

National Experience of Clinical Audit: The Belgian Experience Nuclear Medicine

Marleen Vandecapelle, PhD

Coordinator Nuclear Medicine

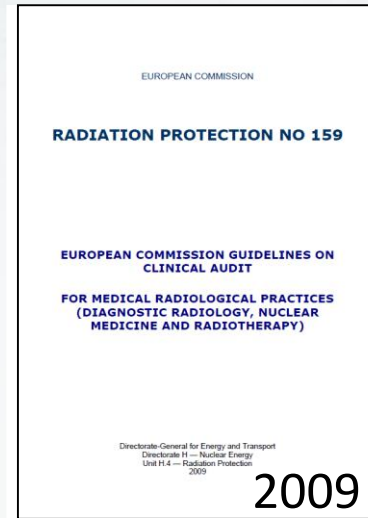
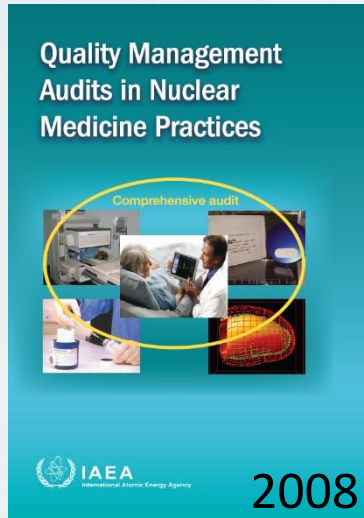
Marleen.vandecapelle@fanc.fgov.be



federal agency for nuclear control



(Inter)national initiatives



Legislation 2001:

“Clinical audits shall be performed...”
(but no details on who and how)

BE-MIP

B-QUADRILL

Sufficient guidance to determine modalities for clinical audits in Nuclear Medicine in Belgium



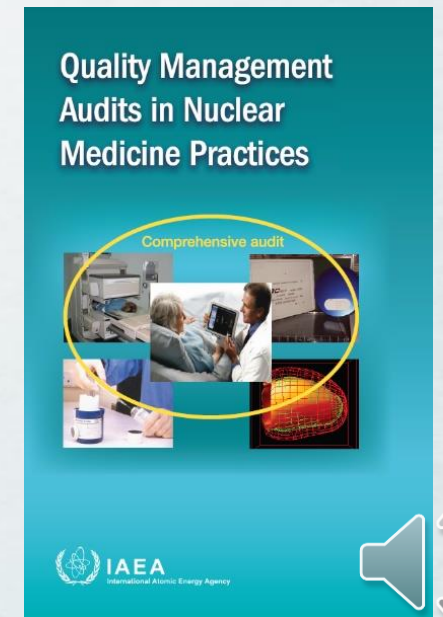
Belgian initiative 2010

- Stakeholder meetings by FANC:
 - Active participation and support of:
 - FPS for Public Health
 - Medicines Agency
 - Reimbursement Agency
 - BelNuc (Belgian Society for NM)
 - Several individual stakeholders



Results:

- Clinical audits based on QUANUM (2008)
- Different phases and timing agreed



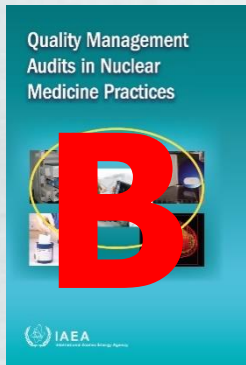
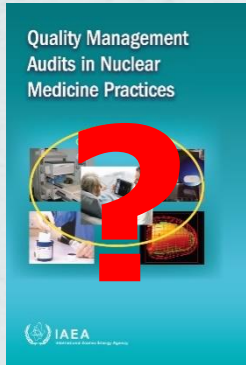
Belgian initiative 2010

	Different phases		
	Self-assessment	Internal clinical audit	External clinical audit
Level	Department	Hospital	Nationwide
Who carries out?	Personnel of the department	Auditors from other departments within the hospital/institution	Auditors from other hospitals/institutions
Result	Self-assessment report	Internal audit report	External audit report
Initial timing	07/2011	07/2012	07/2013

Identify areas for improvement → Actions for improvement



Belgian initiative 2010



- QUANUM (2008):
 - General part + 13 checklists of yes/no questions on ≠ topics
 - Principles and methodology feasible for Belgian NM?
 - All checklists/questions relevant and clear for Belgian NM?
- Pilot study (September 2010 - July 2011):
 - Performed by 18 NM departments (> 10%) on a voluntary basis
 - Goal 1: evaluation of QUANUM (2008) with focus on clarification and adaptation of checklists
 - Goal 2: suggestions for extra support



