The ALARA principle in radiation protection and medicine a precautionary approach

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Training Session Introduction

ALARA in de medische sector

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Overview

• ALARA history
• Risk uncertainty - BSS context
• Justification link to ALARA
• Optimisation characteristics
• Present RP challenges in medicine
• E&T Requirements for risk governance
• Precaution Principle
ALARA history
Paradoxal failure of TLV concept started history of ALARA

- 1930 Threshold Limit Value questioned any dose could cause a risk!
- ICRP in 4 steps:
  - 1955...every effort made to reduce exposure to lowest possible level
  - Recom. 1, 1959 ...to the lowest practicable level
    Justification: ...unnecessary exposure to be avoided
  - Recom. 9, 1965 ...all doses be kept to the lowest practicable level readily achievable
  - Recom. 22 1973 Present utilitarian definition:
    As Low As Reasonably Achievable, social and economic factors taken into account --> BSS
ALARA has always started to focus on challenging high doses

- USA: J. Baum, Brookhaven -> NPP doses
- EU: NRPB & CEPN pioneering work
- Successful implementation in NPP in Be and Fr

- Be: SCK.CEN crisis 1989
  - Decom BR3 (CEPN)
  - ALARA was structured
  - Thesis P. Govaerts (VUB, 1994, "In search of the reasonable")
  - Link with safety culture

- Now driven by networking: EAN ---> EMAN (med.)
Risk uncertainty - BSS context
LA RELATION DOSE-EFFET EFFETS STOCHASTIQUES AUX FAIBLES DOSES

Probabilité d'apparition d'un effet sanitaire radioinduit

Application du principe de précaution

Dose instantanée

Facteur de réduction du ddd

Relation dose-effet retenue

Niveau d'exposition individuel (SV)

Probabilité significative - années 60

probabilité significative - années 70

probabilité significative - années 2000
Le modèle de l’acceptabilité du risque

- **RISQUE RESIDUEL ACCEPTABLE**
- **RISQUE LIMITÉ**
- **Niveau “ALARA”**
- **TOLERABLE**
- **INACCEPTABLE**
ALARA: between unacceptable and marginal risk an answer to uncertainty

- IARC (WHO) classified IR as carcinogen hazard

- UNSCEAR PEER REVIEW confirms LNT as best simplification for RP practise controversy!

- ICRP 26 BSS introduction in 1976
  - Avoid deterministic effects: TLV? Cataract?
  - Reduce probability stochastic effects: LNT hypothesis + DDREF

- IAEA, WHO, ILO & NEA BSS

- EC directives BSS & patients (EURATOM GoE art.31)

- Be 1987 ARBIS/RGPTI art 20, 51 (med.), i.a.
BSS triple system was set up for consistency on risk at low dose

- Prudent avoidance in order to use IR considering advantages & natural IR

Justification (J)

Responsible attitude flexible system

Optimisation (O)

Limits (L)

- Combines utilitarian with egalitarian ethics

- But only fully applied for minority of all exposures
  - No limits for patients and Rn

- J & O of major importance in medicine
Justification link to ALARA
**Justification** of a practise is a take up of responsibility for using IR at each level

- 1° in hierarchy of the BSS system
  - net positive benefit required
- J is RP & more than radiation protection
- J is indirectly linked to ALARA (stochastic)
- J in authorisation procedures (prove ALARA)
- Generic J (with revision): medical TA, role HC
- Specific J: medical act requires net benefit professional guidance
- Daily acts of RP experts
Optimisation - core element in RP
Optimisation of protection is formal expression process of ALARA principle

- Allows handling of the LNT simplification
- Prospective way of thinking and acting
- Self limiting process: priority high doses
- Logical & consistent for various sources
- Management approach
- Feedback of experience: incident reporting

www.reli.r.cep.n.asso.fr
An approach in evolution

- Cost benefit & monetary value of cost of detriment was not successful
- Focus on work management and prospective Dos.
- New generation of tools (e.g. Visiplan)
- Broader scope of application: NORM, Waste
- Involvement to manage distribution of detriments:
  - Individual and collective Dose
Organisational characteristics ALARA

- Set measurable objectives *(reference levels in Med)*
- Dosimetry as a tool & data acquisition system
- Management commitment *(EdF, SCK,…)*
- Information, *Motivation*
- Budget and company structure *(ALARA committees)*
- Participation of actors
- Integration of RP in QA *(QC of src. and processes)*
- Feedback of experience
National and International networking

- Recommendations of Health Council on optimisation (IR, CT, NUGE, waste management, brachytherapy) [www.health.fgov.be](http://www.health.fgov.be)

