

HERCA: Heads of the European Radiological Protection Competent Authorities

Stakeholder Involvement in medical practices:

Report on HERCA WG medical application action plan with CT manufacturers

Philipp R. Trueb, Jürgen Griebel;
Federal Office of Public Health, Switzerland
Federal Office for Radiation Protection (BfS), Germany



HERCA: Mission and Vision

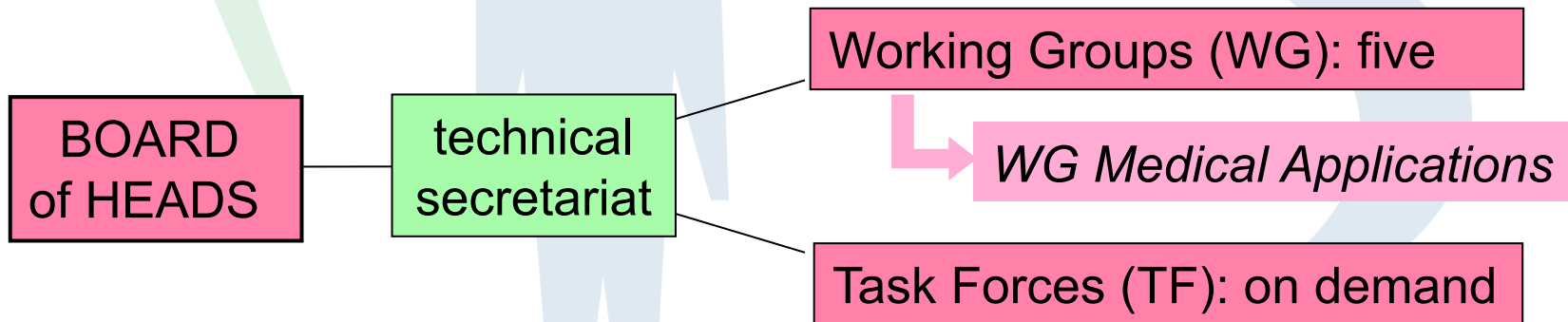
HERCA is a young association, set up in 2007, which gathers the **H**eads of the **E**uropean **R**adiological Protection **C**ompetent **A**uthorities.

Through HERCA, the national regulators in Europe have joined their efforts to strengthen radiation protection in Europe in all fields of the application of ionizing radiation.

Hereby, HERCA works in close collaboration with EC, WHO and IAEA.

HERCA: Mission and Vision

The management structure of HERCA consists of:



HERCA: Mission and Vision

Through the *WG Medical Applications (MA)*, the national regulators in Europe have joined their efforts to strengthen radiation protection in:

X-ray diagnostics, nuclear medicine, and radio-oncology.

The WG Medical Applications has established five sub-WGs on:

Justification,

Optimisation,

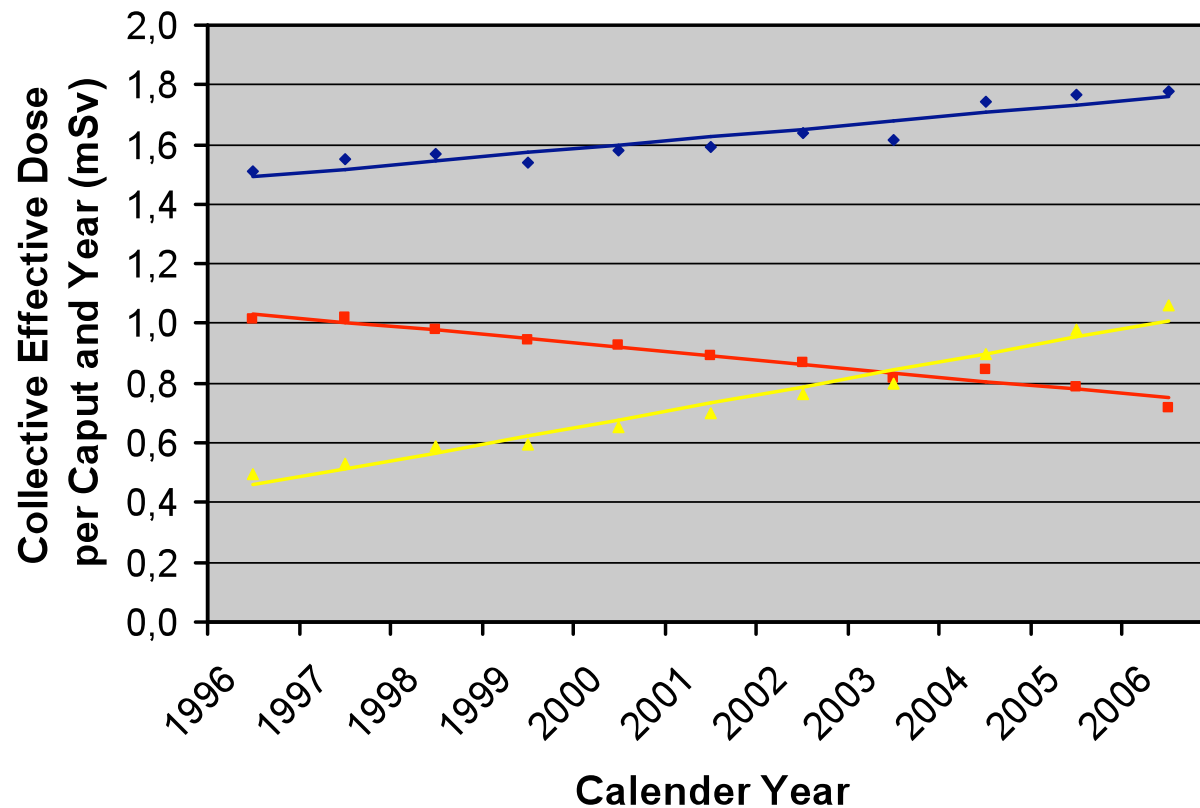
Stakeholder Involvement: CT Manufacturers,

