	3	3	9



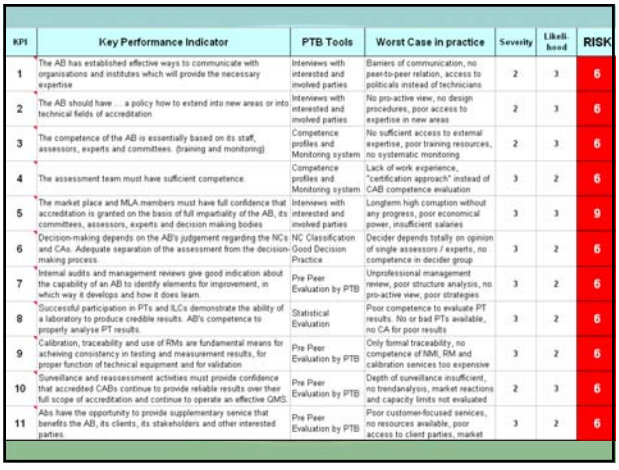
Risk Analysis ISO 17011 Examples

Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
4.3.7	The AB shall ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality...	SPO and Risk Analysis	Related body has multiple access to acc data, in practice	2	3	6
4.3.7	The AB, with the participation of interested parties ... shall identify, analyse and document the relationships with related bodies	SPO and Risk Analysis	No analysis with interested parties, no transparency of relations	2	2	4
4.3.7	Where potential conflicts of interests are identified, appropriate action shall be taken.	Risk Management	Conflicts are still active in the background, no measures taken	2	3	6
4.5.2	The AB shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities	Financial 5 y Plan, Business Plan	no financial stability by shareholders, national economy	3	3	9
4.6.3	The AB shall establish procedures for extending its activities and to react to demands of interested parties.	Interviews with interested parties	no design scheme for new areas, no access to market demands	3	3	9
4.6.3	Possible elements to be included in the procedures are: a) analysis of its present competence, suitability of extension, resources	AB Capacity Analysis	No capacity available: no time, money, experts, training	3	3	9
5.2.1	The AB top management shall ensure effective communication of the needs of the interested parties.	Interviews with interested parties	No feedback by interested parties, no sustainable effects	3	2	6
5.2.2	The AB shall operate a management system appropriate to the, type, range and volume of work performed	AB Capacity Analysis	AB totally overloaded with work, expon. Growth, linear planning	3	3	9
5.5	The AB shall establish procedures for the identification and management of nonconformities in its own operations	Pre Peer Evaluations	no permanent internal quality control, no four- eyes check	2	3	6
5.5	The AB shall also .. take actions to eliminate the causes of NCs. The procedures shall cover: b) determining the causes of NC	NC Classification Scheme	No professional cause analysis, only surface effects detected	2	3	6
5.5	The AB procedures shall cover: g) reviewing the effectiveness of corrective actions	NC Classification Scheme	no effective CAs, no structure analysis, indicators and measures	2	3	6
5.6	The AB shall establish procedures to identify opportunities for improvement and to take preventive actions to eliminate causes of potential NCs	NC Classification Scheme	no tools for preventive actions, only reacting quality instruments	2	3	6
5.6	The AB procedures shall define requirements for a) identifying potential NCs and their causes	NC Classification Scheme	No professional cause analysis, only surface effects detected	2	3	6
5.6	The AB procedures shall define requirements for d) reviewing the	NC Classification	no effective PAs, no structure	2	3	6

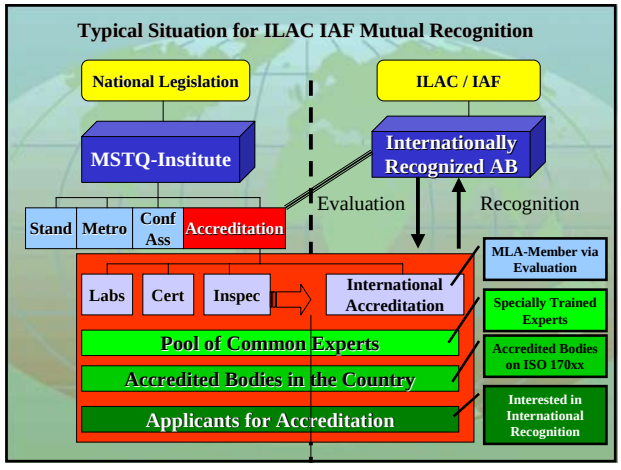


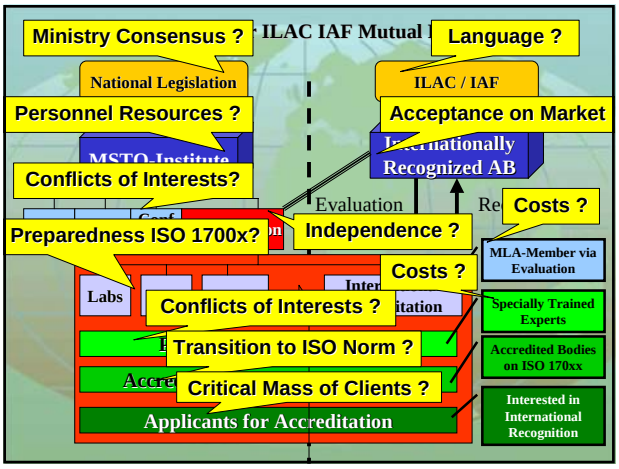
Risk Analysis ISO 17011 Examples

Clause	ISO 17011 Text	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
5.6	The AB procedures shall define requirements for d) reviewing the effectiveness of the preventive actions taken.	NC Classification Scheme	no effective PAs, no structure based analysis and measures	2	3	6
5.8.1	The AB top management shall establish procedures to review its management system to ensure its continuing adequacy and effectiveness in satisfying the relevant requirements	Pre Peer Evaluations	No benchmarking, no measurable quality goals; no indicators, only formal check	2	3	6
5.8.2	Inputs to management reviews shall include.... e) new areas of accreditation, j) changes that could affect the management system	AB Capacity Analysis	No market knowledge, no pro-active view of analysis, only formal check	2	3	6
5.8.3	The outputs from the management reviews shall include actions related to c) need for resources	AB Capacity Analysis	Linear planning, but exponential growth	2	3	6
5.9	The Ab shall establish procedures for dealing with complaints.	Interviews with interested parties	No professional complaint management, suppressed complaints	2	2	4
6.1.1	The AB shall have a sufficient number of competent personnel (internal, external, temporary, or permanent, full time or part time).	AB Capacity Analysis	Staff overloaded with work, insufficient financial resources, poor work conditions	3	3	9
6.1.1	... Having the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed	Competence profiles	Insufficient work experience for complex scopes, no external support	3	3	9
6.1.2	The AB shall have access to a sufficient number of assessors, including lead assessors, and experts to cover all its activities	AB Capacity Analysis	No sufficient experts available on competing market	3	3	9
6.2.2	The AB shall establish procedures for selecting, training and formally approving assessors and experts used in the assessment process	Train the Trainer Program	AB uses only standard training offers, no check of effectiveness, no selection because lack of experts on the market	2	3	6
6.2.3	The AB shall identify the specific scopes in which each assessor and expert has demonstrated competence to assess	Competence profiles	No detailed scope description, only general classification	2	2	4
6.3.1	The AB shall review the performance and competence of its personnel in order to identify training needs.	Competence profiles	Insufficient tools for measuring performance and competence	2	2	4
6.3.2	Each assessor shall be observed on-site regularly.	Trainee Concept	Practice: Mostly one assessor in surveillance assessments	2	2	4
7.3.1	The AB shall review its ability to carry out the assessment of the applicant CAB, in terms of its own policy, competence and ability of suitable assessors and experts	Competence profiles	No "contract review", AB accepts always all applications	2	2	4

