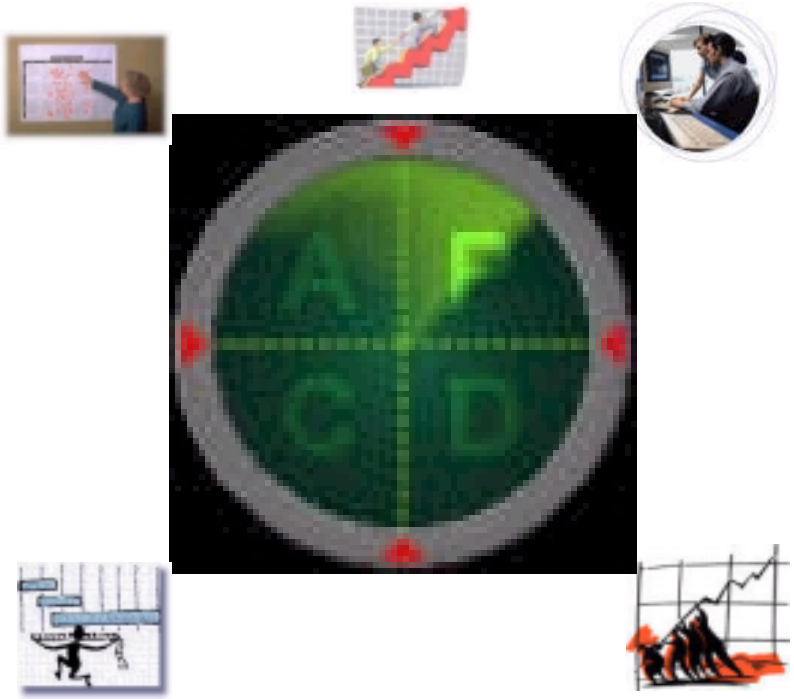
BEMA
Benchmarking European Medicines Agencies



linking competence to achieve excellence

EU/EEA Medicines Network

linking loose pearls
to
a chain

EU/EEA Medicines Network

linking loose pearls
to
a chain

without any weak link

EU/EEA Medicines Network

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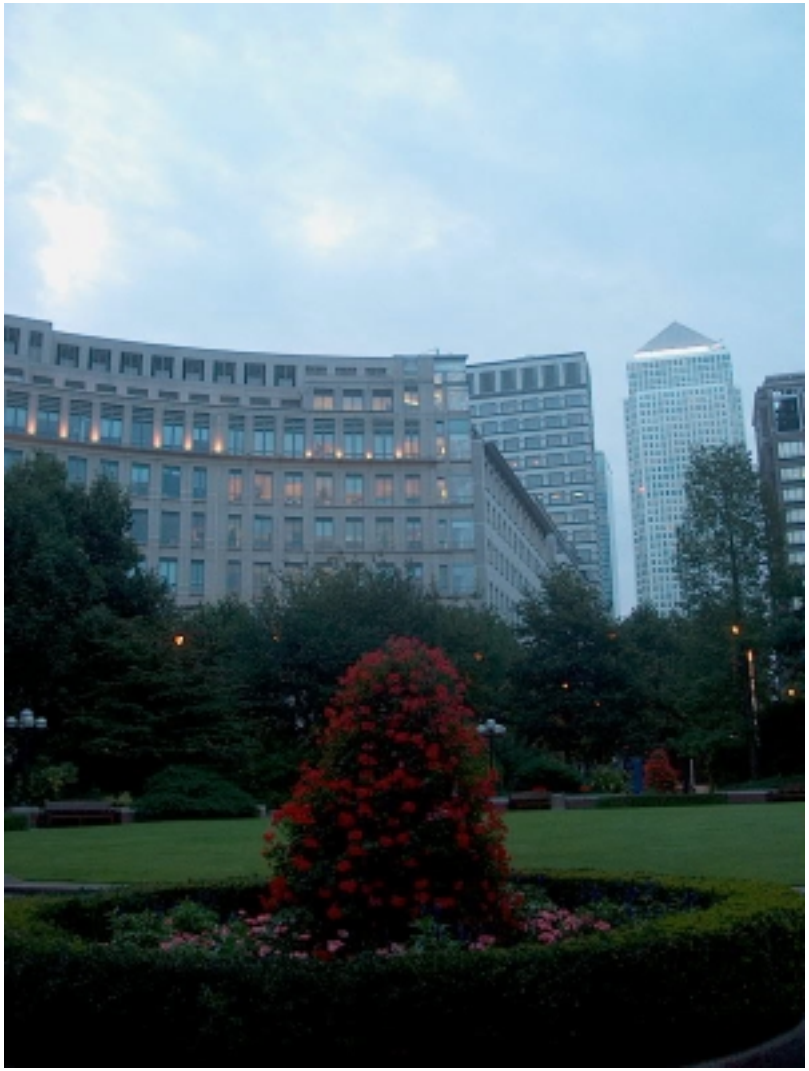
How to ensure
Consistency
Quality?

Good Regulatory Practices?

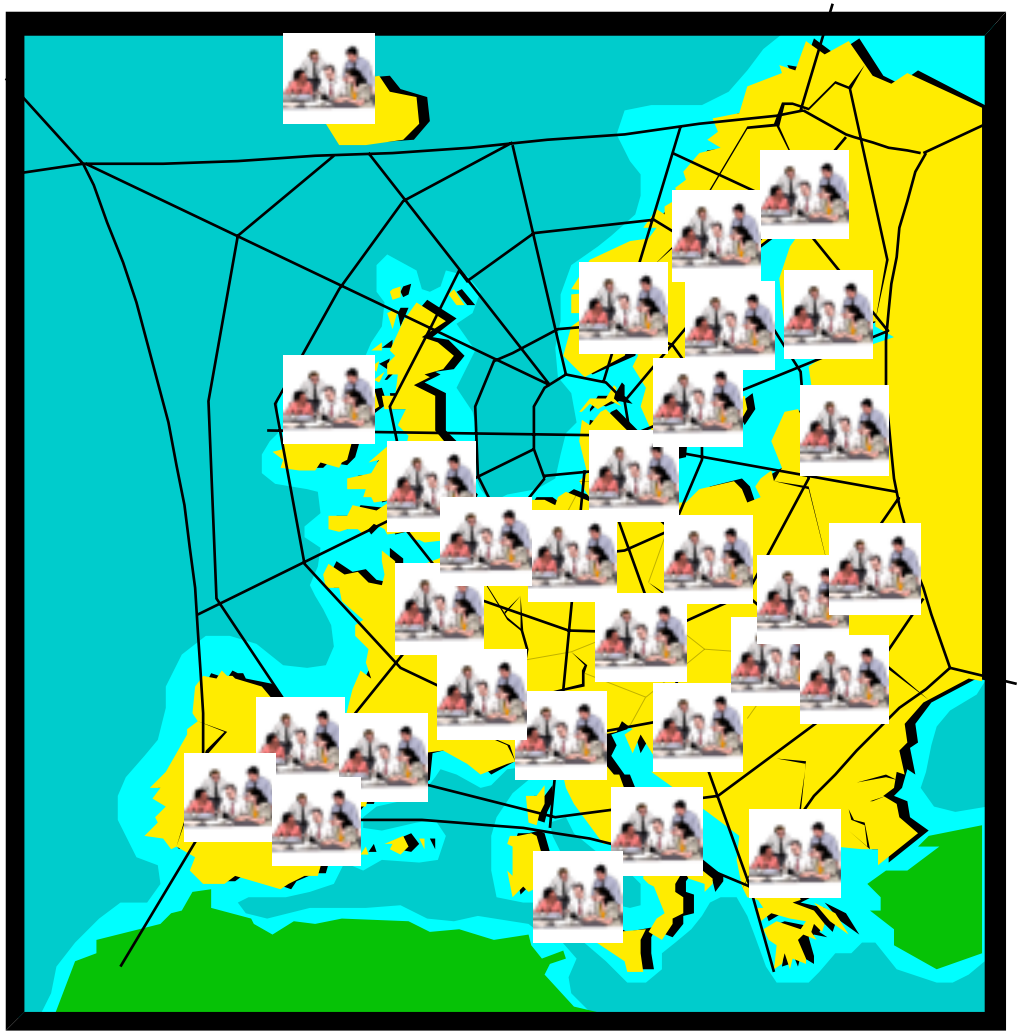
Good Regulatory Practices (GRP)

