



How to maintain a permanent audit service?

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CAT·ClinART

Objectives of the lecture

- Current structure and support
- Pitfalls / SWOT
- The future



B-QUATRO and BELdART: Implementation and support

- **Legal Framework:** A National legislation
- **Structural framework:**
 - Presence of an organizational structure and coordinator
- **Audit tool:**
 - B-QUATRO tool
 - Postal audit system
- **Financial support:**
 - B-QUATRO annual budget: **€17200,00**
 - Reimbursement of auditors (travel, hotel, food): €10000,00
 - A dedicated coordinator (0.2 FTE): 6000,00
 - Yearly auditors' meeting; €1200,00
 - (A dedicated IT platform: €1200,00)
 - BELdART annual budget: **€200000,00**
- **Collaborative framework:**
 - Structured interaction with the regulatory body / ministry of Health
 - Open communication with, and support from the departments
- **Experts:** Well-trained auditors with clinical expertise



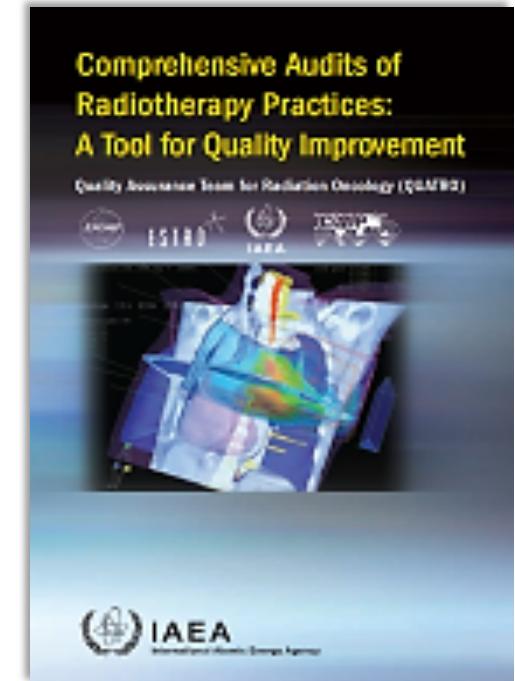
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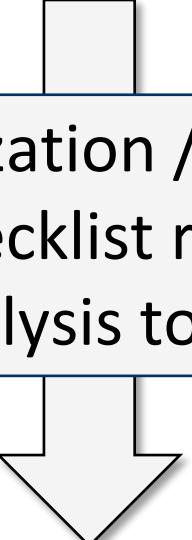
B-QUATRO

A tool for quality improvement adapted to national situation

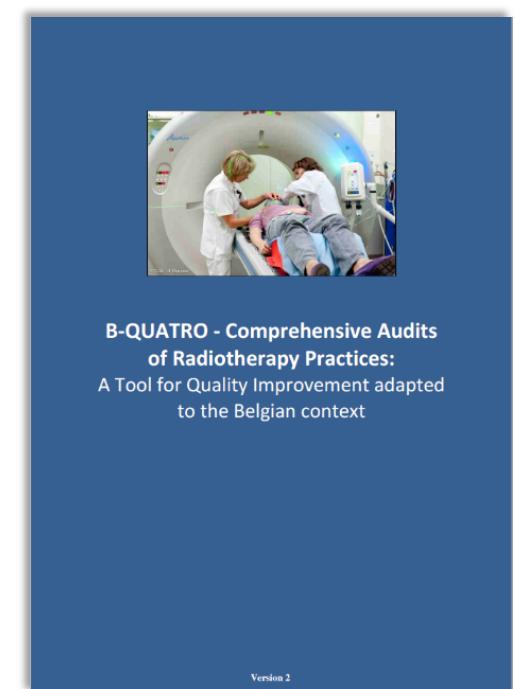
QUATRO: Comprehensive peer review clinical audits
(2011-2015)



Belgian contextualization / new technologies/
QMS auditing/ checklist reformatting/ data
analysis tools



B-QUATRO: Belgian - Comprehensive peer review clinical audits
(2017- ...)