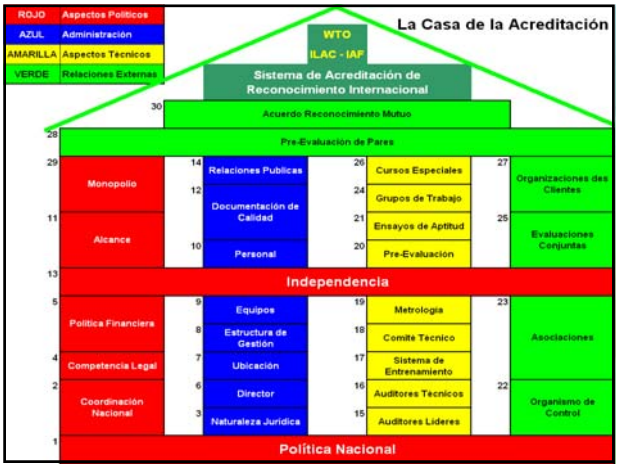


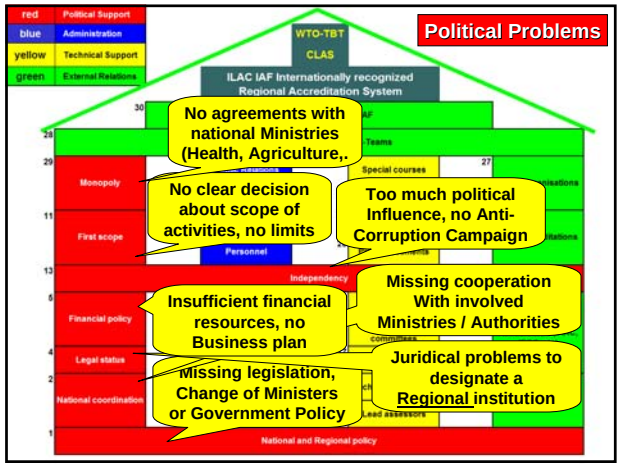
KPI	Key Performance Indicator	PTB Tools	Worst Case in practice	Severity	Likeli-hood	RISK
1	The AB has established effective ways to communicate with organisations and institutes which will provide the necessary expertise	Interviews with interested and involved parties	Barriers of communication, no peer-to-peer relation, access to politicals instead of technicians	2	3	6
2	The AB should have ... a policy how to extend into new areas or into technical fields of accreditation	Interviews with interested and involved parties	No pro-active view, no design procedures, poor access to expertise in new areas	2	3	6
3	The competence of the AB is essentially based on its staff, assessors, experts and committees. (training and monitoring)	Competence profiles and Monitoring system	No sufficient access to external expertise, poor training resources, no systematic monitoring	2	3	6
4	The assessment team must have sufficient competence.	Competence profiles and Monitoring system	Lack of work experience, "certification approach" instead of CAB competence evaluation	3	2	6
5	The market place and MLA members must have full confidence that accreditation is granted on the basis of full impartiality of the AB, its committees, assessors, experts and decision making bodies	Interviews with interested and involved parties	Longterm high corruption without any progress, poor economical power, insufficient salaries	3	3	9
6	Decision-making depends on the AB's judgement regarding the NCs and CAs. Adequate separation of the assessment from the decision-making process.	NC Classification Good Decision Practice	Decider depends totally on opinion of single assessors / experts, no competence in decider group	3	2	6
7	Internal audits and management reviews give good indication about the capability of an AB to identify elements for improvement, in which way it develops and how it does learn.	Pre Peer Evaluation by PTB	Unprofessional management review, poor structure analysis, no pro-active view, poor strategies	3	2	6
8	Successful participation in PTs and ILCs demonstrate the ability of a laboratory to produce credible results. AB's competence to properly analyse PT results.	Statistical Evaluation	Poor competence to evaluate PT results. No or bad PTs available, no CA for poor results	3	2	6
9	Calibration, traceability and use of RMs are fundamental means for achieving consistency in testing and measurement results, for proper function of technical equipment and for validation	Pre Peer Evaluation by PTB	Only formal traceability, no competence of NMI, RM and calibration services too expensive	3	2	6
10	Surveillance and reassessment activities must provide confidence that accredited CABs continue to provide reliable results over their full scope of accreditation and continue to operate an effective QMS.	Pre Peer Evaluation by PTB	Depth of surveillance insufficient, no trendanalysis, market reactions and capacity limits not evaluated	2	3	6
11	Abs have the opportunity to provide supplementary service that benefits the AB, its clients, its stakeholders and other interested parties.	Pre Peer Evaluation by PTB	Poor customer-focused services, no resources available, poor access to client parties, market	3	2	6

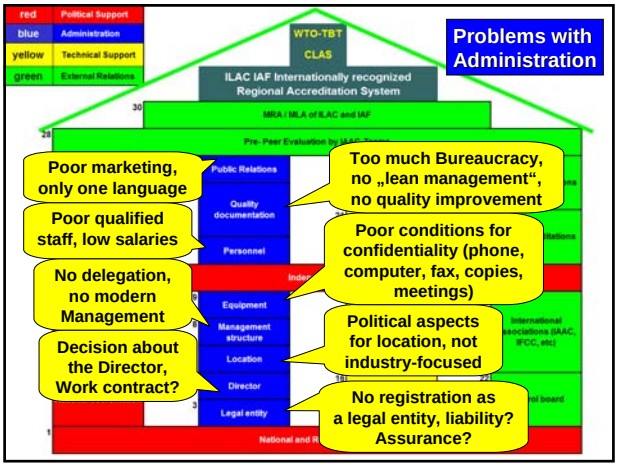


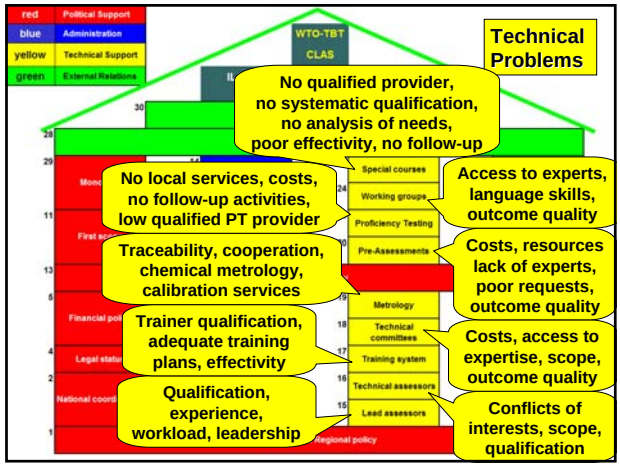

Ministry Consensus ?
ILAC IAF Mutual
Language ?
National Legislation
ILAC / IAF
Personnel Resources ?
Acceptance on Market
Conflicts of Interests?
Recognized AB
Evaluation
Costs ?
Preparedness ISO 1700x?
Independence ?
MLA-Member via Evaluation
Costs ?
Labs
Conflicts of Interests ?
Specially Trained Experts
Transition to ISO Norm ?
Accredited Bodies on ISO 170xx
Critical Mass of Clients ?
Interested in International Recognition
Applicants for Accreditation

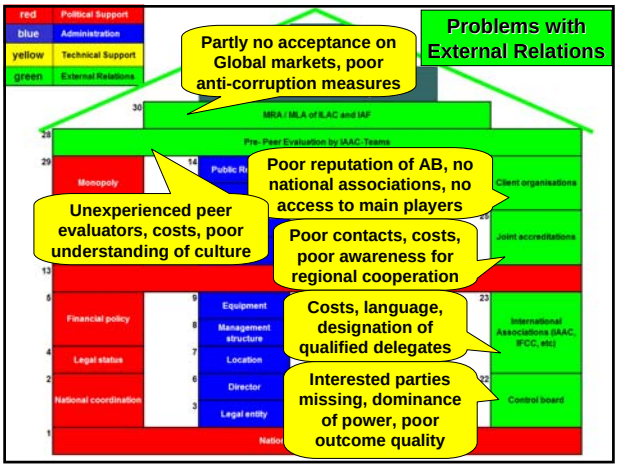

How to build the
„House of Accreditation“

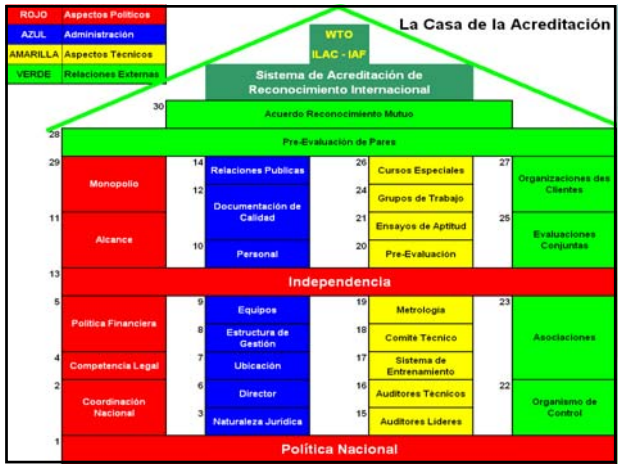

ROJO Aspectos Políticos
AZUL Administración
AMARILLA Aspectos Técnicos
VERDE Relaciones Externas
La Casa de la Acreditación
WTO
ILAC - IAF
Sistema de Acreditación de Reconocimiento Internacional
Acuerdo Reconocimiento Mutuo
Pre-Evaluación de Pares
Monopolio
Alcance
Relaciones Publicas
Documentación de Calidad
Personal
Cursos Especiales
Grupos de Trabajo
Ensayos de Aptitud
Pre-Evaluación
Organizaciones des Clientes
Evaluaciones Conjuntas
Independencia
Política Financiera
Competencia Legal
Coordinación Nacional
Equipos
Estructura de Gestión
Ubicación
Director
Naturaleza Jurídica
Metrología
Comité Técnico
Sistema de Entrenamiento
Auditores Técnicos
Auditores Líderes
Asociaciones
Organismo de Control
Política Nacional