Exposure of Asymptomatic Individuals,

Patient release and Patient Card in Nuclear Medicine

Relevance of CT in radiation protection

BfS Annual Surveys: Germany, 1996 -2006



survey 2006:
CT
contribution
≈ 60%

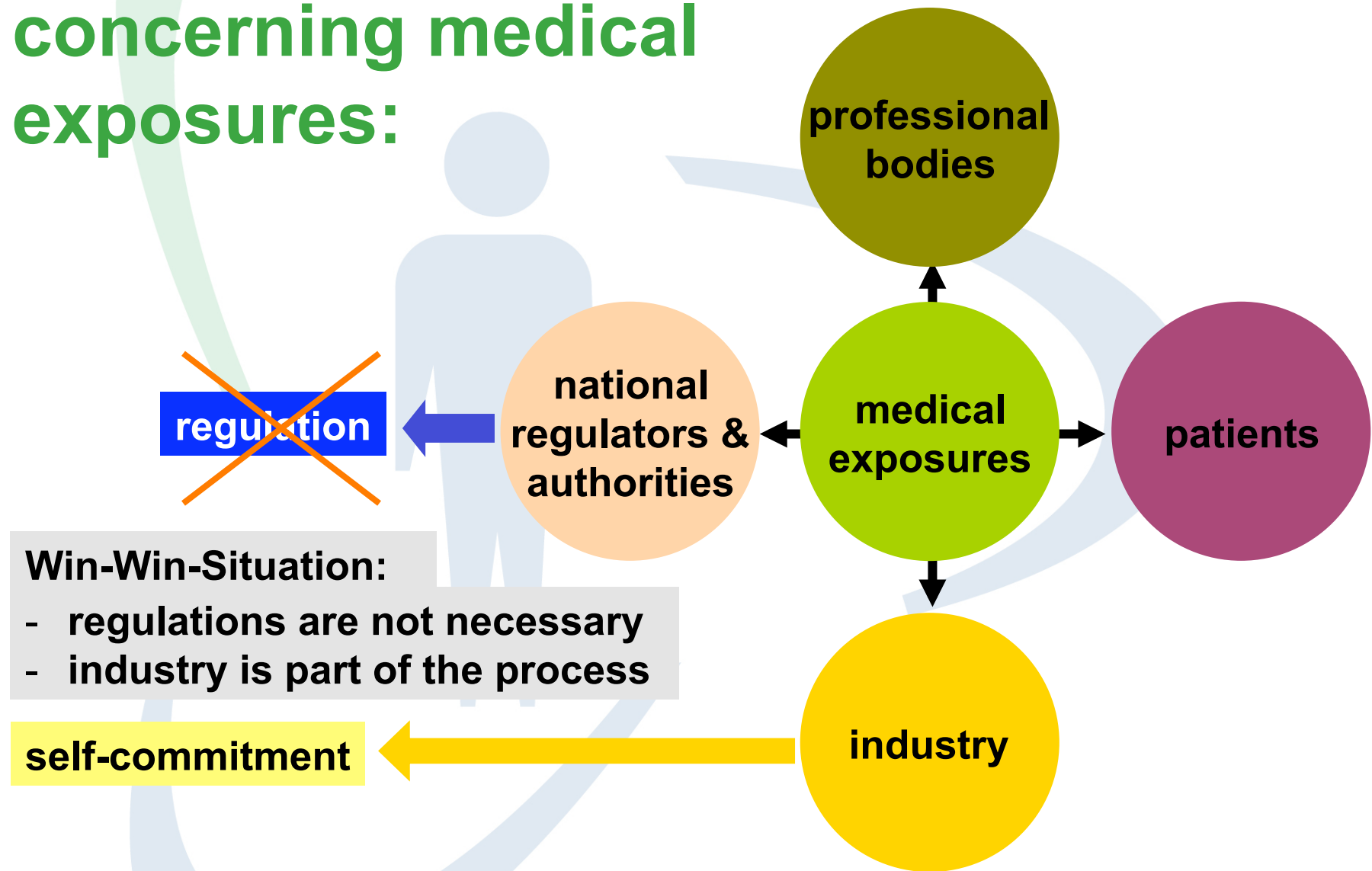
Relevance of CT in radiation protection

2008/1998 ratios of the frequency and dose in Switzerland

Radiological modality	Number of examinations	Collective dose	Number of examinations /1000 population	Effective dose per capita
Radiography	1.32	0.45	1.21	0.42
Conventional fluoroscopy	0.98	0.34	0.90	0.31
Interventional – diagnostic	0.79	1.00	0.73	0.93
Interventional – therapeutic	1.72	2.06	1.59	1.90
Computed tomography	2.38	3.11	2.19	2.86
Dental radiography	1.32	0.87	1.21	0.80
Mammography	1.73	1.43	1.60	1.32
Bone densitometry	3.64	7.55	3.36	6.96
Total	1.36	1.30	1.26	1.20

survey 2008: CT contribution ≈ 68%

Main stakeholders concerning medical exposures:



Win-Win-Situation:

- regulations are not necessary
- industry is part of the process

self-commitment

CT manufacturer involvement

Kick-off meeting of HERCA with CT manufacturers was held
on the 8th of February, 2010
at the Federal Ministry for the Environment, Nature Conservation and
Nuclear Safety (BMU) in Bonn, Germany.

The meeting was hosted by the Head of BMU-Directorate RS II
(Radiological Protection):

Mr. K.-E. Huthmacher

and chaired by the HERCA Chair:

Mr. O. Harbitz (Norwegian Radiation Protection Authority - NRPA)

Participating CT-manufactures:

GE, Philips, Siemens, Toshiba and
a representative of COCIR

COCIR: European Coordination Committee of the Radiological, Electromedical and
Healthcare IT Industry

CT manufacturer involvement

The ultimate goal of the meeting with the CT-Manufacturers was to arrive at the agreement

- (1) that measures are strongly needed to reduce patient CT doses in the health care setting, and