- European Alara Network EAN:
  - 20 countries + RECAN
  - Be represent: Fernand Vermeersch (SCK)
  - Workshops: e.g. ALARA in Medecine, Croatia, 2006
  - European ALARA Newsletter [www.eu-alara.net](http://www.eu-alara.net)
  - Incident reporting RELIR [www.cepn.asso.fr](http://www.cepn.asso.fr)

- EUTERP platform
- EMAN in preparation
Definition of ALARA culture
(WG EAN Workshop, Prague 2006)

A reference framework, a state of mind and attitude

- Allowing an individual and/or an organization to act in a responsible way in order to manage risks and giving safety the priority it should have;
- Characterized by risk awareness, balanced judgement of risk and benefits, and the capability to develop and use required skills and tools for risk assessment and management;
- Realized through transdisciplinary education and training tailored at each level;
- Supported by management commitment, guidance and supervision of competent authorities on European and national level;
- Making use of a clear definition of responsibilities.
Alara Culture should have a continuous character covering all processes where RP is involved. It should have full support of authorities and professional organizations, while systematically integrated in CQI (continuous quality improvement).

Some Recommendations

1. Regulatory bodies should develop a new interactive approach to stimulate the implementation of ALARA which requires a transdisciplinary framework; exchange of information; set up of an ALARA framework in each country.

2. Constructors should take the lead in improving technologies to create opportunities for the implementation of ALARA

3. Workers, public and patients: involvement should be organized based on adequate information on the way ALARA is taken into account
Present RP Challenges in Medicine
Specific nature of medical exposure and ALARA

• Doses are given for patient benefit, but large variety for similar result
• Individual Dose Limits not applied
• Quality of justified medical act requires reasonable level of exposure
• High change dynamic can require \textit{J revision}
• Transdisciplinary optimisation approaches:
  Prescriptions, Resol.-D awareness, relevant dose follow-up, Ref Lev., QA procedures, stakehold. Part.
Challenges: high individual doses for staff and dominant collective dose for public

• Digital imaging in radiology and the rush for resolution
  – Radiology and (PET)CT
  – Total body CT not justified
  – Interventional Radiology (DD, detriments)
  – QC Mammography
  – Pediatrics
• Dosimetry of workers: extremities, eye
• Nuclear Medicine: new! Pediatric dose diversity
• Future: Neurological implants
• RT Incident feedback & QA
  
  Optimisation and integration RP in QA crucial!
Is ALARA precursor of precaution?
Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
“Le PP est un P d’action et d’expertise pour réduire l’incertitude, un P de vigilance et de transparence. Il doit être interprété comme un P de responsabilité”

• Nicolas Sarkozy (25/10/2007) correcting J. Attali

• PART of EU law extending to health policy:
  - When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish harm (UNESCO)

• Common sense approach (Prof W. Bijker; nanotech)

• Ethical attitude and social responsibility to manage uncertainties on risk, to keep them in a reasonable range with participative & distributive attention,
Justification and Optimisation are precautionary approaches

- Taking up responsibilities for practices LNT based
- Development of innovative risk management approaches
- Awareness of safety culture (group aspects)
- Attention for communication and involvement

Requires input from other disciplines but also training of other skills
What if? ... the real world

“At present, the nuclear expert is struggling with society, lacking a scientific approach and insight in complex human behavior and societal interaction” (PISA)

- What if a young nurse got scared of contamination in the controlled area?

- What if a leading radiologist tells his staff not to care about low doses, as having no risk?

- What if an hospital physicist opposes daily radiology doses for premature baby’s
Requirements of real world in complex problem solving

Responsible acting should face complexity: uncertainties & ambiguity of the 'real world'

- no factual logic or procedures available
- situations not trained in the laboratory
- no reliance on comparable cases

Example: Theft of a source or unusual spread of contamination

Communicative requirements & networking
E&T Requirements
Some new requirements for training in safety and RP (PISA, SCK)

- Development of critical sense
  - Broader risk assessment capacities
  - Openess of mind; flexibility
  - Attention for alternatives
  - Statement of uncertainties

- Respect for non expert views (humility)
- Communicative skills & curious attitude
- Feeling for equilibria equity/utility
- Explicitation of ethics - transparency
- IRPA code, RISCOM model
Radiation Protection as transdisciplinary job requires

- Good basic knowledge and skills
- Capacities in many hard Sciences
- Assessment capacity
- Understanding of system of RP (J+O+L)
- Complex problem solving capacity
- Interactive use of diverse disciplines
- Understanding of a social context (soft sc.)
- Value insight (ethics) and communication
ALARA fits the new Risk Governance policy of EU
O. Renn, Risk Governance, towards an integrative approach (IRGC, 2005); www.irgc.org

and new IRPA guidance

It was a precursor of precaution and
It has a lot of tools to offer
but first of all ... it needs a breakthrough in medicine
Transdisciplinarity

- Transdisciplinarity as an attitude: problem solving oriented thinking and acting, being ‘curious’ and taking into account that own knowledge is always relative.