A quality system

to ensure that the users of medicinal products, the applicants and the regulators are satisfied with the scientific advice, opinions,
the establishment of Maximum Residue Levels,
inspection and assessment reports and related documents,
taking into consideration legal requirements and guidance in order to protect and promote human and animal health.



As any Agency
any body
has its
(integrated)
quality management system



The virtual Agency
needs
its
integrated
quality management system

EU/EEA Medicines Network

Building a Medicines Agencies' Network
implies
the need
to address management
and logistics
and not only key/core tasks
foreseen in the regulatory framework

Hence the need for
BENCHMARKING

EU/EEA Medicines Network

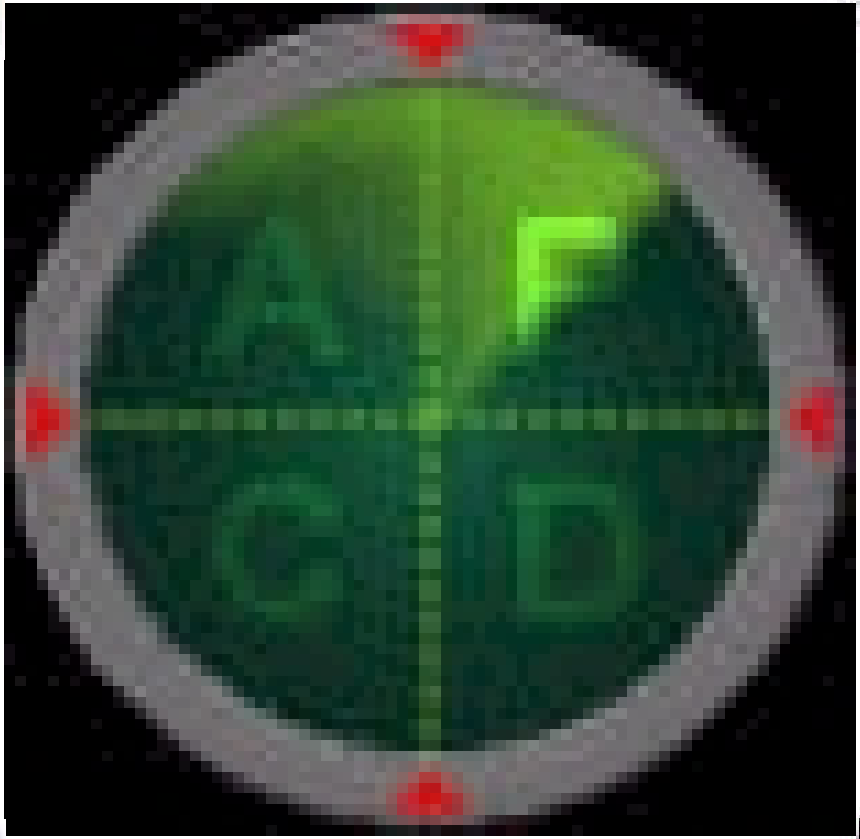
What is
BENCHMARKING
of
EUROPEAN MEDICINES AGENGIES
BEMA?

Compare
to enrich, to learn, to find best practices, which are (cost)-effective, efficient, feasible

ACT

COMPARE

CHECK

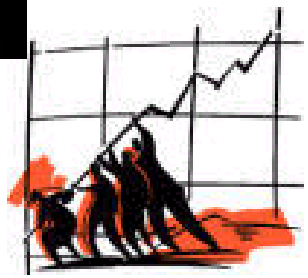


PLAN

BEMA

DO

for continuous improvement



Difference between benchmarking process, audits and inspections

- Benchmarking is **not** focussing on non-compliance/non-conformities*,
- Benchmarking tries to **reveal the strengths, the innovative, cost-effective and efficient approaches**.
- The **best practices** encountered should be the ones we should aim for all together.

*** It is evident that opportunities for improvement are addressed by management**

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- Benchmarking tries to **reveal the strengths, the innovative, cost-effective and efficient approaches**.
- The **best practices** encountered should be the ones we should aim for all together.
- **Hence the need to describe them well**