About Clinical Audits

- Belgium has an exemplary function internationally by adopting the B-QUATRO "peer review"
- It's strength: peer review!
 - **“Peer”**: colleagues / multidisciplinary
 - **Volunteers**: motivation
 - Comprehensive audit **focused on quality improvement** of the complete patient's carepath (not only about compliance to procedures)
- The B-QUATRO comprehensive audit is **NOT** designed for:
 - Investigation of accidents or reportable medical events (misadministration)
 - Assessment for entry into cooperative clinical research studies
 - **Regulatory purposes**, i.e. audit is not an enforcing tool but an impartial source of advice on quality improvement.



Peer review!!! – TRUST!!! – Confidentiality!!!

Legislation: Clinical audits



Basic Safety Standards Directive

Better radiation protection



D. Verellen - MaintainPermanentAudits

BELGISCH STAATSBLAD

MONITEUR BELGE

Publicatie overeenkomstig artikelen 472 tot 478 van de programmawet van 24 december 2002, gewijzigd door de artikelen 4 tot en met 8 van de wet houdende diverse bepalingen van 20 juli 2005 en artikelen 117 en 118 van de wet van 5 mei 2019.

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100e ANNEE

JEUDI 20 FEVRIER 2020

SOMMAIRE

Lois, décrets, ordonnances et règlements

Cour constitutionnelle

Extrait de l'arrêt n° 22/2020 du 13 février 2020, p. 10056.

Legislation: Clinical audits

Art 30, §4 and §5

§5 For radiotherapy: An **external clinical audit** (including dosimetry audit) is **mandatory** at least **every 5 years**.

§4 The audit team

- At least 3 **trained/accredited auditors**
- Auditors not connected to the audited centre
- Members:
 - At least an accredited radiation oncologist and an accredited MPE
 - Other members: quality coordinator, RTT, radio-pharmacist, physics expert
 - Sufficient knowledge and experience concerning the carepaths and independent from the audited centre

Legislation: Clinical audits

Some challenges

- As it became a legal obligation: the concept of “**peer review**” and trust is challenged ...
- **Who certifies the auditors**, based on what criteria?
- Currently, B-QUATRO is based on **VOLUNTEERS**, financed (expenses for 3-4 day audit) by the College of Radiotherapy and Oncology ... which has been dismantled in 2023.



Clinical Audits: SWOT

- **Strengths:**

- Multidisciplinary, comprehensive audit
- Peer review - TRUST

- **Weaknesses:**

- Finding, retaining volunteers (free time or supported by own department?)
- Reimbursement of volunteers
- Supported by College of Radiotherapy and Oncology ... which is officially cancelled
- Training of new volunteers
- Currently one VERY MOTIVATED national coordinator ;-)

- **Opportunities:**

- All centres participate and support the initiative
- Overall quality of radiation oncology and patient safety increases on a national level
- Every patient has access to state-of-the-art radiotherapy

- **Threats:**

- Being an obligation, the concept of trust is challenged
- Who certifies the auditors?
- What if reimbursement disappears?
- What if no volunteers can be found?

