Second European Workshop on the Ethical Dimensions of the Radiological Protection System Madrid, *4-6 February 2015*

Ethics in the nuclear sector and ethical issues in occupational exposures

Dr Patrick Smeesters

MD, Radiation Protection Advisor FANC (hon), Chairman ABR/BVS, Lecturer (UCL, ULB), Member of Euratom Art 31 GoE Chairman of Art 31 RIHSS WP (Research Implications on Health Safety Standards) Alternate Belgian Representative in UNSCEAR

Classical ethical lecture of the current RP System

- Justification: utilitarian ethics: do more good than harm
- Optimisation: utilitarian ethics: maximize good vs harm
 - Dose constraints: deontological ethics: equity
- Dose limits: deontological ethics: no individual is unduly harmed; unduly character evaluated by comparison with parallel « acceptable » (or accepted) situations
- All the system includes *some* consideration of precaution: use of LNT with DDREF of 2 (eval. of harm in just/opt; choice of limits by comparison of risks)

Ethical lecture is more complex in fact C. Clement, Milano 2013

- Utilitarianism alone ignores justice and uncertainty
- Deontology alone ignores potential consequences
- Frequently conflicting values to balance
- How? By seeking values widely accepted internationally today

Ethical issues in the current system

- The right implementation supposes day to day implication of responsibles, but:
 - What about training? Misinformation? conflicts of interest?
- All the system supposes taking due account of the « harm » from exposures, but:
 - What about scientific updatings? Waiting for « certainty »?
 - What about more or less hidden ethical choices made within the RP system? management of epistemic uncertainties? Precaution?
- Choice of values *widely accepted internationally :*
 - What about the "club" effect? the conflicts of interest?
 - Stakeholders outside the field are hardly consulted

Day to day implication of responsibles: some frequent problems

- Radiological protection and its medical rationale is frequently insufficiently or erroneously explained during education and training (engeneers !) Rightly informed about risks?
- Frequent minimization or negation of the risks in the field
- Maximum permissible dose concept still largely present; continuous distrust and brake on the use of dose constraints
- Protection of women of reproductive capacity inadequate: dose limits replaced by mandatory information, but is the provided information right?

Harm and scientific updatings R&D and Policy: a continuous loop

- Research : production of new data
- Follow up and evaluation of the data
- Implications of new data: regulation, guidance, policy, other R&D
- Residual uncertainties, research needs and priorities

Updating or waiting for certainty?

Recent developments regarding the late recognized radiation effects of low to moderate doses on the lens of the eye and on the circulatory system are good illustrations of a lack of vigilance and responsiveness regarding early warnings that were described many years ago.

Radiation induced cardiovascular effects

Why were CV effects "recognized" so late?

- Too slow "digestion" of new scientific results by the existing assessment organizations?
- Resistance to change of paradigm?
- Mainly excessive focus on hard evidence and wrong comprehension of precautionary approaches

Precautionary measures were/are easy to take!

- Adaptation of radiotherapy protocols (breast cancer)
- Management of cumulative high diagnostic exposures
- Use of dose constraints to limit cumulative organ doses of workers (EU BSS)

Regulatory/User ethical concern

Could they wait for ICRP statement and change of the BSS before acting and taking practical protective measures for the lens of the eyes?

Should they wait for ICRP and IAEA serious taking into account the risk for the circulatory system before acting? More or less hidden ethical choices in the « balance » of values and management of uncertainties:

The example of irradiation in utero

Irradiation in utero in early phases: new data (2001 RIHSS Scientific Seminar; 2011 SCK/FANC Symposium)

- Pre-implantation period: Current view: possible death of embryo above 0.1 Gy; if not killed the embryo develops normally; no congenital malformation
- New (not always!) data: Irradiation in animals during the pre-implantation period **can** induce congenital malformations (sometimes non lethal) or genomic instability, with or without genetic factors of predisposition; zygote stage more sensitive; thresholds uncertain; similar observations with chemicals
- Early organogenesis (incl. gastrulation): more congenital malformations in genetically susceptible mice (alteration of genes involved in DNA-damage response)
- Mechanism: persistence of unrepaired or misrepaired DNA-damaged cells("teratogenically damaged cells") (instead of the classical loss of cells)

Precaution in Science is relevant!

Although frequently limited to the decision-making processes in situations of uncertainty, the precautionary approach is also relevant and appropriate in research.