*** It is evident that opportunities for improvement are addressed by management**

EU/EEA Medicines Network

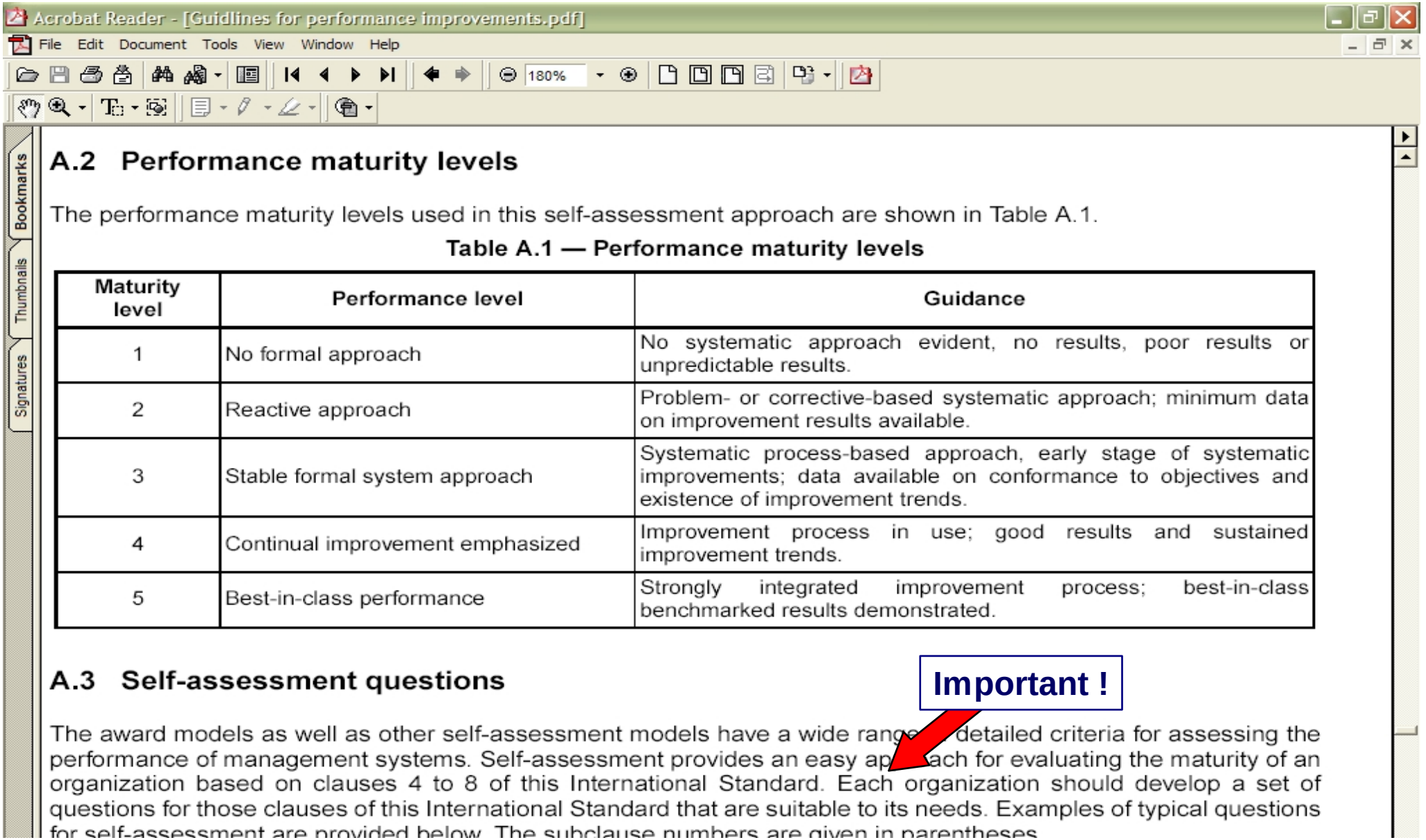
linking loose pearls
to
a chain

without any weak
link

PERF III Quality Management Strategy
in view of EU enlargement based on ISO 9004:2000

Let's detect together
the weak links in the chain
and strengthen
the network

ISO 9004:2000 rating scale was used in PERF III



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The performance maturity levels used in this self-assessment approach are shown in Table A.1.

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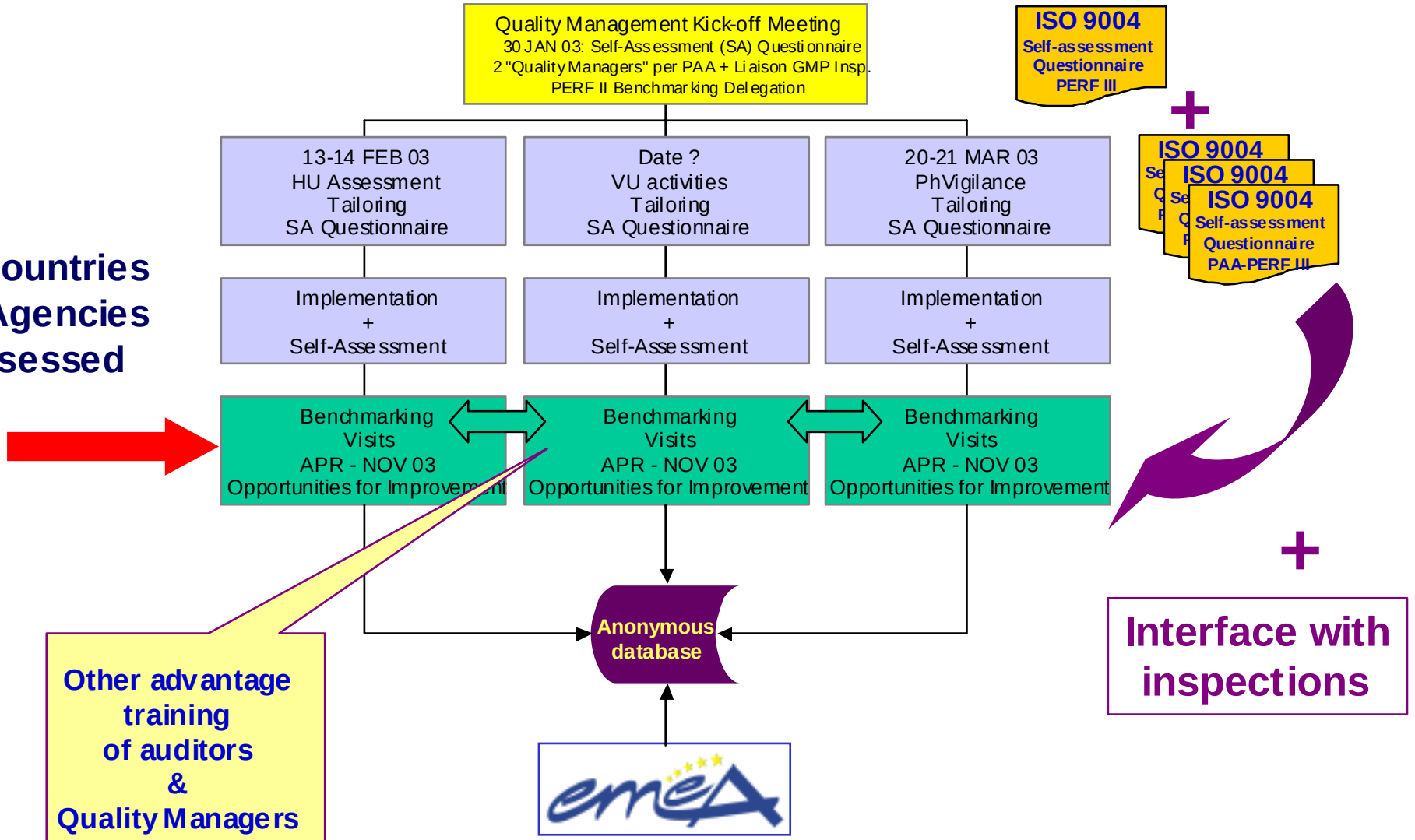
A.3 Self-assessment questions