BELdART

BELdART

BELgian dosimetry Audits in Radio Therapy

BELdART audit results





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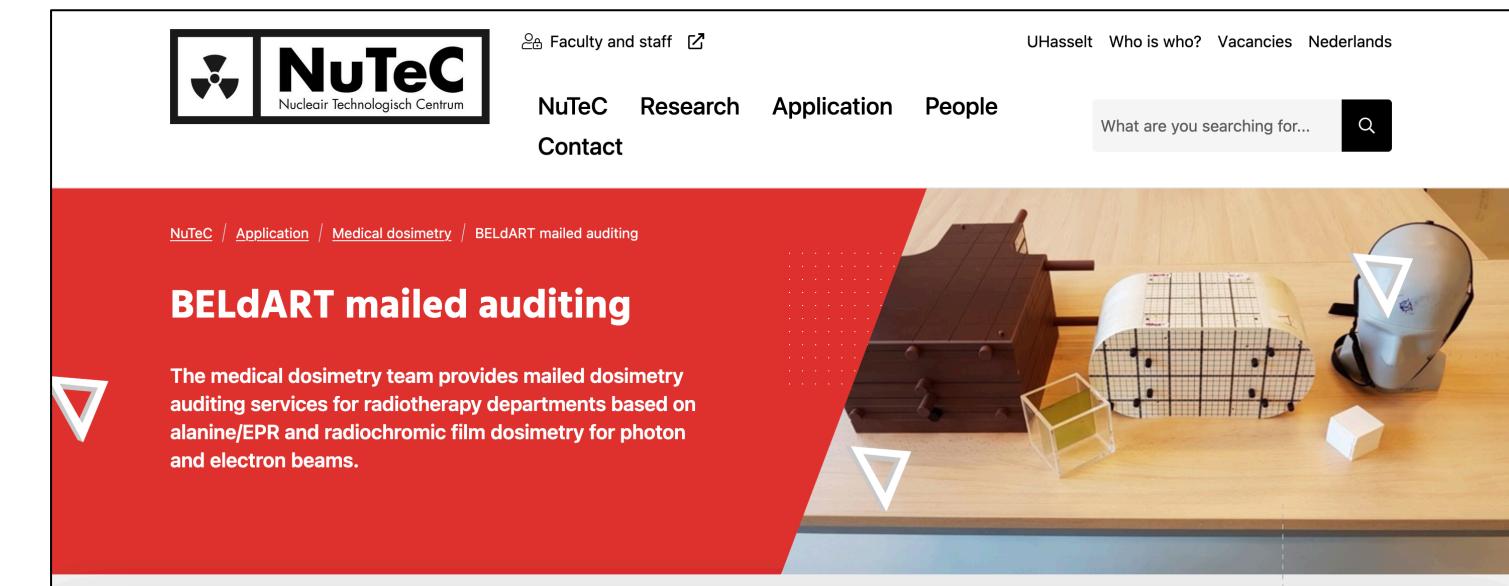
About BELdART

Started on voluntary basis

- Initiative of Belgian Hospital Physics Association (BHPA)
- Group of volunteers (teams of 1 expert, 1-2 young physicists)
 - Calibrated IC and electrometer traceable to primary standard, small water tank, thermometer and barometer
 - **Full Weekend**, sandwiches provided to volunteers, no reimbursement of expenses
 - **Basic beam output and irregular/wedged fields calculated by TPS**
- PhD Bob Schaeken: alanine EPR dosimetry
 - Onsite visits comparable to BHPA audits, IC replaced by alanine
- Creation of BELdART
 - Postal audits supported by College of Radiotherapy and Oncology (acquisition of spectrometer, phantoms, dosimetry box, ...)
 - Spectrometer moved to Uhasselt/NuTeC
 - BELdART 1, 2, 3, 4, ... sponsored by college
 - Payed audits on demand
- Generally accepted as “**Good Practice**” to perform audit



The screenshot shows the homepage of the Belgian Hospital Physicists Association (BHPA). The header features the BHPA logo and a navigation menu with links to ACTUA, ASSOCIATION, SPONSORS, SYMPOSIUM, and LINKS, along with a LOG IN button. The main content area has a dark blue background with a network-like graphic. The title "BHPA" is at the top left, and "BELGIAN HOSPITAL PHYSICISTS ASSOCIATION" is prominently displayed in the center. Below the title, there is a brief description of the association's mission and responsibilities.