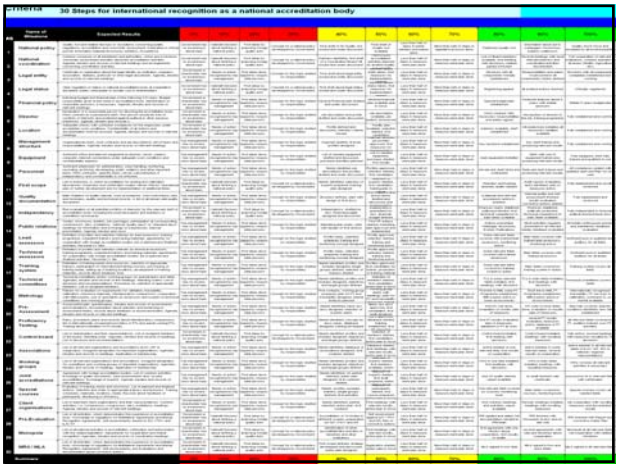

red Political Support
blue Administration
yellow Technical Support
green External Relations
WTO-TBT
CLAS
ILAC IAF Internationally recognized Regional Accreditation System
Political Problems
No agreements with national Ministries (Health, Agriculture,..
No clear decision about scope of activities, no limits
Too much political Influence, no Anti-Corruption Campaign
Missing cooperation With involved Ministries / Authorities
Insufficient financial resources, no Business plan
Juridical problems to designate a Regional institution
Missing legislation, Change of Ministers or Government Policy
National and Regional policy


red Political Support
blue Administration
yellow Technical Support
green External Relations
WTO-TBT
CLAS
ILAC IAF Internationally recognized Regional Accreditation System
Problems with Administration
Poor marketing, only one language
Too much Bureaucracy, no „lean management“, no quality improvement
Poor qualified staff, low salaries
Poor conditions for confidentiality (phone, computer, fax, copies, meetings)
No delegation, no modern Management
Political aspects for location, not industry-focused
Decision about the Director, Work contract?
No registration as a legal entity, liability? Assurance?

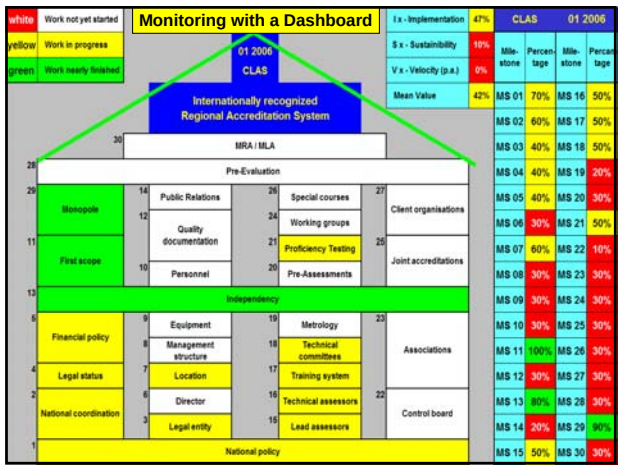

red Political Support
blue Administration
yellow Technical Support
green External Relations
WTO-TBT
CLAS
Technical Problems
No qualified provider, no systematic qualification, no analysis of needs, poor effectivity, no follow-up
No local services, costs, no follow-up activities, low qualified PT provider
Access to experts, language skills, outcome quality
Traceability, cooperation, chemical metrology, calibration services
Costs, resources lack of experts, poor requests, outcome quality
Trainer qualification, adequate training plans, effectivity
Costs, access to expertise, scope, outcome quality
Qualification, experience, workload, leadership
Conflicts of interests, scope, qualification