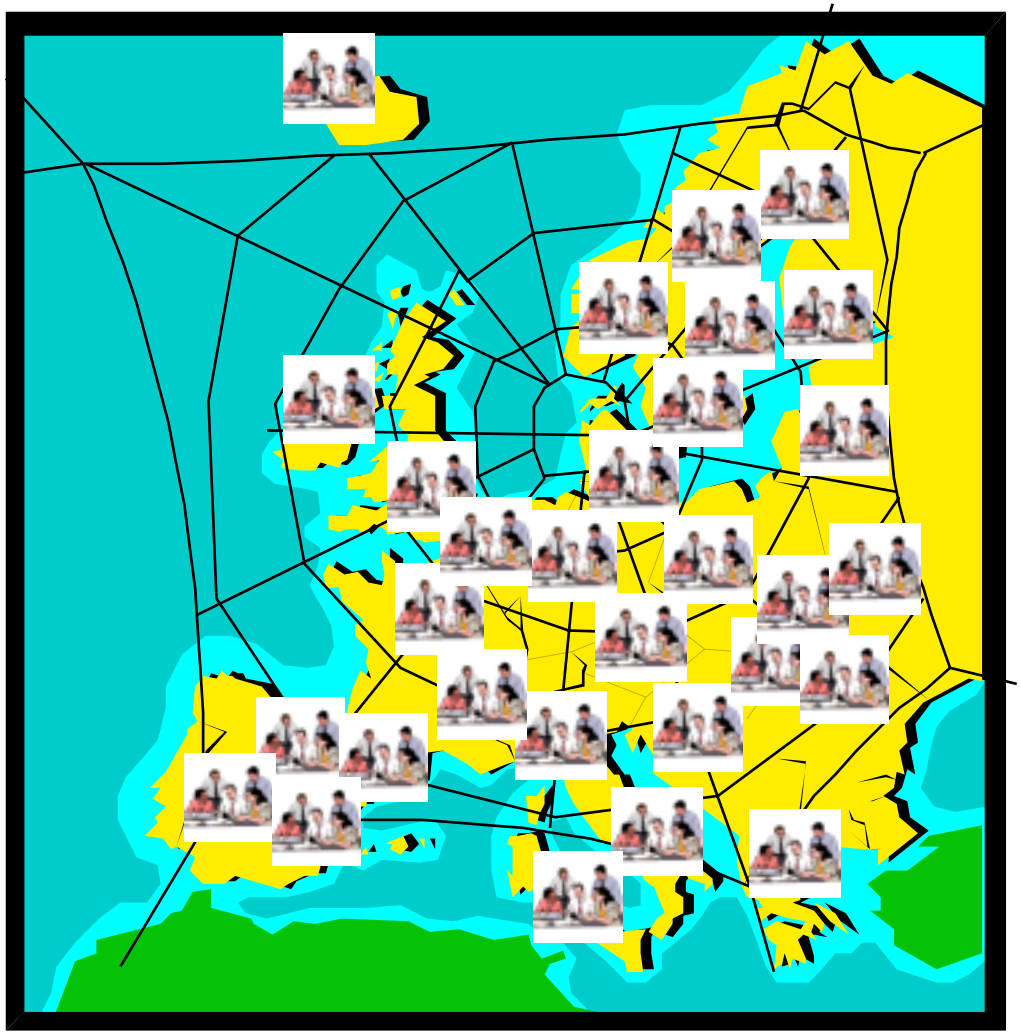
Important !

The award models as well as other self-assessment models have a wide range of detailed criteria for assessing the performance of management systems. Self-assessment provides an easy approach for evaluating the maturity of an organization based on clauses 4 to 8 of this International Standard. Each organization should develop a set of questions for those clauses of this International Standard that are suitable to its needs. Examples of typical questions for self-assessment are provided below. The subclause numbers are given in parentheses

PERF III Quality Management Strategy
in view of EU enlargement based on ISO 9004:2000



PERF= Pan-European Regulatory Forum



PERF III Benchmarking resulted in the EU benchmarking system BEMA applicable to all EU/EEA Competent Authorities for Medicines (Human and Veterinary Use)

From PERF to EU Benchmarking System

The PERF III benchmarking self-assessment was perceived as a useful tool for management of the interlinked Agencies, forming together a medicines agencies network in the EU/EEA,

- Therefore the European Commission assigned to the Medicines and Healthcare products Regulatory Agency (MHRA-UK) and the Paul-Ehrlich-Institut (PEI-Germany) the task to develop the EU benchmarking system further for medicines for human use.
- A similar task was assigned to the Irish Medicines Board for the veterinary medicinal products

From PERF to EU Benchmarking System

- For the Agencies involved in medicinal products for human use, a Steering Group consisting of delegates from MHRA, PEI, BfArM, the Italian, Finish and Czech Medicines Agencies, as well as EMEA, **developed a questionnaire based on the PERF III questionnaires and the G10 key performance indicators**, allowing to address a series of performance indicators for Agencies involved in medicines for human use.
- Similarly Ireland together with Hungary and the EMEA started the tailoring of the questionnaire for use by Agencies for medicinal products for veterinary use.
- At the time the BEMA training course was shaped in October 2004 the separate questionnaires were in the process of being finalized.

From PERF, EU Benchmarking to BEMA

- Since then, **for cost benefit reasons** and to address comments received after the training sessions, **the questionnaires were merged and finalized** after representatives from the Irish and French veterinary medicines agencies joined the Steering Group (SG)
- The name **B**enchmarking of **E**uropean **M**edicines **A**gencies **BEMA was proposed**
- The BEMA-SG also considered the concerns raised by the GMP inspection services working group related to the risk of duplicating the work of the Joint Audit Programme. The **Heads of Medicines Agencies decided on 24 FEB 05 in Reykjavik to continue with the questionnaire containing also GXP inspection related questions covering the interface with Inspection Services**

The PERF benchmarking as well as the resulting current EU benchmarking system BEMA are addressing the G10 recommendations (Lisbon Agenda) using Key Performance Indicators derived from

- the G10 Medicines Report of 07 May 2002 and the 01 July 2003 COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGION

  A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient - A Call for Action **COM (2003) 383 final.**

The benchmarking process/methodology

International standards at the basis of the approach

- The use of an International Standard and Guidance allows mutual understanding between partners worldwide.
- **The subsequent tailoring of the questions to serve better the Medicines Agencies make the choice of a particular management model less relevant**, although for the purpose of comparison and to serve these Agencies that have also the certification as an objective, the link with PERF III questions and ISO 9004:2000 questions, as well as G10 and EU MJA (Joint Audit Programme JAP) is provided in the questionnaire.