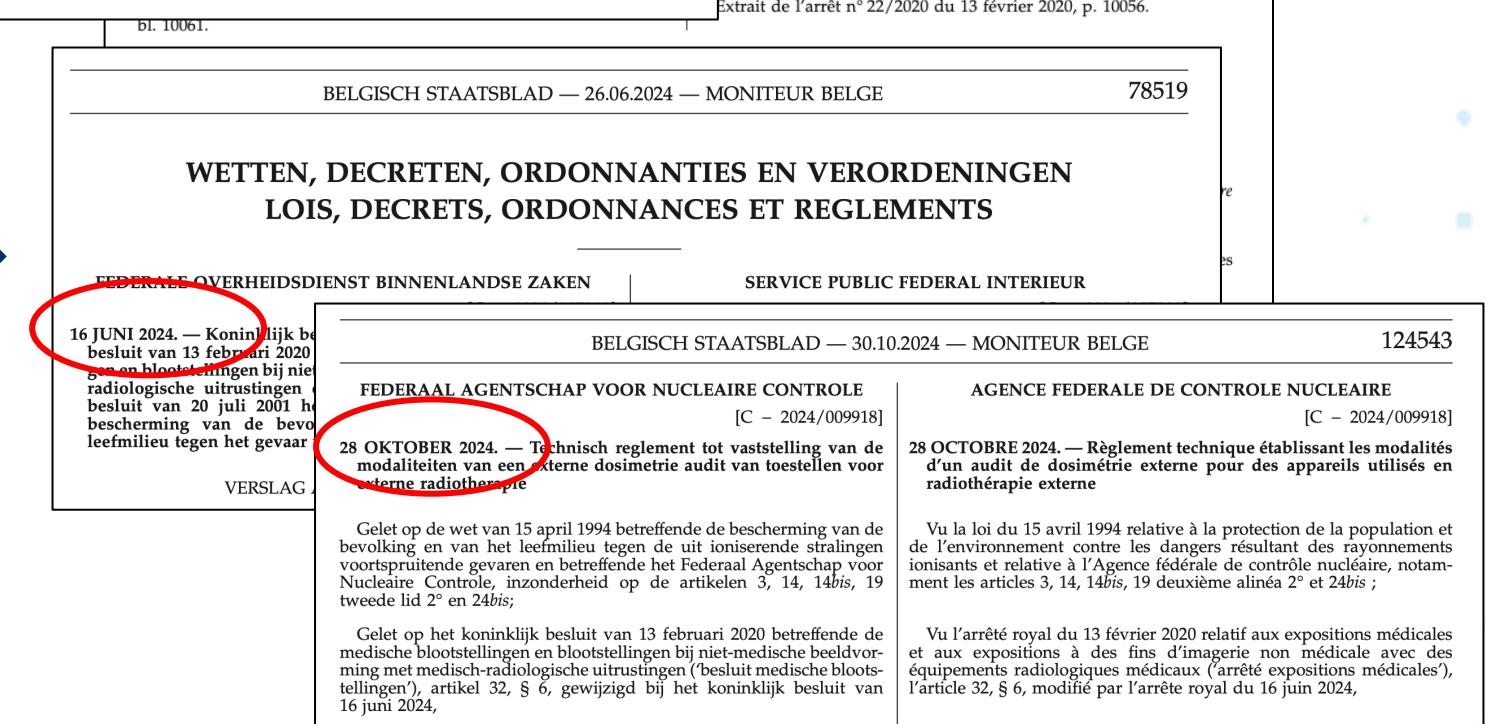
The screenshot shows the homepage of NuTeC (Nuclear Technologisch Centrum). The header includes the NuTeC logo, a search bar, and links for Faculty and staff, UHasselt, Who is who?, Vacancies, and Nederlands. The main content features a section about "BELdART mailed auditing" with a description of the service and a photograph of dosimetry equipment including a wooden phantom, a lead brick, and a dosimeter.

Legislation: Dosimetry audits



Basic Safety Standards Directive

Better radiation protection



Legislation: Dosimetry audits

Art 32, §6 and technical regulations

§6 For **external beam radiotherapy** treatment machines with nominal energy > 1 MeV a dosimetric audit is **MANDATORY BEFORE clinical implementation**.

Technical regulations

- Created in collaboration between Federal Agency and representatives of Belgian MPE's.
- Based on traffic light protocol.
- Art 2, §1: The audit consists minimally of calibration of output in reference conditions **for every beam energy clinically used**.
- Art 2, §2: The audit includes verification of the **complete therapeutic treatment chain** (excl. IORT).
- Art 2, §3: The audit is not mandatory for new treatment machines for which (inter)national standards are not yet available.
- Art 4,5,6: The auditor can be accredited MPE or (inter)national organization recognized for dosimetry audits. The dosimetry equipment should be calibrated and traceable to a primary standard.