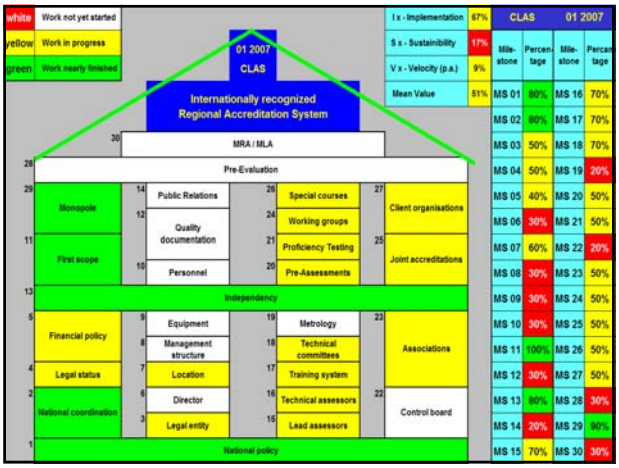


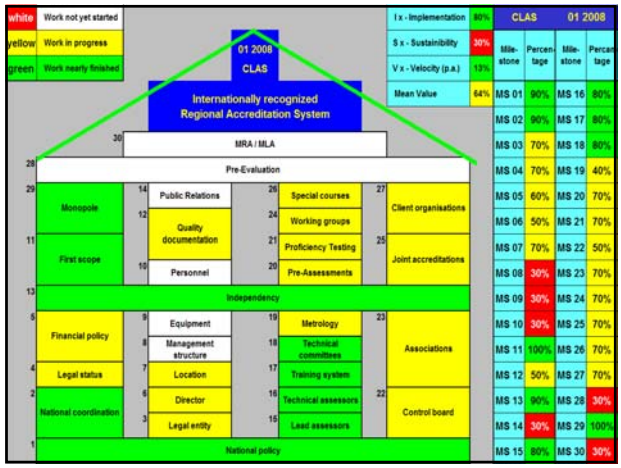


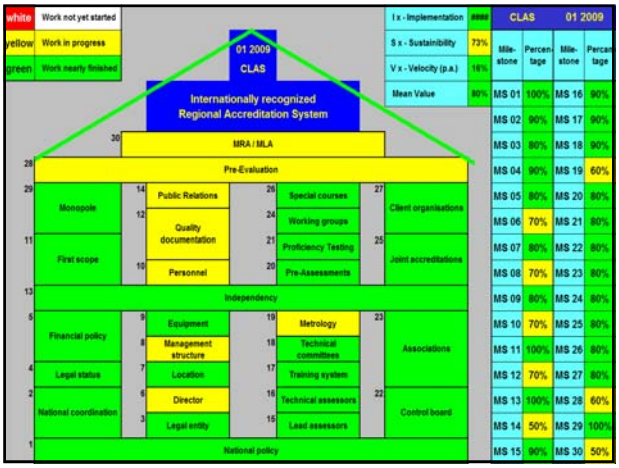


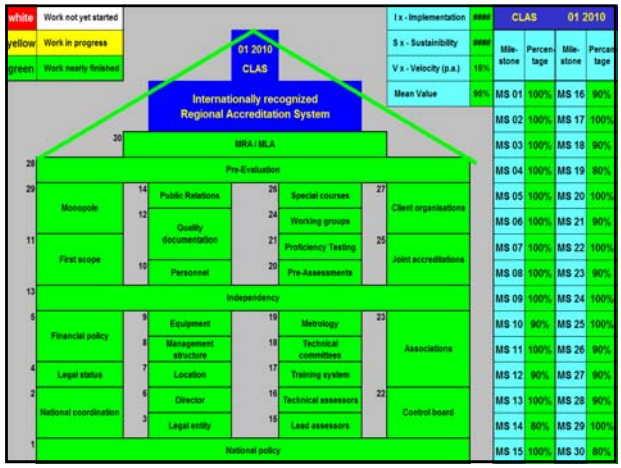
Milestones		Absolute Values						Yearly Changes			
MS	NAB xyz	11 2004	09 2005	07 2006	02 2007	07 2007	07 2008	2004-05	2005-06	2006-07	2007-08
1	National policy	80%	90%	90%	90%	100%	100%	10%	0%	10%	0%
2	National coordination	80%	80%	90%	90%	90%	100%	0%	10%	0%	10%
3	Legal entity	50%	90%	100%	100%	100%	100%	40%	10%	0%	0%
4	Legal status	50%	80%	100%	100%	100%	100%	30%	20%	0%	0%
5	Financial policy	50%	60%	80%	80%	90%	100%	10%	20%	10%	10%
6	Director	10%	50%	70%	70%	70%	100%	40%	20%	0%	30%
7	Location	30%	50%	80%	80%	100%	100%	20%	30%	20%	0%
8	Management structure	30%	50%	80%	80%	90%	100%	20%	30%	10%	10%
9	Equipment	30%	50%	70%	70%	90%	100%	20%	20%	20%	10%
10	Personnel	30%	40%	70%	70%	70%	100%	10%	30%	0%	30%
11	First scope	20%	40%	70%	70%	80%	90%	20%	30%	10%	10%
12	Quality documentation	30%	50%	70%	80%	90%	100%	20%	20%	20%	10%
13	Independency	50%	50%	70%	70%	80%	100%	0%	20%	10%	20%
14	Public relations	20%	40%	70%	70%	80%	90%	20%	30%	10%	10%
15	Lead assessors	50%	80%	80%	90%	90%	90%	30%	0%	10%	0%
16	Technical assessors	50%	80%	80%	80%	90%	90%	30%	0%	10%	0%
17	Training system	20%	80%	90%	90%	90%	90%	60%	10%	0%	0%
18	Technical committees	20%	30%	40%	60%	70%	90%	10%	10%	30%	20%
19	Metrology	50%	80%	90%	90%	90%	100%	30%	10%	0%	10%
20	Pre-Assessment	20%	30%	40%	60%	70%	90%	10%	10%	30%	20%
21	Proficiency Testing	20%	20%	40%	60%	70%	90%	0%	20%	30%	20%
22	Control board	30%	50%	60%	60%	60%	90%	20%	10%	0%	30%
23	Associations	20%	80%	90%	90%	90%	100%	60%	10%	0%	10%
24	Working groups	20%	80%	90%	90%	90%	100%	60%	10%	0%	10%
25	Joint accreditations	30%	40%	70%	70%	80%	100%	10%	30%	10%	20%
26	Special courses	20%	70%	90%	90%	90%	90%	50%	20%	0%	0%
27	Client organisations	10%	40%	60%	70%	80%	90%	30%	20%	20%	10%
28	Pre-Evaluation	30%	50%	60%	60%	60%	100%	20%	10%	0%	40%
29	Monopole	30%	80%	80%	80%	90%	100%	50%	0%	10%	10%
30	MRA / MLA	10%	40%	40%	60%	60%	90%	30%	0%	20%	30%
	Mean Value	33%	58%	74%	77%	83%	96%	25%	15%	10%	13%

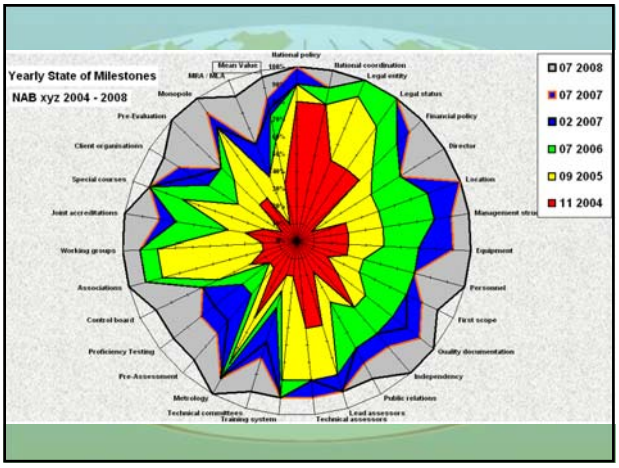


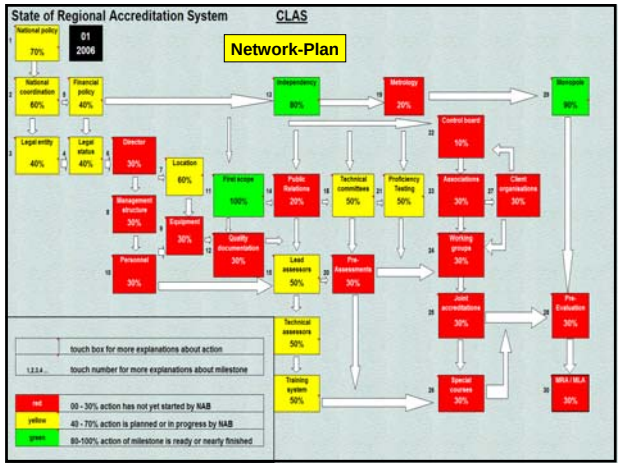

white Work not yet started
yellow Work in progress
green Work nearly finished
01 2007
CLAS
Internationally recognized
Regional Accreditation System
MRA / MLA
Pre-Evaluation
Monopole
First scope
Public Relations
Quality documentation
Personnel
Special courses
Working groups
Proficiency Testing
Pre-Assessments
Client organisations
Joint accreditations
Independency
Financial policy
Legal status
National coordination
Equipment
Management structure
Location
Director
Legal entity
Metrology
Technical committees
Training system
Technical assessors
Lead assessors
Associations
Control board
National policy
I x - Implementation 67%
S x - Sustainibility 17%
V x - Velocity (p.a.) 9%
Mean Value 51%
CLAS 01 2007

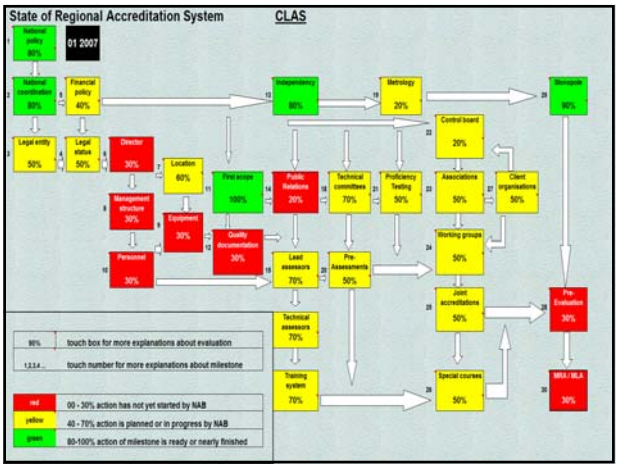

white Work not yet started
yellow Work in progress
green Work nearly finished
01 2008
CLAS
Internationally recognized
Regional Accreditation System
MRA / MLA
Pre-Evaluation
Monopole
First scope
Public Relations
Quality documentation
Personnel
Special courses
Working groups
Proficiency Testing
Pre-Assessments
Client organisations
Joint accreditations
Independency
Financial policy
Legal status
National coordination
Equipment
Management structure
Location
Director
Legal entity
Metrology
Technical committees
Training system
Technical assessors
Lead assessors
Associations
Control board
National policy
I x - Implementation 80%
S x - Sustainibility 30%
V x - Velocity (p.a.) 13%
Mean Value 64%
CLAS 01 2008