EU Benchmarking Objectives

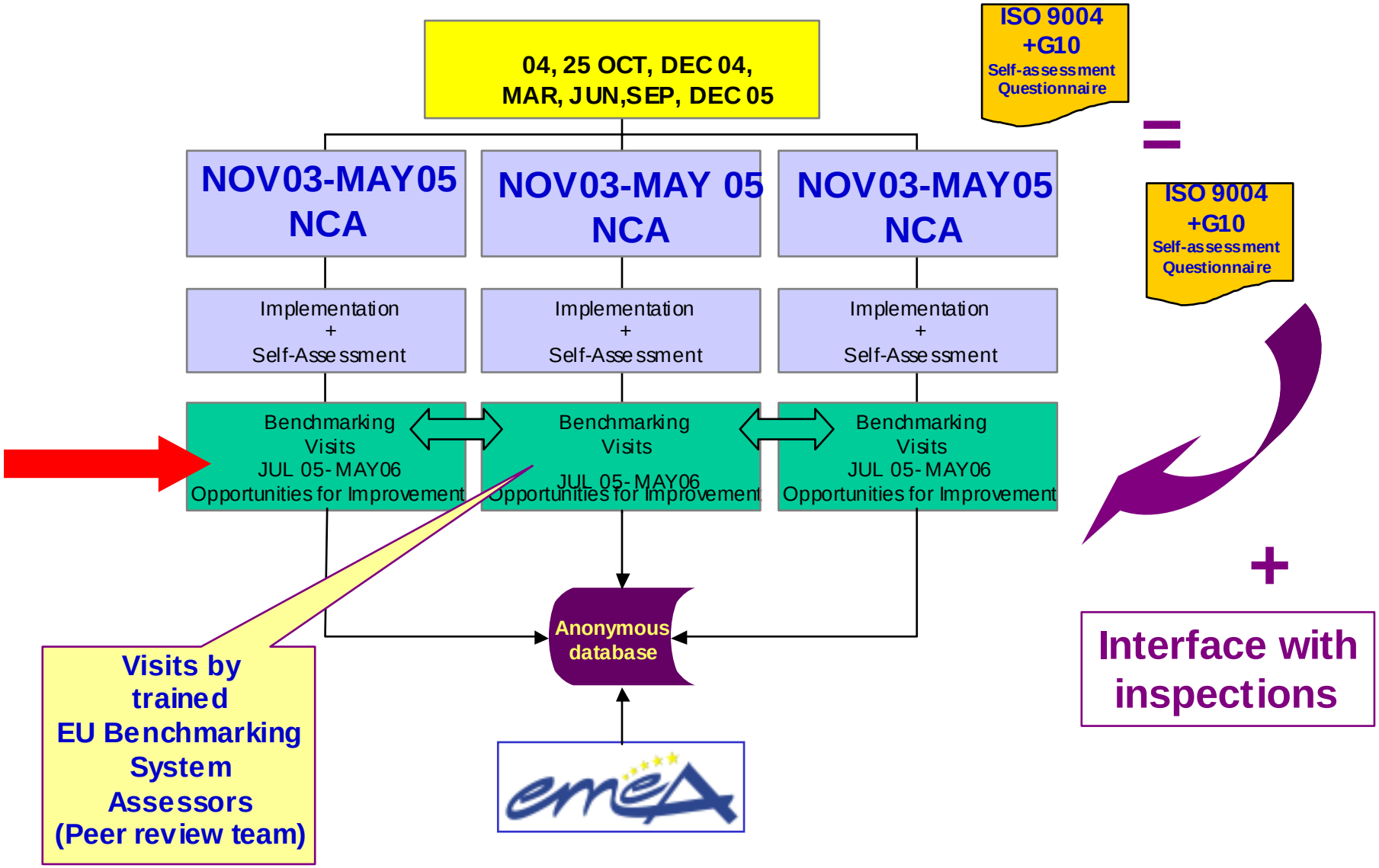
- Aim of the EU Benchmarking System BEMA:

- **“To contribute to the development of a world class medicines regulatory system for medicinal products based on a network of agencies operating to best practice standards”.**

Creating a world-class system

- Creating a world-class system:
- it sounds arrogant
- over-optimistic
- not very realistic.
- **Will this really be possible for a network organisation if it is already difficult for one isolated enterprise?**
- **Just do it!**

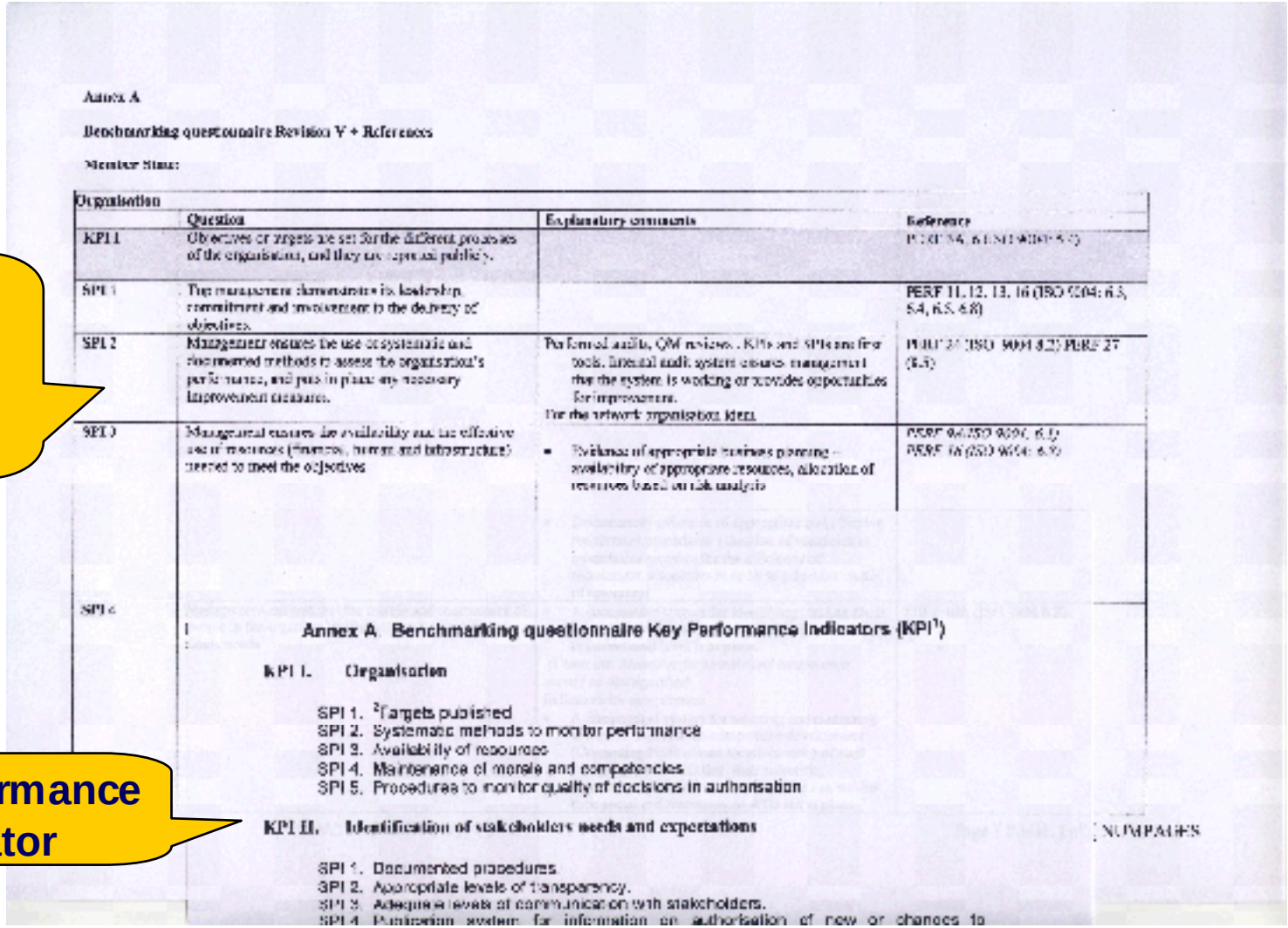
EU Benchmarking System Strategy



What will be rated?