Legislation: Dosimetry audits

Technical regulations

Art 8, §1: The results of the dosimetry audit should be available **BEFORE clinical implementation.**

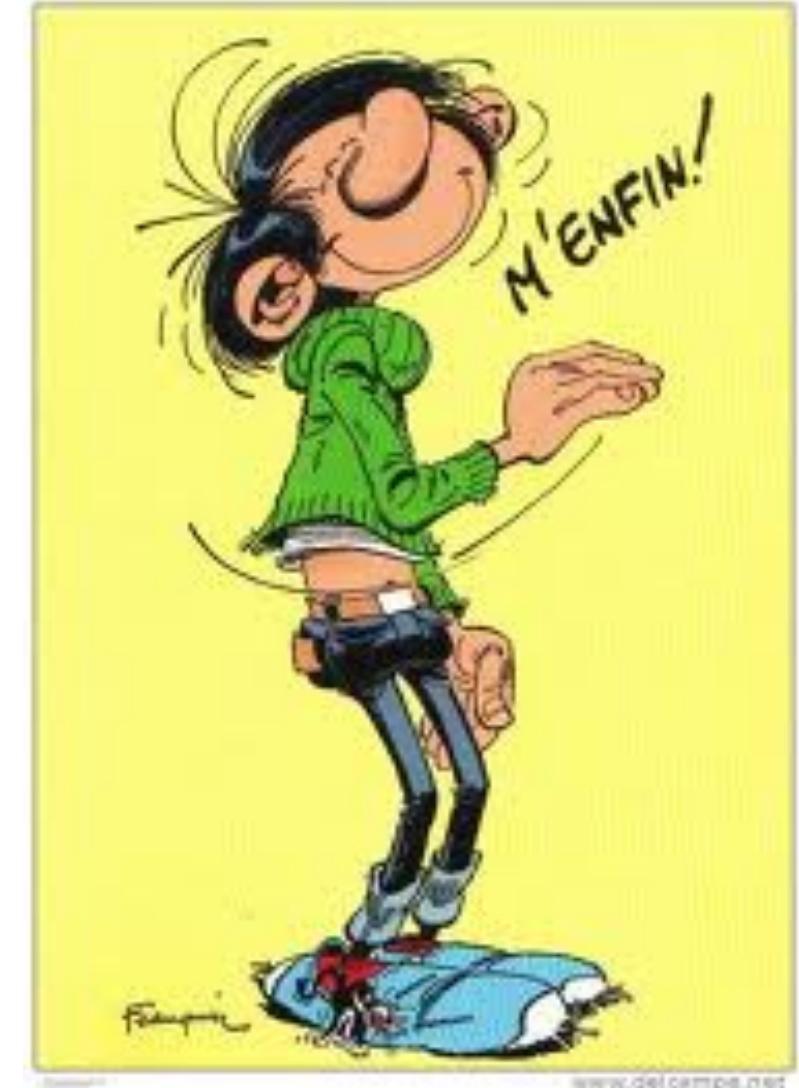
Art 8, §2: Traffic light protocol

- **Green:**
 - Output deviation < 3% compared to reference dose
 - Beam can be used clinically
- **Orange:**
 - Output deviation > 3% and < 5% compared to reference dose
 - beam can be used clinically (on local MPE's responsibility), but new audit mandatory within 3 months.
- **Red:**
 - Output deviation > 5% compared to reference dose
 - Beam **CANNOT** be used clinical, until new and succesful audit

Legislation: Dosimetry audits

Some issues / challenges not considered properly by legislation

- Only one audit centre (BELdART) in Belgium, with limited capacity
 - Waiting times ~ months
 - What if BELdART terminates?
- What if independent MPE performs audit?
 - Liability
 - Insurance?
- Basic dosimetry audit or complex treatment techniques?
- What in case of dispute, experimental set-up errors?
- False negative will result in delay of clinical implementation of replacement/new linacs:
 - Double shifts on remaining machines ... increased risk in incidents!
 - Increased waiting times for patient treatments ... quality of treatment decreases!
 - Loss of revenue!