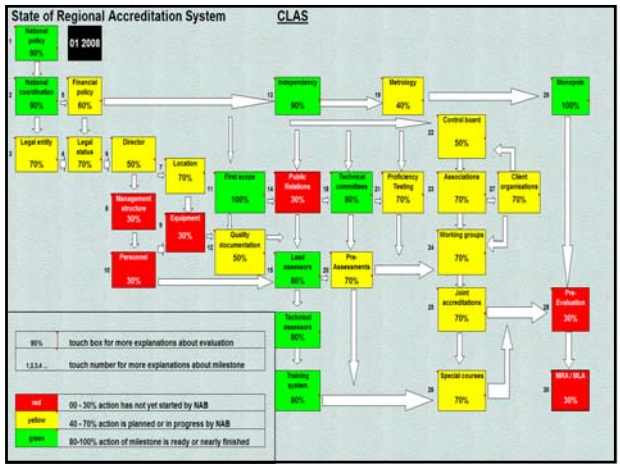

white Work not yet started
yellow Work in progress
green Work nearly finished
01 2009
CLAS
Internationally recognized
Regional Accreditation System
MRA / MLA
Pre-Evaluation
Monopole
First scope
Public Relations
Quality documentation
Personnel
Special courses
Working groups
Proficiency Testing
Pre-Assessments
Client organisations
Joint accreditations
Independency
Financial policy
Legal status
National coordination
Equipment
Management structure
Location
Director
Legal entity
Metrology
Technical committees
Training system
Technical assessors
Lead assessors
Associations
Control board
National policy
I x - Implementation ####
S x - Sustainibility 73%
V x - Velocity (p.a.) 16%
Mean Value 90%
CLAS 01 2009

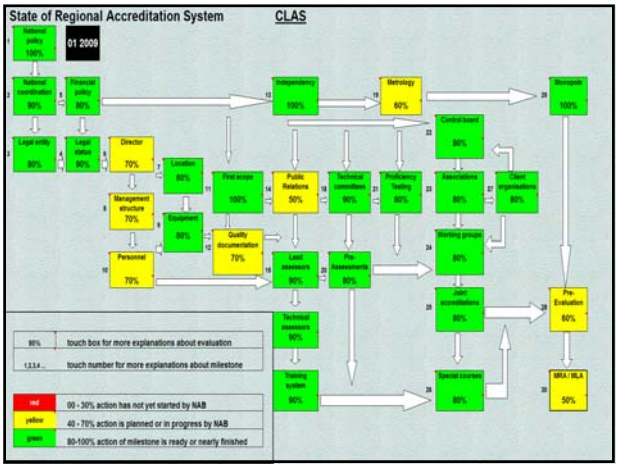

white Work not yet started
yellow Work in progress
green Work nearly finished
01 2010
CLAS
Internationally recognized
Regional Accreditation System
MRA / MLA
Pre-Evaluation
Monopole
First scope
Public Relations
Quality documentation
Personnel
Special courses
Working groups
Proficiency Testing
Pre-Assessments
Client organisations
Joint accreditations
Independency
Financial policy
Legal status
National coordination
Equipment
Management structure
Location
Director
Legal entity
Metrology
Technical committees
Training system
Technical assessors
Lead assessors
Associations
Control board
National policy
I x - Implementation ####
S x - Sustainibility ####
V x - Velocity (p.a.) 16%
Mean Value 90%
CLAS 01 2010

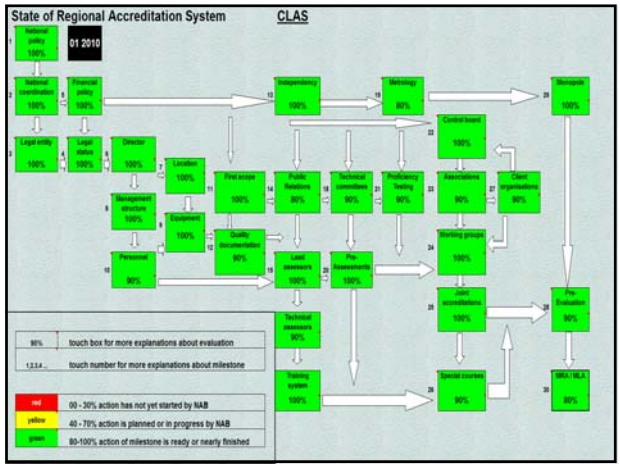

Yearly State of Milestones
NAB xyz 2004 - 2008
07 2008
07 2007
02 2007
07 2006
09 2005
11 2004


State of Regional Accreditation System
CLAS
Network-Plan
01
2006
touch box for more explanations about action
touch number for more explanations about milestone
00 - 30% action has not yet started by NAB
40 - 70% action is planned or in progress by NAB
80-100% action of milestone is ready or nearly finished



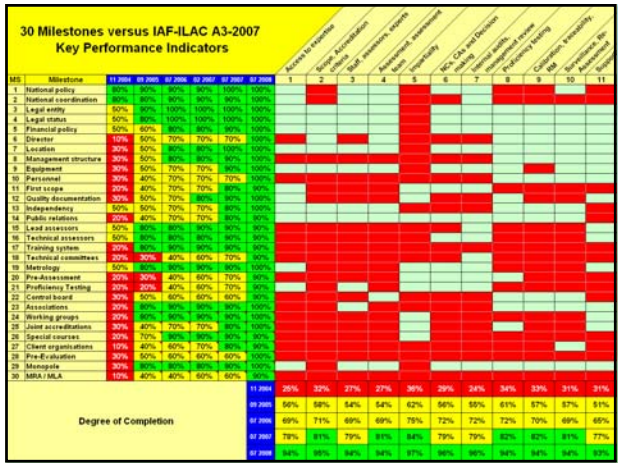


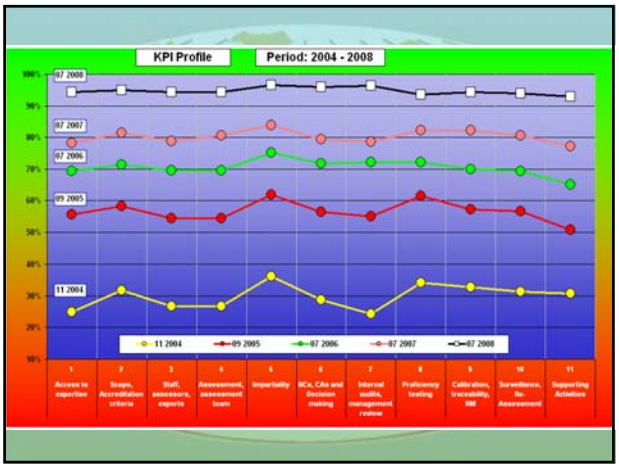


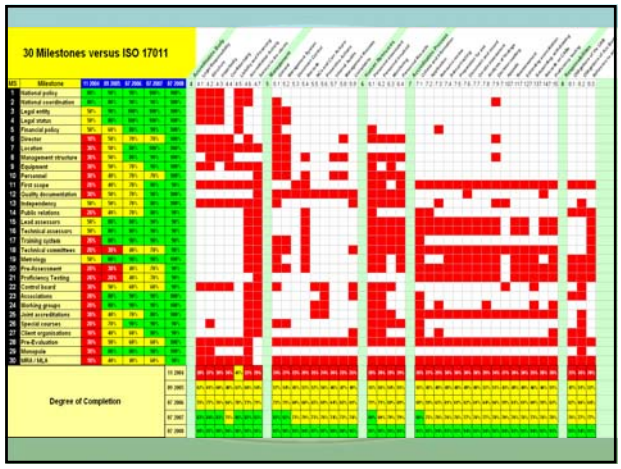


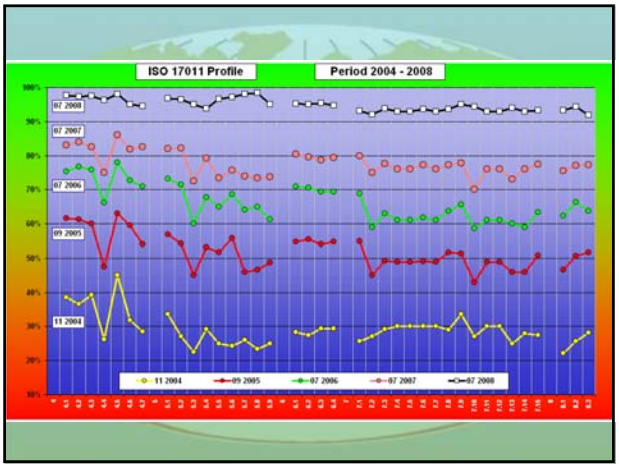
ISO 17011 and KPI's

- and the 30 Milestones









„I think we made a good show!“

- the Key Parameter

Key Parameter Matrix

		National policy	National coordination	Legal entity	Legal status	Financial policy	Director	Location	Management structure	Equipment	Personnel	First scope	Quality documentation	Independency	Public relations	Lead assessors	Technical assessors	Training system	Technical committees	Metrology	Pre-Assessment	Proficiency Testing	Control board
Qua	Key Parameter: Quality	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
S	Structure Quality	1		1	1	1	1	1	1	1	1			1				1	1	1		1	
P	Process Quality		1									1	1		1						1	1	
O	Outcome Quality											1	1		1	1	1						
Sup	Key Parameter: Support	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
P	Political Aspects	1	1		1	1						1		1									
A	Administrational Aspects			1			1	1	1	1	1		1		1								
T	Technical Aspects															1	1	1	1	1	1	1	
E	External Relations																						1
Sco	Key Parameter: Scope	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
I	Internal Orientation						1	1	1	1	1		1		1	1	1	1			1		
N	National Orientation	1	1	1	1	1						1		1					1	1		1	1
G	Global Orientation																			1		1	
BSC	Key Parameter: BSC	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
F	Finances	1		1	1	1								1									1
C	Customers		1												1					1		1	
H	Human Resources						1	1	1	1	1					1	1	1	1				