Specific (Sub to *Key*) **Performance Indicator**

Key Performance Indicator



Annex A

Benchmarking questionnaire Revision V + References

Member State:

Organisation			
	Question	Explanatory comments	Reference
KPI 1	Objectives or targets are set for the different processes of the organisation, and they are reported publicly.		
SPI 1	The management demonstrates its leadership, commitment and involvement to the delivery of objectives.		PERF 11, 12, 13, 16 (ISO 9004: 6.3, 6.4, 6.5, 6.8)
SPI 2	Management ensures the use of systematic and documented methods to assess the organisation's performance, and puts in place any necessary improvement measures.	Performance audits, QM reviews, KPIs and SPIs are five tools. Internal audit system ensures management that the system is working or provides opportunities for improvement. For the network organisation item:	PERF 24 (ISO 9004 8.2) PERF 27 (8.5)
SPI 3	Management ensures the availability and the effective use of resources (finances, human and infrastructure) needed to meet the objectives	• Evidence of appropriate business planning – availability of appropriate resources, allocation of resources based on risk analysis	PERF 9a (ISO 9004: 6.1) PERF 9b (ISO 9004: 6.2)
SPI 4			

Annex A Benchmarking questionnaire Key Performance Indicators (KPI[1])

KPI I. Organisation

SPI 1. [2]Targets published
SPI 2. Systematic methods to monitor performance
SPI 3. Availability of resources
SPI 4. Maintenance of morale and competencies
SPI 5. Procedures to monitor quality of decisions in authorisation

KPI II. Identification of stakeholders needs and expectations

SPI 1. Documented procedures
SPI 2. Appropriate levels of transparency.
SPI 3. Adequate levels of communication with stakeholders.
SPI 4. Provision system for information on authorisation of new or changes to

NUMPAGES

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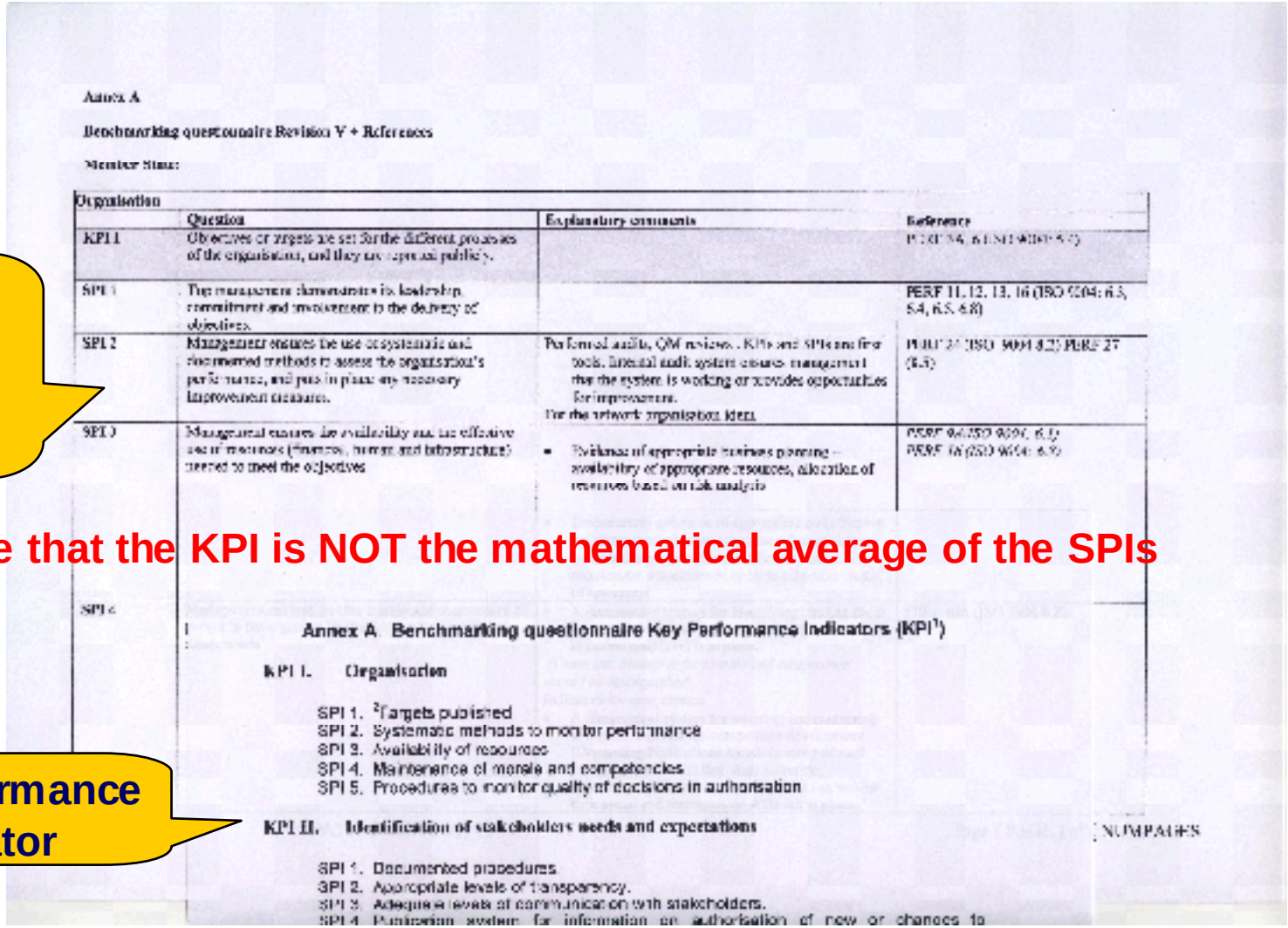