Quality Management Audits in Nuclear Medicine Practices



AUDITS DE GESTION DE LA
QUALITE EN MEDECINE
NUCLEAIRE -
AUDIT GLOBAL

Quality Management Audits in Nuclear Medicine Practices



AUDITS VAN HET
KWALITEITSBEHEER IN DE
NUCLEAIRE GENEESKUNDE -
UITGEBREIDE AUDIT

B-QUANUM 2011

- General part: WHAT? WHO?
- Belgian checklists specific for Belgian context
- Extra support documents:
 - Example annual report of department NM¹
 - Extract ISO Manual²
 - Extract Quality Manual²
 - List of all Standard Operating Procedures (SOP)
 - Extract SOP Bone scintigraphy²
 - Extract SOP Whole Body [¹⁸F]-FDG²

¹Courtesy to dr. J. Rutten (emiritus), AZ Turnhout

²Courtesy to prof. dr. K. Van Laere, UZ Leuven

Quality Management Audits in Nuclear Medicine Practices



AUDITS DE GESTION DE LA
QUALITE EN MEDECINE
NUCLEAIRE -
AUDIT GLOBAL

Quality Management Audits in Nuclear Medicine Practices



AUDITS VAN HET
KWALITEITSBEHEER IN DE
NUCLEAIRE GENEESKUNDE -
UITGEBREIDE AUDIT

B-QUANUM 2011

- Practical guideline:
HOW TO START IMPLEMENTING CLINICAL AUDIT?
 - Who can help you within the hospital in answering the questions?
 - Composition of audit teams?
 - Need to have “trained auditors”?
 - How to document audit process?
 - ...
- Information sessions by FANC
- Webpage with all information + documents + FAQs

<https://fanc.fgov.be/nl/professionelen/medische-professionelen/nucleaire-geneeskunde/klinische-audits-de-nucleaire>
<https://afcn.fgov.be/fr/professionnels/professions-medicales/medecine-nucleaire/audits-cliniques-en-medecine-nucleaire>



B-QUANUM 2011 checklists

Checklist 6: Quality Assurance System

No	Component	Class	%	Comments	Date achieved	Regul. basis
6.1	Are Standard Operating Procedures available for all tasks performed by the department?	A				RD2001 article 51.4 § 3
6.10	Does the department perform self-evaluation or internal audit once a year?	B				
6.11	a. Is the satisfaction of the patients evaluated? b. Is the satisfaction of the referring physicians evaluated?	C				



B-QUANUM 2011 checklists

Checklist 6: Quality Assurance System

No	Component	Class	%	Comments	Date achieved	Regul. basis
6.1	Are Standard Operating Procedures available for all tasks performed by the department?	A		Required by legislation. Urgent corrective action should be instituted.		RD2001 article 51.4 § 3
6.10	Does the department perform self-evaluation or internal audit once a year?	B		Are expected to be reached by all departments. Corrective action is recommended.		
6.11	a. Is the satisfaction of the patients evaluated? b. Is the satisfaction of the referring physicians evaluated?	C		Desirable but not essential. Corrective action may improve the overall functioning of the department.		



B-QUANUM 2011 checklists

Checklist 6: Quality Assurance System

No	Component	Class	%	Comments	Date achieved	Regul. basis
6.1	Are Standard Operating Procedures available for all tasks performed by the department?	A	0 25 50 75 100	Nothing is done Planned Planned and started implementation Planned and implemented Fully implanted and reviewed, clearly documented		
6.10	Does the department perform self-evaluation or internal audit once a year?	B		If < 100%: explanation/action plan in "Comments"		
6.11	a. Is the satisfaction of the patients evaluated? b. Is the satisfaction of the referring physicians evaluated?	C		Indicate date of certain % in "Date achieved"		