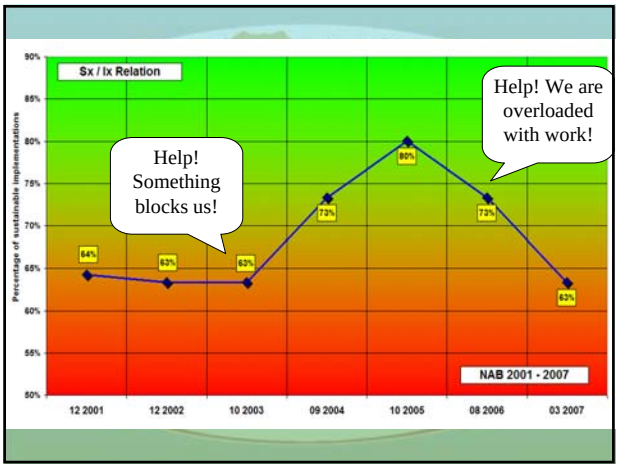
Main Key Parameter

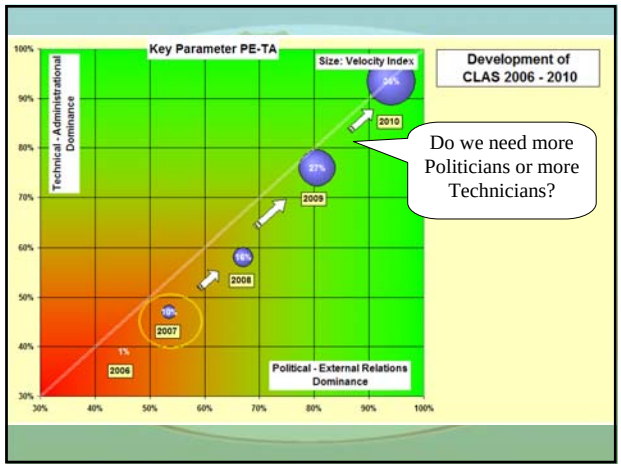
	CLAS	01 2006	01 2007	01 2008	01 2009	01 2010
I x	Implementation-Index	47%	67%	80%	100%	100%
S x	Sustainability-Index	10%	17%	30%	73%	100%
Mean	Mean Value	42%	51%	64%	80%	95%
V x	Velocity - Index		8,7%	13,0%	16,0%	15,0%

Qua	Key Parameter: Quality	01 2006	01 2007	01 2008	01 2009	01 2010
S	Structure Quality	42%	49%	64%	82%	97%
P	Process Quality	51%	57%	71%	81%	95%
O	Outcome Quality	46%	53%	63%	77%	92%

	Priority Index	01 2006	01 2007	01 2008	01 2009	01 2010
SPI	1st Structure Political Internal	45%	53%	66%	83%	97%
PAN	2nd Process Admin. National	47%	52%	65%	81%	96%
OEG	3rd Outcome Extern.Rel Global	38%	47%	59%	73%	91%

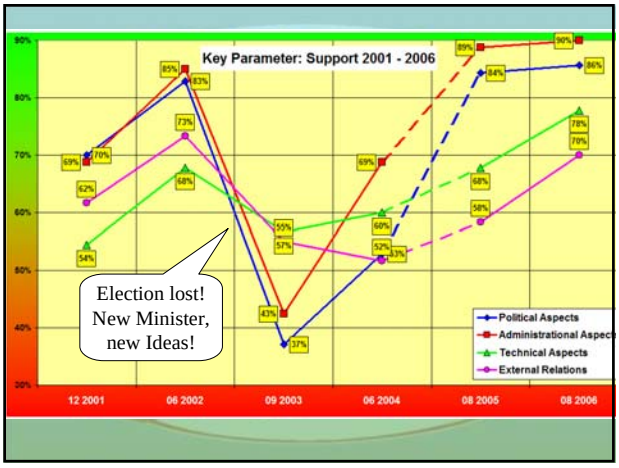
	Horizontal Index	01 2006	01 2007	01 2008	01 2009	01 2010
1st	1st Floor House of Accreditation	39%	49%	63%	81%	97%
2nd	2nd Floor House of Accreditation	43%	52%	66%	79%	94%

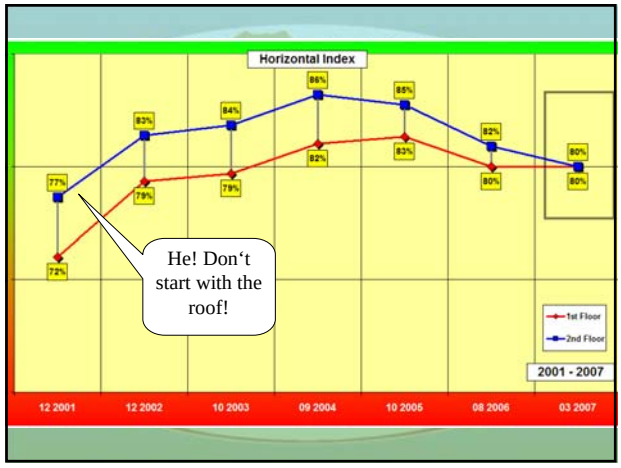

Sx / Ix Relation
Help! Something blocks us!
Help! We are overloaded with work!
NAB 2001 - 2007
12 2001
12 2002
10 2003
09 2004
10 2005
08 2006
03 2007

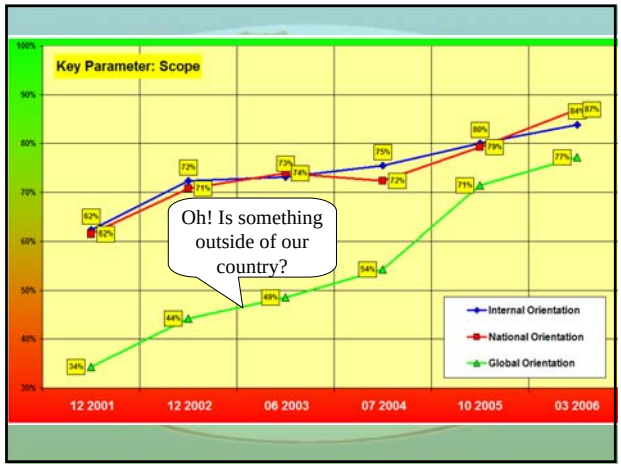

Key Parameter PE-TA
Size: Velocity Index
Development of CLAS 2006 - 2010
Technical - Administrational Dominance
Political - External Relations Dominance
Do we need more Politicians or more Technicians?
2006
2007
2008
2009
2010

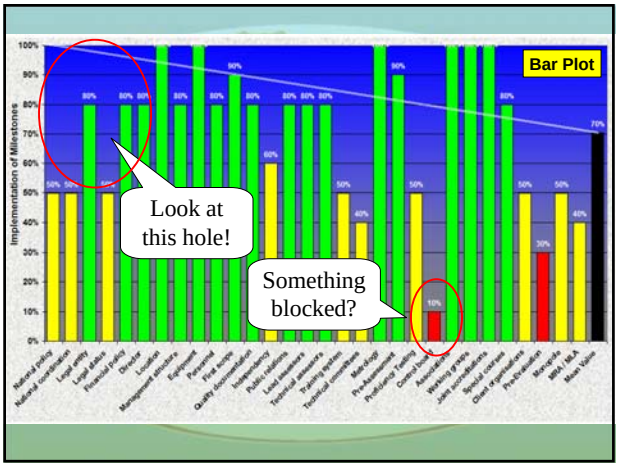

Relation to Mean
Relative Support Index
CLAS 2006 - 2010
Don‘t be so Dominant!
Political Aspects
Administration
Technical Aspects
External Relations
01 2006
01 2007
01 2008
01 2009
01 2010