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SPI 4			

Note that the KPI is NOT the mathematical average of the SPIs

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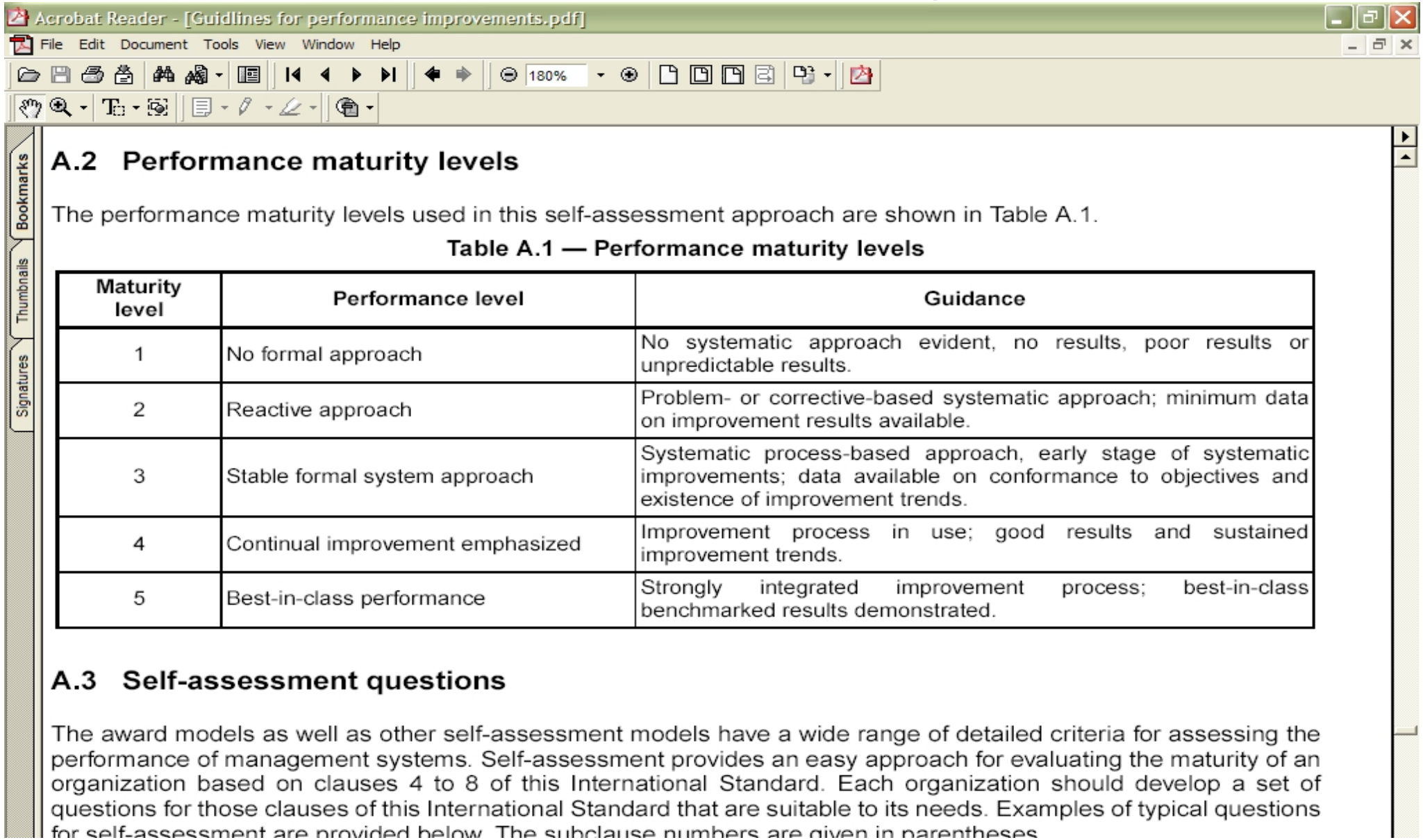
NUMPAGES

Key Performance Indicator

We rate in the same way using the ISO 9004:2000 rating scale



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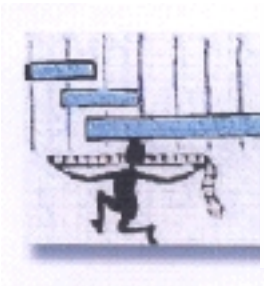
Validation of the rating system is crucial for reliable data/baseline rating

- Criteria for BEMA assessors were established by the Steering Group and endorsed by Heads of Medicines Agencies (HMA) and are described in the BEMA maual. Lead assessors must have previous benchmarking or twinning experience
- Training and quarterly improvement BEMA seminars at EMEA (working group of BEMA assessors – train the trainer principle) with reimbursement (EMEA budget) of one delegate per Agency (Medicines for Veterinary and Human use)
- Logistics for planning, team composition, training (+manual) and coaching (hints and Q&A) of teams are EMEA task as per HMA decision
- Helpdesk for BEMA assessors (EMEA + MHRA + Paul Ehrlich Institute simultaneously to ensure prompt resolution of issue and feedback to BEMA Steering group)



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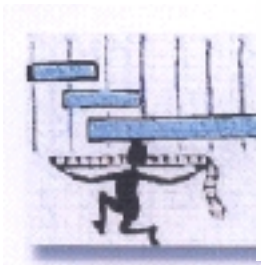
- The BEMA 2005-2006 assessment by visiting peer review teams consisting of 3 BEMA assessors is part of the validation and continuous improvement of the system in view of the 2008 BEMA assessment round.
- Since the HMA decided that the HMA secretariat is keyholder of the codes assigned to each assessment and EMEA receives batches of 5 or more anonymous assessments, improvement action can't be immediate as in PERF, but takes place quarterly.
- Training and quarterly improvement BEMA seminars will continue at EMEA (working group of BEMA assessors) to prepare in 2007 the 2008 BEMA assessment round.
- Assessments will be repeated every 2-3 years with self-assessments annually at each Agency as management tool (monitoring of improvement actions and implementation of new legislation).



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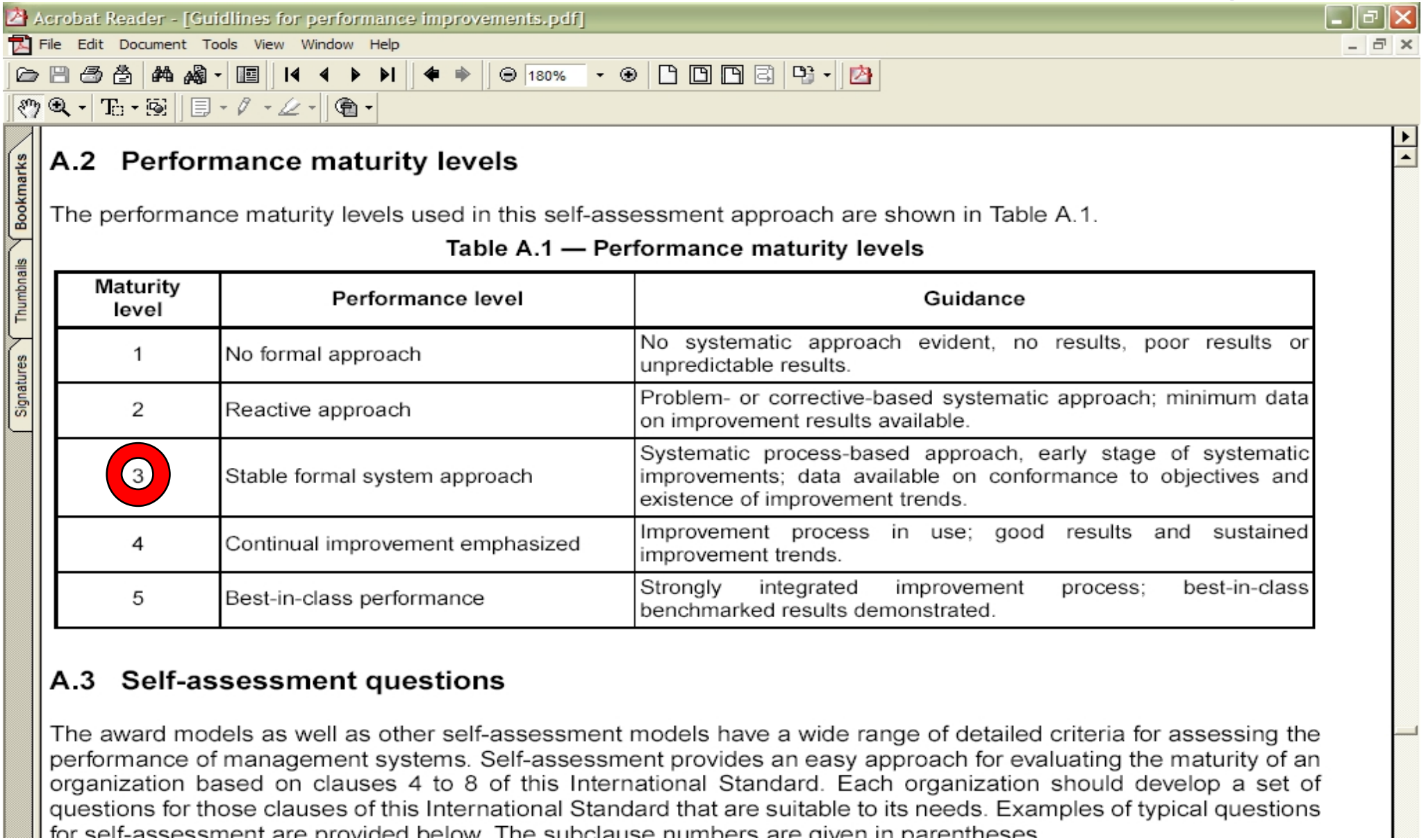

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Validation of the rating system is crucial for reliable data/baseline rating

- Overrating should be avoided. Leading to overrating is the absence of verification of **sustained improvement trends.** How long is a system/procedure/policy and management review in use? That must be recorded to justify the rating.
- Evidence described must **address the whole performance indicator** and not just one of the examples given in the questionnaire.
- In the case **documented procedures, or a documented system is in the question**, it is really meant to be a documented system.