- (2) that the CT manufacturers have a particular responsibility in this important process.

It was made clear by HERCA that

- the CT manufacturers have to give a clear signal that they accept their responsibility on patient dose reduction by committing themselves to actions which offer the potential to achieve this goal
⇒ *self-commitment*.

Content of the self-commitment

- (1) Implementation of a standardized benchmarking characterizing the dose efficiency of CT systems - related to image quality - in several relevant clinical scenarios.

The aim of this action is

- to guarantee a high level of transparency in radiation exposure of CT systems and
- to provide a base for both the comparison between CT systems of different manufacturers and for the validation of technical measures to reduce dose.

Content of the self-commitment

- (2) Implementation of technical dose reduction measures in CT.
- (3) Implementation of a reliable and easy-to-use dose reporting software to inform the health professional of the actual medical exposure of each individual patient and to enable him to critically analyze the protocols of individuals and also of groups of patients (patient dose records).
- (4) Provision of specific training curricula, which enable CT users to optimize patient dose.

It was made clear that HERCA expects

- a clear statement by the CT manufacturers whether they are willing to commit themselves to these actions, and
- an agreement that a road map will be developed by the CT manufacturers, which clearly outlines the realization of these actions.

Time Schedule: A Long Way to Success

8th of February 2010:

HERCA-Meeting with CT-Manufacturers in Bonn.

19th of February 2010:

HERCA-Summary of Commitments was sent to CT-Manufacturers.

14th of June 2010:

HERCA-Meeting with CT-Manufacturers in Bern - on a working level.

24th of June 2010:

Concept paper of CT-Manufacturers was received.