- Transdisciplinarity as a new approach to research and problem solving: the core idea is that researchers, practioners and stakeholders must cooperate in order to address the complete challenges of society. [ETHZ Transdisciplinarity conference, 2000]

- The transdisciplinary attitude implies putting into practice transcultural, transreligious, transpolitical and transnational visions. [www.unesco.org/education/educprog]
Second mode science, precautionary science, post-normal science share the insight that scientific knowledge is, in essence, a social construct, and therefore the attention is directed towards the context(s) of application of scientific knowledge, rather than to its ‘truth’ in an absolute sense. [Beck (1992), Risk Society]

The monopoly of science on ‘truth’ is challenged.

Example: traditional scientific approaches to risk assessment face increasing difficulties when applied to the complex (i.e. global, long-term, potentially catastrophic, etc.) problems
Conclusion

Education and training should start from an attitude of curiosity (of both the teacher and the student)

- taking into account historical lessons
- stating and accepting uncertainties instead of trying to exclude them
- trying to understand social mechanisms, also in the working environment
- trying to broaden the risk scope to ‘multifactorial concerns’ in complex (hazardous) situations

E&T should continuously stimulate the development of a critical sense. This sense is an essential ‘tool’ needed to gain more confidence in the own work and credibility towards the outside world
Recommendations

1. Definition of ALARA culture

2. Implementation of ALARA culture should be a new priority for international organizations, systematic support is needed.

3. Regulatory bodies should develop a new interactive approach to stimulate the implementation of ALARA which requires a transdisciplinary framework; exchange of information; set up of an ALARA framework in each country.

4. Constructors should take the lead in improving technologies to create opportunities for the implementation of ALARA.

5. Workers, public and patients: involvement should be organized based on adequate information on the way ALARA is taken into account.

6. Licensees should stimulate information, E&T, open communication and transparency; provide a clear and transparent reporting and acting structure.
Role of constructors/suppliers

- Should take the lead in improving technologies to create opportunities for the implementation of ALARA at the level of the operators (design equipment in such a way that optimization can be organized on the workfloor);
- Improve safety culture in maintenance;
- Provide adequate information for and feedback of the end-users.
Public, patients and workers

- Should have the right to be fully informed, resp. educated and trained on the risks they occur. They should be guaranteed sufficient protection based on justification and well developed optimization.
- This could be realized more effectively through involvement.
- Keep a questioning attitude.
- Be aware of its responsibilities.
Let us clarify some terminology

ref.: O.Renn, Risk Governance, towards an integrative approach (IRGC, 2005); [www.irgc.org](http://www.irgc.org)

• Risk  \textbf{new framing in precaution}
  – Hazard evaluation: Scientific expertise
  – Risk Analysis: Uncertainties (prob./conseq.)
  – Context: perception, values, communication

• Governance: \textit{collective decision making with processes and structures, involving:}
  – All relevant actors: governm., econ. + social
  – Different relevant levels: global, nat., local, firm,…

considering relevant contextual factors
Governance and community involvement in nuclear requires more levels and integration

- **CHALLENGE**: long term trust building at national level
  - Nuclear waste is a broader controversy
  - History has shaped perception on fuel cycle
  - Perception studies: social support not yet obtained
  - Process implementation in agencies ? (Author.process)
  - More transparency required: RISCOM, QA
  - Independent stable strong agencies needed (or guardians)
  - Critical expertise and risk communication is crucial
  - Delay in implementation at relevant European level

- **Awareness of broader distributive justice**
  - Compensation, fund access in global elect. market
Basic claims made for transparency in risk communication

RISCOM
K. Anderson & R. Espejo

Doing things right?
Science
Truth,
Legitimacy, social
Authenticity, integrity
Is this right & fair?
No hidden agenda?
Human communication is influenced by many factors at many levels

- Leadership, authority
- Group norms, dynamics
- Rhetoric
- Subsystems (QC, perception factors)
- Lobbying, economic drive
- Unequal distribution of expertise
- Need of legitimacy,…