Validation of the rating system is crucial for reliable data/baseline rating

- **One can NOT compare the results of an Agency assessed in January with one assessed in November of the same year**. The time elapsed is used for continual improvement and one rates that effect in the first place. Hence the need for no more than 10 months for the network assessment.
- Average ratings per Agency are nonsense, since Agencies may have different regulatory tasks and different phases of implementation of new legislation.
- Average ratings of one particular performance indicator over the whole network constitutes the baseline value in view of the 2008 BEMA assessment.

Benchmarking visit plan	The plan is prepared by the lead assessor, with help from EMEA IQM/Audit team. The lead assessor will send the draft plan to the agency to be visited, and to the team members.
Assessors	There will be three assessors per visit. Team leader will be appointed, based on experience and knowledge of the benchmarking system.
Role team leader	The team leader will: 1. Receive team members CV's from EMEA 2. Receive agency profiles from EMEA 3. Introduce team members to each other by e-mail or at briefing meeting 4. Draft peer review visit plan and send to agency and team members 5. Organise preparatory briefing meeting with assessors prior to the assessment 6. Ask for short agency/management presentation at opening meeting 7. Responsible for questionnaire and sending this to the appropriate HMA contact, after quality check by the assessment team and the agency
How long will the visit last	In principle the visit will last 2.5 days per agency (depending on the size of the organisation). If the agency covers both medicinal products for human and veterinary use, 3 days may be required if most managerial processes are in common. If managerial processes are completely separate, i.e. 2 separate organisations under one umbrella, there may be 2 separate assessments, with 2 questionnaires and the need for 2 x 2.5 days for the visit.
Who will organise the visits	EMEA will coordinate the visits (contact ester.meijer@emea.eu.int with questions relating to logistics and practicalities): - Details of assessors (and team leader) will be provided to the agency - Details on the agency to be visited will be provided to the assessors - Help will be given with preparing the visit plan - Templates and documents will be sent to the assessors, well ahead of the visit - A copy of the questionnaire will be provided to both the assessors and the visited agency

Very practical:
PC projection in room for assessors
Evidence instantly available on intranet

Use of several portable PCs by assessors
Allows work to be continued at hotel
Don’t forget the adaptors!

Tasks after the visit, communication and continual improvement

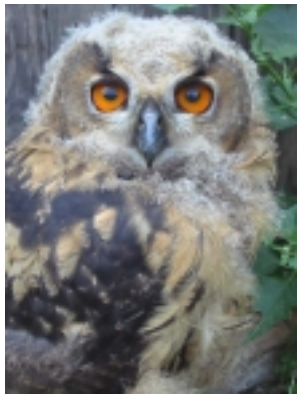
- In the BEMA system a database is required to hold anonymous results of the peer review visits (including the scores and the narrative/comments).
- The BEMA peer review team submits its full report/completed questionnaire to the visited agency to allow internal performance improvement plans to be put in place if needed and to control the anonymous database provided to the Agency after “cleaning”.
- In addition, an anonymised “cleaned” version is submitted by the peer review team and reviewed by the visited agency (QC step)
- The anonymous material is, after QC by the Agency and an additional verification by the assessors, **mailed by courier** to the HMA secretariat as per SOP, and after coding by the key holder forwarded to the EMEA for entry in the accumulated Access database.

Tasks after the visit, communication and continual improvement

- All participating agencies receive the anonymous data (rating and descriptions) listed per indicator.
- It is an HMA decision that data which are part of this management tool are not published.
- A report based on all data of the 2005-2006 BEMA assessment will be provided to the HMA for the SEP 06 meeting.
- HMA decides about communication with stakeholders.

Tasks after the visit, communication and continual improvement

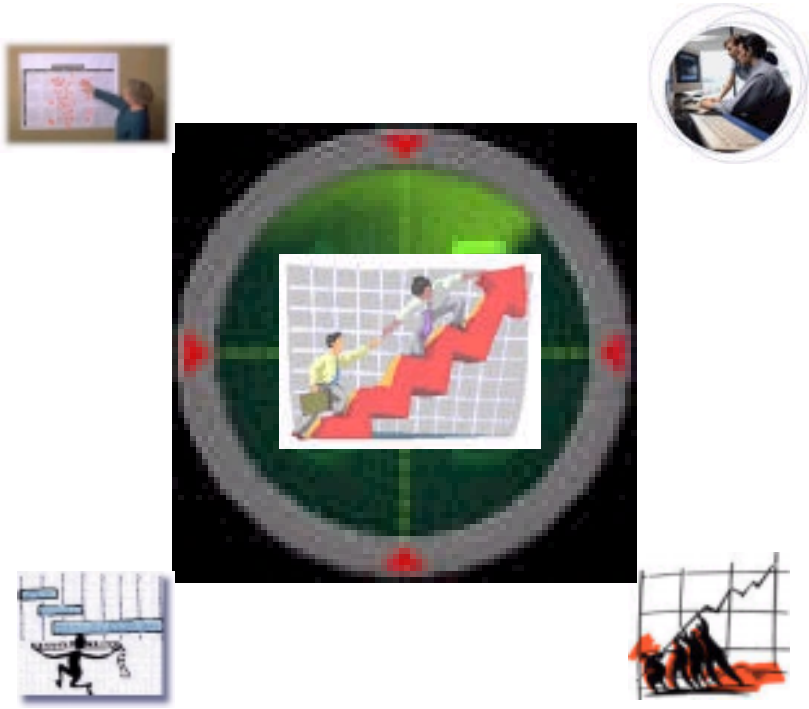
- VERY IMPORTANT for benchmarking: **descriptions are of much more value than ratings**.
- **Owners of high ratings for particular indicators might volunteer to be known** in order to allow other agencies to address questions and requests for advice to the best performers. In this way an Agency **becomes a "benchmark consultant" for a particular indicator** with high rating.



And so we contribute to the development of a world class medicines regulatory system for medicinal products based on a network of agencies operating to best practice standards

The value of the growing database

The longer the EU benchmarking system BEMA lasts the more assessments



the larger the data base
the more accurate the ratings will be
the better tool to develop a world class medicines regulatory system