As underlined in the COMEST report from UNESCO, the precaution approach in science includes:

- a systematic search for surprises ("thinking the unthinkable"), particularly for possible long term effects,
- a responsiveness to the first signals ("early warnings")
- and, last but not least, a <u>focus on risk plausibility rather than</u> <u>on hard evidence</u>.

Irradiation in utero: Rationale for precaution (1)

The same could exist in humans.

The risk could also exist during the "safe" periods of pre- and early post-implantation

Irradiation in utero: Rationale for precaution (2)

There are many genes implicated in the DNA-damage response and involved in the genetic susceptibility to cancer induction by irradiation ; if the mechanisms are similar (misrepair), it is plausible that a genetic susceptibility to the radiation-induction of congenital abnormalities or other non-cancer effects is associated with the human genotypes leading to cancerproneness.

Irradiation in utero Rationale for precaution (3)

There are **still many other uncertainties**: radiation effects on gene expression, subtile effects or long term effects of NCS irradiation, internal (OBT ...) and chronic exposures,

Unsuspected low dose effects from in utero exposure are currently somewhat out of concern, but could cause bad surprises in the future.

The potential implications are important.

More research is needed in this field but this is not considered as a priority and there are no budgets.

Regulatory/User ethical concern

- In utero exposure: can we wait for taking into account the new research data on the first days of pregnancy (radiological procedures, internal contaminations, urgency of declarations of pregnancy, right information of women of reproductive capacity..)?
- Due to the uncertainties (and to the high cancer risk), can we accept the 100 mSv value being regularly presented as the limit of concern in medical exposures and prolonged exposure situations ?
- These new data are currently not considered enough relevant (or "proven") for changing the practice but this is an ethical choice (management of uncertainty and precaution) that is not transparent for the exposed persons and that is susceptible to be different for the different stakeholders.
- Responsibles are not aware and give then unbalanced information to the individuals concerned (and for the public in other circumstances)

Other hidden ethical choices in the RP system (1)

Cancer risk: as a lot of new data point to a DDREF lower than 2, is a DDREF of 2 still justified? Is 1 = 2 a fair answer?

From a Radiation Protection point of view, we need strong evidence for assuming a lower risk per unit dose at low or protracted exposures than for high acute doses. Other hidden ethical choices in the RP system (2)

The radiation-induced cancer risk (ERR) is significantly higher for women (v/men).

Does the (current) equivalence of the respective EAR fundamentally change the ethical concern?

Should we favor equivalence of limits or equivalence of risks?

Other hidden ethical choices in the RP system (3)

Hereditary effects: Considering the "numerous uncertainties" put forward by UNSCEAR/ICRP for not estimating the long term genetic risk, it seems paradoxical to recognize that considerable uncertainties still exist in this field, while concluding that enough is known as regards the mechanisms of radiation-induction of genetic effects to allow minimizing the possibility of significant long term risks.

Do we know enough to draw final conclusions? Should we not be more "cautious"?

Values *widely accepted internationally* Objectivity and **the club spirit**

Science cannot escape from some intrinsic subjectivity. In an attempt to control this, one often appeals to consensus as a guarantee for objectivity.

Doing so, one forgets that scientists, coming from the same melting pot, spontaneously favour cognitive consonance and share the same interpretative language, the same paradigm (a whole of reference presuppositions, which are often unconscious).

On these grounds, interpretations of reality are not seen by them as subjective and have in their eyes an indisputable value A broader approach is needed when risk problems are characterised by

complexity

uncertainties

value judgements

The stakeholder opening

Stakeholder involvement is the appropriate remedy for avoiding club thinking, allowing new views and perspectives to emerge and favouring creative thinking about mechanisms, scenarios or implications.

But...

Unfortunately stakeholder involvement is currently often just a façade. The invited stakeholders and experts are very few and their opinion often considered as irrelevant and hardly taken into account: the real experts and the others...

Conclusions (1)

- The RP system implies right implementation by the local responsibles; this can be jeopardized by insufficient or erroneous education or information (and of course by conflicts of interest).
- All the system supposes taking due account of the « harm » from exposures, but scientific updatings are frequently too late by lack of precautionary spirit, and the « scientific » basis contains frequently hidden ethical choices.

Conclusions (2)

The RP system tries to rest on values widely accepted internationally, but the "consensus" is biased by a club effect: lack of independent fora and poor implication of the "weak" stakeholders; expertise coming from outside is often considered with arrogance