Key Parameter: Quality 2001 - 2007
Sorry! The Minister fired the Director!
Structure Quality
Process Quality
Outcome Quality


Key Parameter: Support 2001 - 2006
Election lost! New Minister, new Ideas!
Political Aspects
Administrational Aspect
Technical Aspects
External Relations
12 2001
06 2002
09 2003
06 2004
08 2005
08 2006


Horizontal Index
He! Don‘t start with the roof!
1st Floor
2nd Floor
2001 - 2007
12 2001
12 2002
10 2003
09 2004
10 2005
08 2006
03 2007



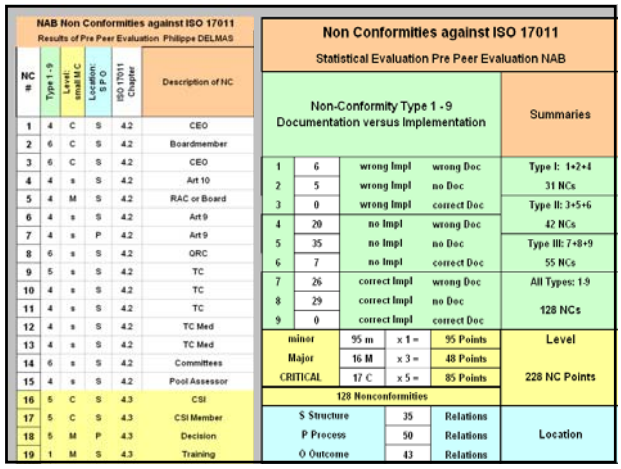


How to evaluate

Peer Evaluations?

DELMAS Report

NC	Chapter	Title	Basis	Suggestion	Type	Level	Source	Milestones
101	4,2,5	CEO	Regulation		4	CRITICAL	STRUCTURE	1,3,6
102	4,2,5	Boardmember	Practice		6	CRITICAL	STRUCTURE	1,2,6, 22
103	4,2,5	CEO	Practice		6	CRITICAL	STRUCTURE	1,3,6,8
104	4,2,5	Art 10	Regulation		4	minor	STRUCTURE	1,2
105	4,2,5	RAC or Board	Regulation		4	Major	STRUCTURE	1,2,22
106	4,2,6	Art 9	Regulation		4	minor	STRUCTURE	1,2
107	4,2,6	Art 9	Regulation	301, 302	4	minor	Process	1,2
108	4,2,6	QRC	Practice		6	minor	STRUCTURE	1,2,12
109	4,2,6	TC	Quality Manual		5	minor	STRUCTURE	18
110	4,2,6	TC	Quality Manual		4	minor	STRUCTURE	18
111	4,2,6	TC	Quality Manual		4	minor	STRUCTURE	18
112	4,2,6	TC Med	Quality Manual		4	minor	STRUCTURE	18
114	4,2,6	TC Med	Quality Manual		4	minor	STRUCTURE	18
115	4,2,7	Committees	Practice		6	minor	STRUCTURE	18,24
116	4,2,8	Pool Assessor	Practice	303	4	minor	STRUCTURE	15,16,17
117	4,3,2	CSI	Quality Manual		5	CRITICAL	STRUCTURE	12,13
118	4,3,2	CSI Member	Practice	304,305,306	5	CRITICAL	STRUCTURE	13
119	4,3,5	Decision	Practice		5	Major	Process	13,18
120	4,3,6	Training	Practice		1	Major	STRUCTURE	17
121	4,3,6	Consultancy	Practice	307	5	Major	Process	13
122	4,3,6	Registration	Quality Manual		5	minor	STRUCTURE	12,13
123	4,3,6	Auditors Reg	Practice	308	1	CRITICAL	STRUCTURE	13



NAB Non Conformities against ISO 17011

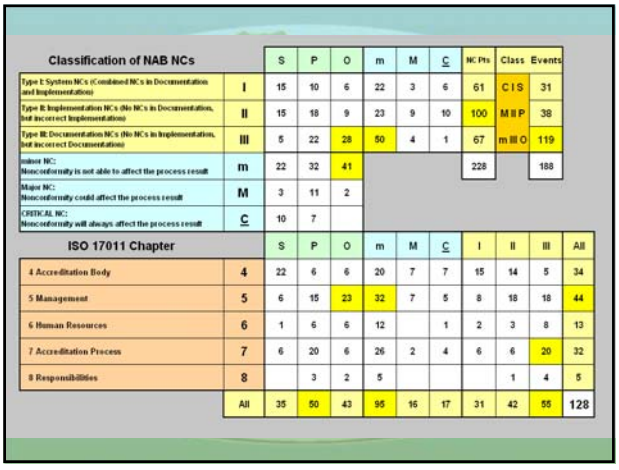
Results of Pre Peer Evaluation Philippe DELMAS

NC #	Type 1 - 9	Level m M C	Location: S P O	ISO 17011 Chapter	Description of NC
1	4	C	S	4.2	CEO
2	6	C	S	4.2	Boardmember
3	6	C	S	4.2	CEO
4	4	s	S	4.2	Art 10
5	4	M	S	4.2	RAC or Board
6	4	s	S	4.2	Art 9
7	4	s	P	4.2	Art 9
8	6	s	S	4.2	QRC
9	5	s	S	4.2	TC
10	4	s	S	4.2	TC
11	4	s	S	4.2	TC
12	4	s	S	4.2	TC Med
13	4	s	S	4.2	TC Med
14	6	s	S	4.2	Committees
15	4	s	S	4.2	Pool Assessor
16	5	C	S	4.3	CSI
17	5	C	S	4.3	CSI Member
18	6	M	P	4.3	Decision
19	1	M	S	4.3	Training

Non Conformities against ISO 17011

Statistical Evaluation Pre Peer Evaluation NAB

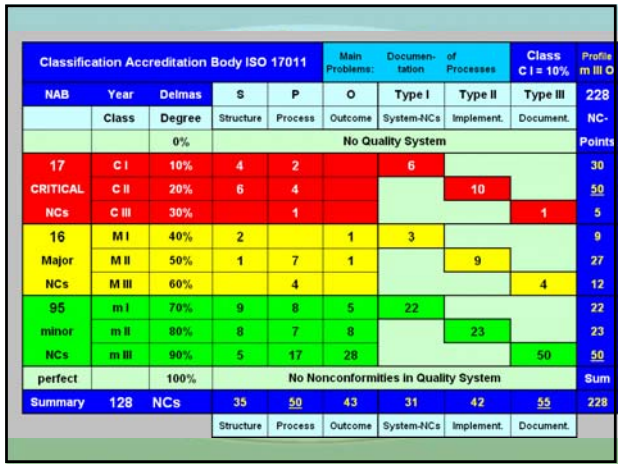
Non-Conformity Type 1 - 9 Documentation versus Implementation				Summaries
1	6	wrong Impl	wrong Doc	Type I: 1+2+4
2	5	wrong Impl	no Doc	31 NCs
3	0	wrong Impl	correct Doc	Type II: 3+5+6
4	20	no Impl	wrong Doc	42 NCs
5	35	no Impl	no Doc	Type III: 7+8+9
6	7	no Impl	correct Doc	55 NCs
7	26	correct Impl	wrong Doc	All Types: 1-9
8	29	correct Impl	no Doc	128 NCs
9	0	correct Impl	correct Doc	
minor	55 m	x 1 =	55 Points	Level
Major	16 M	x 3 =	48 Points	
CRITICAL	17 C	x 5 =	85 Points	228 NC Points
128 Nonconformities				
S Structure	35	Relations		Location
P Process	50	Relations		
O Outcome	43	Relations		