Impact of legislation on BELdART

Support and goodwill decreases because of legal consequences

- Some centres had “red” audit since legislation
 - Bad result due to mishandling of alanine pellets
 - Bad result due to experimental set-up issues
 - Bad results disagree with local cross reference on matched beam machines, reason unknown ...
 - ...



Confidence in BELdART is falling



Impact of legislation on BELdART

Support and goodwill decreases because of legal consequences

- Failed audits BELdART

- Photon beams:

	# of beams	% of beams
Retest beam output known reason	2	0.8
Retest beam output unknown reason	9	4.0
Retest beam output (known + unknown)	11	4.8
Total beams	227	100.0

- Electron beams:

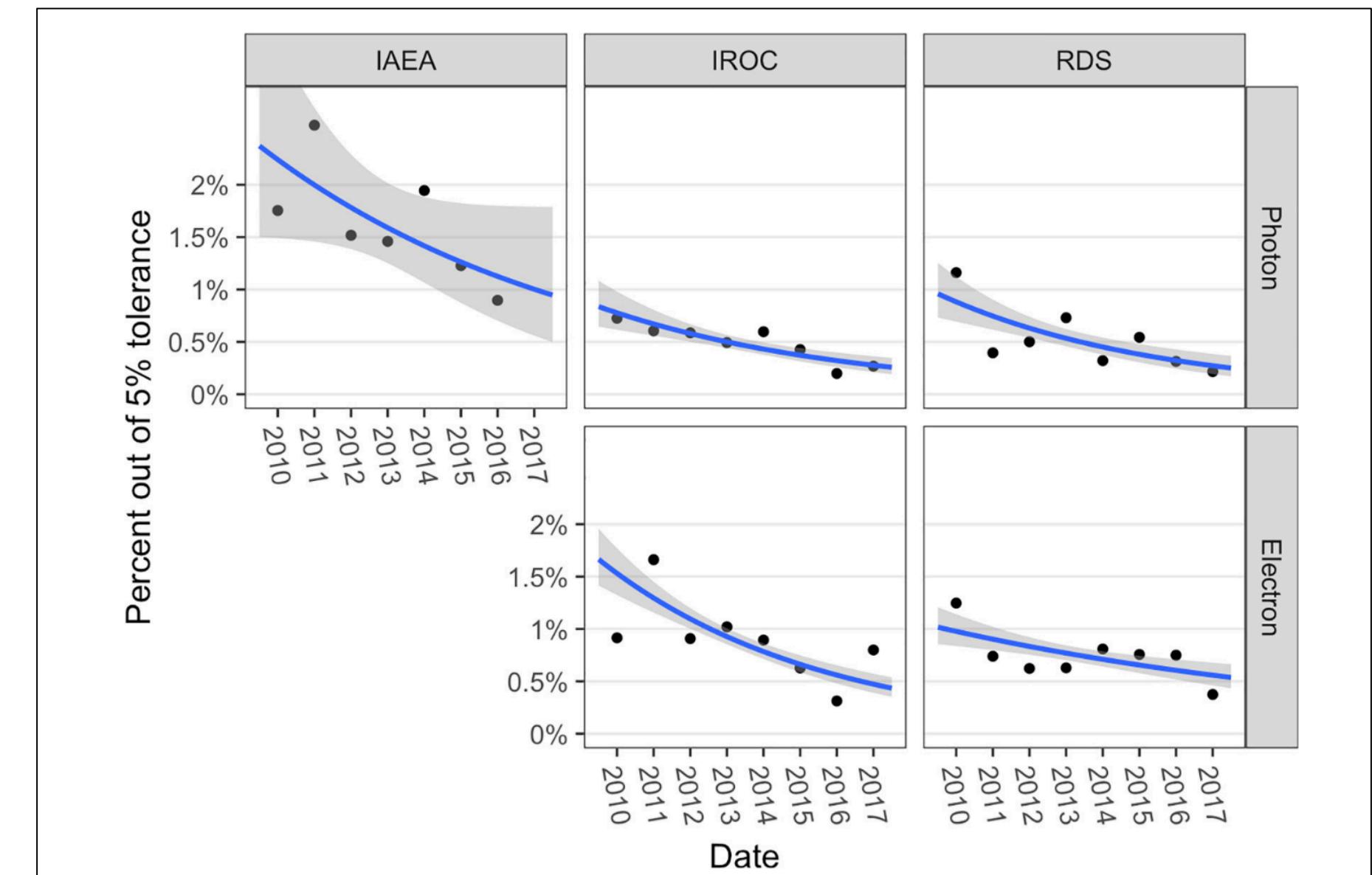
	# of beams	% of beams
Retest beam output known reason	8	14.0
Retest beam output unknown reason	0	0.0
Retest beam output (known + unknown)	8	14.0
Total beams	57	100.0