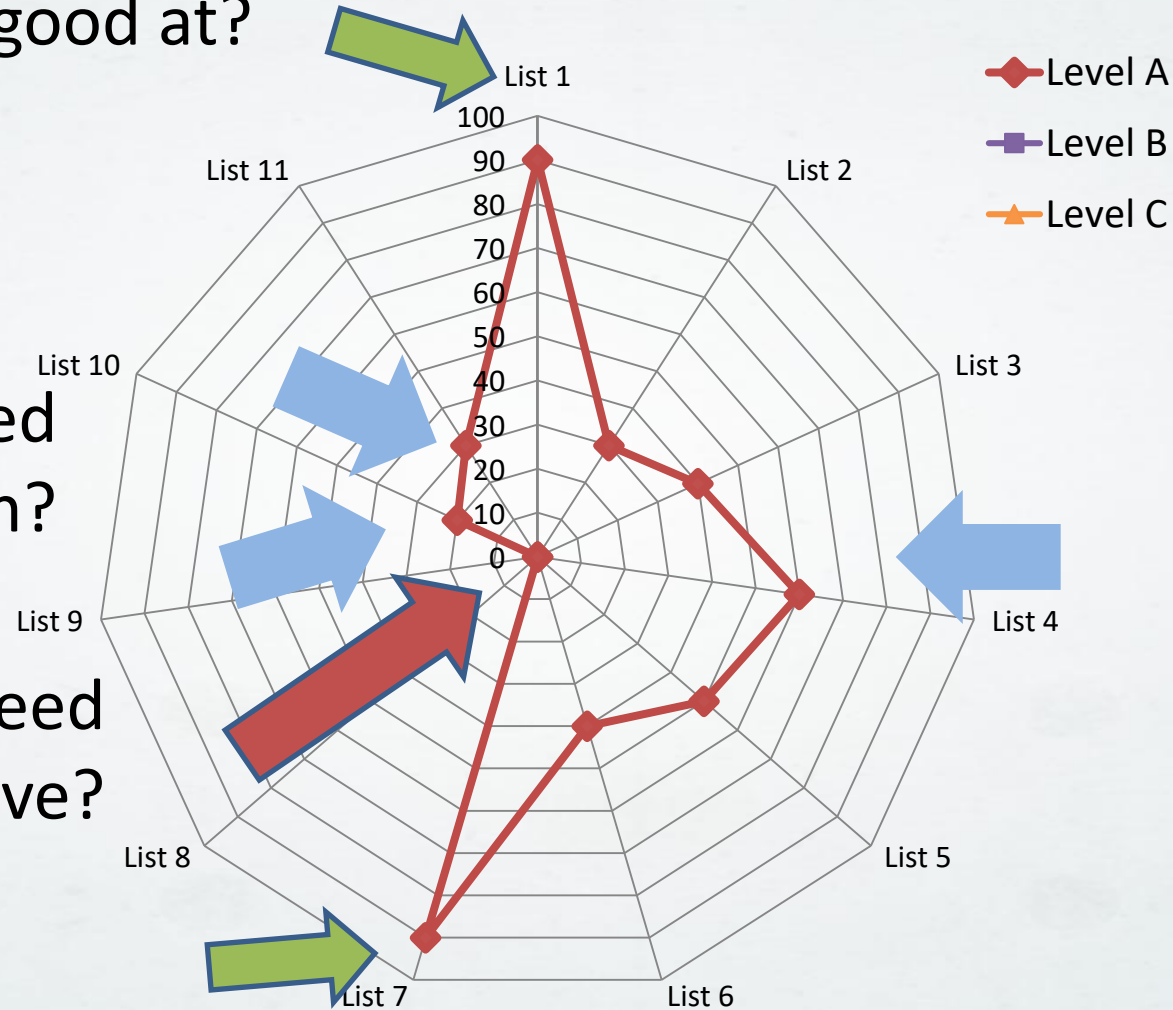
B-QUANUM 2011 checklists	#	A	B	C
1. Strategies and policies	21	2	19	
2. Administration and management	3	1	2	
3. Human resources	38	18	20	
4. Radiation protection of personnel and environment	36	30	6	
5. Radiation protection of the patient and his direct environment	22	18	4	
6. Quality assurance system	71	21	39	11
7. Quality control of imaging equipment and dose calibrator	50	27	23	
8. Computer systems and data handling	12		12	
9. Acceptance tests	27	26	1	
10. General aspects – diagnostics	4	2	2	
11. General aspects - radionuclide therapy	7	1	6	
	Σ 291	146	134	11

B-QUANUM 2011 checklists results

What are we good at?

What do we need to work on?

What do we need to improve?



Available on

Status of clinical audits in NM in Belgium 2020

	Different phases		
	Self-assessment	Internal clinical audit	External clinical audit
Level	Department	Hospital	Nationwide
Who carries out?	Personnel of the department	Auditors from other departments within the hospital/institution	Auditors from other hospitals/institutions
Result	Self-assessment report	Internal audit report	External audit report
Initial timing	07/2011	07/2012	07/2013

Identify areas for improvement → Actions for improvement



Status of clinical audits in NM in Belgium 2020

What helped?

- ✓ 2001: Legal obligation (no details)
- ✓ 2010: EANM course **TAKE HOME**
- ✓ 2011: **B-QUANUM** specific for Belgian context thanks to pilot study
- ✓ Information sessions
- ➡ Convinced a lot of NM departments
- ✓ 2019-2020: detailed legislation: self-assessment + internal CA based on **B-QUANUM** by multidisciplinary team

Difficulties and future work:

- ✓ External clinical audits:
 - Financing???
 - Who should organise?
- ✓ 2021: update **B-QUANUM** 2011:
 - Updates IAEA QUANUM (2008)
 - New radiation protection legislation

Legal obligation

B-QUANUM

B-QUAADRIL



QUATRO

B-QUATRO