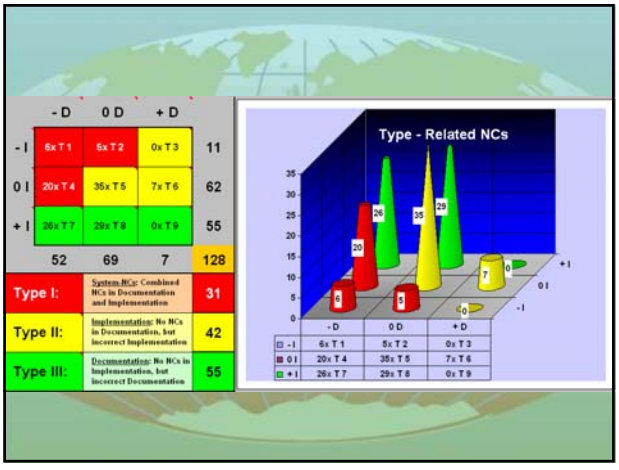
Classification of NAB NCs

		S	P	O	m	M	C	NC Pts	Class	Events
Type I: System NCs (Combined NCs in Documentation and Implementation)	I	15	10	6	22	3	6	61	C I S	31
Type II: Implementation NCs (No NCs in Documentation, but incorrect Implementation)	II	15	18	9	23	9	10	100	M II P	38
Type III: Documentation NCs (No NCs in Implementation, but incorrect Documentation)	III	5	22	28	50	4	1	67	m III O	119
minor NC: Nonconformity is not able to affect the process result	m	22	32	41				228		188
Major NC: Nonconformity could affect the process result	M	3	11	2						
CRITICAL NC: Nonconformity will always affect the process result	C	10	7							

ISO 17011 Chapter		S	P	O	m	M	C	I	II	III	All
4 Accreditation Body	4	22	6	6	20	7	7	15	14	5	34
5 Management	5	6	15	23	32	7	5	8	18	18	44
6 Human Resources	6	1	6	6	12		1	2	3	8	13
7 Accreditation Process	7	6	20	6	26	2	4	6	6	20	32
8 Responsibilities	8		3	2	5				1	4	5
	All	35	50	43	95	16	17	31	42	55	128

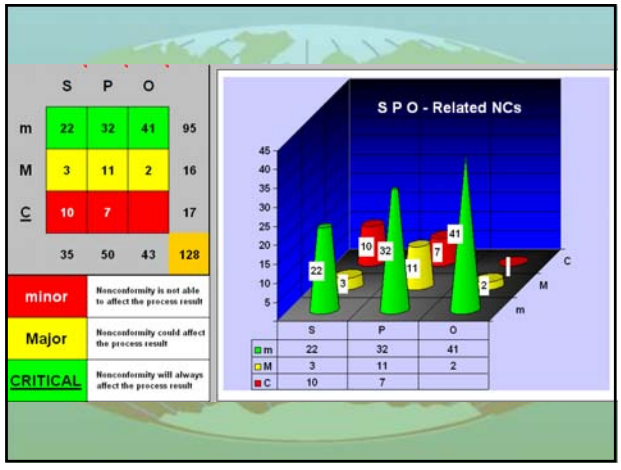


Classification Accreditation Body ISO 17011			Main Problems:		Documen-tation	of Processes		Class C I = 10%	Profile m III O
NAB	Year	Delmas	S	P	O	Type I	Type II	Type III	228
	Class	Degree	Structure	Process	Outcome	System-NCs	Implement.	Document.	NC-Points
		0%	No Quality System						
17	C I	10%	4	2		6			30
CRITICAL	C II	20%	6	4			10		50
NCs	C III	30%		1				1	5
16	M I	40%	2		1	3			9
Major	M II	50%	1	7	1		9		27
NCs	M III	60%		4				4	12
95	m I	70%	9	8	5	22			22
minor	m II	80%	8	7	8		23		23
NCs	m III	90%	5	17	28			50	50
perfect		100%	No Nonconformities in Quality System						Sum
Summary	128	NCs	35	50	43	31	42	55	228
			Structure	Process	Outcome	System-NCs	Implement.	Document.	



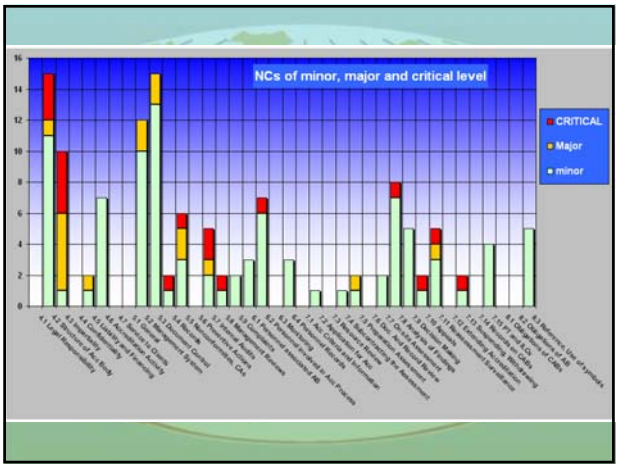
	- D	0 D	+ D	
- I	6x T 1	5x T 2	0x T 3	11
0 I	20x T 4	35x T 5	7x T 6	62
+ I	26x T 7	29x T 8	0x T 9	55
	52	69	7	128

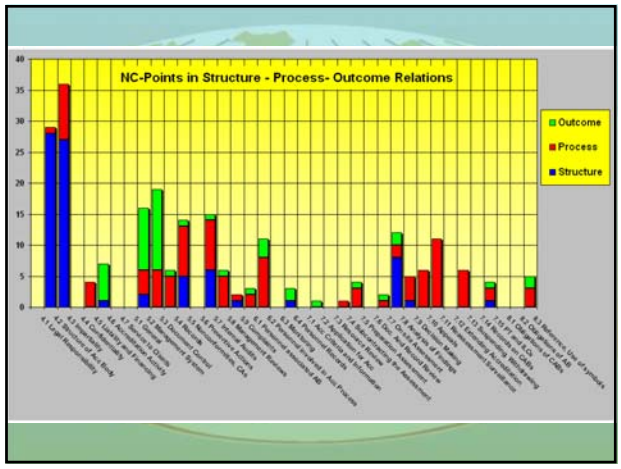
Type I:	System NCs: Combined NCs in Documentation and Implementation	31
Type II:	Implementation: No NCs in Documentation, but incorrect Implementation	42
Type III:	Documentation: No NCs in Implementation, but incorrect Documentation	55



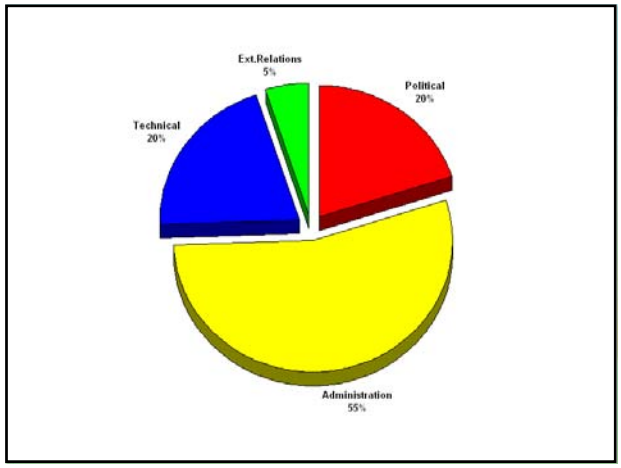
	S	P	O	
m	22	32	41	95
M	3	11	2	16
C	10	7		17
	35	50	43	128

minor	Nonconformity is not able to affect the process result
Major	Nonconformity could affect the process result
CRITICAL	Nonconformity will always affect the process result


NCs of minor, major and critical level
CRITICAL
Major
minor


NC-Points in Structure - Process- Outcome Relations
Outcome
Process
Structure


0
10
20
30
40
50
60
70
80
90
100
National policy
National coordination
Legal entity
Legal status
Financial policy
Director
Location
Management structure
Equipment
Personnel
Floor scope
Quality documentation
Independency
Public relations
Lead assessors
Technical assessors
Training system
Technical committees
Metrology
Pre-Assessment
Proficiency Testing
Control board
Associations
Working groups
Joint accreditations
Special courses
Client organizations
Pre-Evaluation
Monopole
MRA - MLA
14
10
7
1
2
6
1
6
4
93
13
15
16
2
7
3
4
1
7


Ext.Relations
5%
Political
20%
Technical
20%
Administration
55%