- In case of failed audit: re-measurement performed with BELdART expert onsite

Impact of legislation on BELdART

Support and goodwill decreases because of legal consequences

- Benchmarking of audits
- On average **4.5 %** of centres required follow-up auditing every year
- **19 %** of centres had at least one beam out of tolerance at 1st audit. (during the length of the study)



Impact of legislation on BELdART

Support and goodwill decreases because of legal consequences

- IAEA benchmark of BELdART

Co60-based Irradiations irradiations					
SAD=100 cm, depth 5 cm, FS 10x10 cm ²			Date: 2021-08-26		
	Dose Rate :	0.0210 Gy/s			
ID	Set #	D_IAEA (Gy)	Comments	D_DAN (Gy)	D_DAN / D_IAEA
Farmer-shaped Probes irradiated in Solid water	1	1	4.006 Pellets fell out of holder	4.043	1.009
	2	2	4.024 Pellets fell out of holder	4.073	1.012 BLIND 3
	3	3	4.065	4.099	1.008 BLIND 1
	4	4	4.005	4.059	1.013
	5	5	3.955	3.995	1.010 BLIND 2
	6	6	4.095	4.132	1.009 BLIND 4
Straw-shaped Probes irradiated in Solid water	AR588 - 7	7	4.006	4.042	1.009
	AR588 - 8	8	4.066	4.064	1.000 BLIND 1
	AR588 - 1	9	4.023	4.018	0.999 BLIND 3
	AR588 - 2	10	3.955	4.011	1.014 BLIND 2
	AR588 - 4	11	4.095	4.1	1.001 BLIND 4
	AR588 - 10	12	4.005	4.051	1.012
Mean Ratio: 1.008					

Linac-based Photon irradiations					
SAD=100 cm, depth 10 cm, FS 10x10 cm ²			Date: 2021-08-18		
	ID	Energy	Beam quality TPR _{20/10}	D_IAEA (Gy)	D_DAN (Gy)
Standard DAN Probes irradiated in water	37	6MV	0.666	7.990	7.956
	42				7.971
	43	10MV	0.737	8.004	7.986
	45				0.998
	46	15MV	0.762	8.009	7.939
	47				7.981
	13				0.997
	14	6FFF	0.627	8.003	8.022
	16				8.026
	18				8.009
	19	10FFF	0.737	7.995	1.000
	22				7.991
Mean Ratio: 0.998					

- Benchmarks with VSL (NL) and NPL (UK) ongoing

Dosimetry Audits: SWOT

- **Strengths:**

- Good practice
- Postal audit
- Basic beam output and complex treatments (entire treatment chain from planning to treatment)

- **Weaknesses:**

- Capacity and HR: long waiting times now that it is an obligation
- Other international audit centres also face limited capacity
- False negatives (what about false positives?)
- Sensitive to experimental set-up (in water tank)
- If colleague performs audit: liability / insurance?

- **Opportunities:**

- Uniformity and standardisation across Belgian centres
- Creation of more robust set-up (solid water) versus more accurate (water)

- **Threats:**

- Delay of treatment in case of false negative or capacity issues
- Financial support of BELdART
- University support of BELdART / NuTeC, only 1.0 FTE MSc and 0.2 FTE PhD

Summary

- The audit is NOT a pass/fail exam, it's advisory
- Focus on patient safety and quality
- It's more than MSQA and PSQA: process oriented QA
- Dosimetry audits: a must, but practical issues and limitations
- What about brachytherapy?





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Network for Quality Improvement
in Radiotherapy



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