9th of December 2010:

HERCA-Catalogue of Criteria, based on the *HERCA-Summary of commitments*, was sent to CT-Manufacturers.

3rd and 6th of March 2011:

Voluntary self-commitment of CT-Manufacturers, sketching the targets, structured approach and a project schedule, was received.

HERCA-Catalogue of Criteria

0. Purpose:

The *BOARD of HEADS* has to decide on the *Voluntary Commitment of the CT-Manufacturers* based on the *Catalogue of Criteria*.



three groups of criteria were indentified

1. General Criteria:

It is expected that the CT-Manufacturers clearly outline

- that measures are strongly needed to reduce patient CT doses in the health care setting,
- that CT-Manufacturers have a particular responsibility in this important process, and
- that CT-Manufacturers commit to distinct actions to achieve this goal and to transparency and cooperativeness throughout the process and the evaluation.

HERCA-Catalogue of Criteria

2. Criteria Concerning the Measures Defined in the Self-Commitment:

- standardized benchmarking characterizing the dose efficiency related to image quality of CT systems (dose efficiency parameter)
- technical dose reduction measures
- dose reporting software
- specific training curricula

HERCA-Catalogue of Criteria

3. Administrative Criteria:

- road map for each of the measures
- evaluation of each of the measures
- signing of the self-commitment



It is expected

- that —for each measure— targets and milestones are defined with a specific time frame,
- that reports are provided by CT-Manufacturers on a regular base, whenever the specified date of a milestone of a respective target is reached,
- that the voluntary self-commitment of the CT-Manufacturers is signed by the CEOs of the respective companies or competent executives on an adequate level.

Assessment of Voluntary Commitment

Beginning
of April 2011:

First assessment finalized
by *WG Medical Applications*

Thereafter:

Feedback to COCIR:
Status Quo of Assessment

End of April 2011:

Response by COCIR expected

Beginning
of May 2011:

Final assessment provided
by WG MA ⇒
Final Assessment sent
to BOARD of HEADS (BoH)

End of June 2011

Decision of BoH on HERCA Plenary
Meeting

Beginning
of July 2011:

Response of BoH sent to COCIR

Conclusions

1.) The outcomes may be summarized as follows:

- *CT-Manufacturers* accepted the *idea of a voluntary self-commitment* and provided *respective commitments*, which seem to be more or less adequate;
- The process of the involvement of stakeholders needs time to build up a common understanding of the goals to achieve.
- A mutual trust must develop.

2.) Our experience indicates that it is - extremely - helpful:

- to build up some kind of *political pressure* by clearly outlining the *alternative* when the *self-commitment* process fails:
 - ⇒ the development of national or - at best - EU-wide *regulations* enforcing patient dose reduction.

Conclusions

3.) Importance of the follow-up process

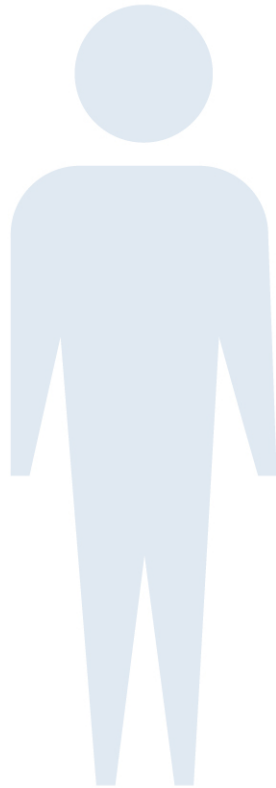
- HERCA is willing to go along with COCIR in the now following process of implementation of the items in the self-commitment.
- COCIR and the CT manufacturers are willing to work on the implementation into practice of the self-commitment.
- HERCA and COCIR work closely together in the near future also including other important stakeholders, like radiologists, technicians and medical physicists in the process.

⇒ EMAN-Workshop 2012

Thank you for your attention!

HERCA: Heads of the European Radiological Protection Competent Authorities

Reserven



Relevance of CT in radiation protection

2008 Swiss annual frequency and dose data

Radiological modality	Number of examinations (in thousands)	Collective dose (man·Sv)	Number of examinations /1000 population	Effective dose per capita (mSv)
Radiography	6000	1330	780	0.17
Conventional fluoroscopy	153	415	20	0.05
Interventional – diagnostic	56	553	7.2	0.07
Interventional – therapeutic	46	528	6.0	0.07
Computed tomography	780	6150	100	0.8
Dental radiography	5430	63	700	0.01
Mammography	387	62	50	0.01
Bone densitometry	117	0.31	15	0.00004
Total	13'000	9100	1700	1.2