V. U. Mme Claire Stievenart
Av. A. Huysmans 206, bte 10
1050 Bruxelles-Brussel

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Hoofdredacteur — Mr C. Steinkuhler — Rédacteur en chef
Rue de la Station 39
B- 1325 Longueville

Redactiesecretariaat — Mme Cl. Stiévenart — Secrétaire de Rédaction
Av. Armand Huysmans 206, bte 10
B- 1050 Bruxelles - Brussel

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Ethical issues in Radiological Protection
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OVERVIEW AND PERSONAL IMPRESSIONS AS REGARDS ETHICAL ASPECTS RELATED TO THE FUKUSHIMA-DAIICHI ACCIDENT

(as discussed during the art. 31 Scientific Seminar of November 2014)

Frank Hardeman
SCK-CEN, Belgian Nuclear Research Centre,
Boeretang 200, B-2400 MOL (Belgium)
frank.hardeman@sckcen.be

Abstract

The entire world has been shocked by the consequences of an earthquake followed by a tsunami hitting the Japanese East cost in March 2011. Besides the immediate devastation of a large part of the coast, a considerable number of lethal victims were to be deplored. The power plant of Fukushima-Daiichi was flooded by this tsunami, leading to the loss of many emergency systems. Ultimately, the cooling of the reactors was lost, and in the end this has led to hydrogen explosions in three nuclear reactors and damage to a spent fuel pond. The releases in the atmosphere and in the sea were considerable.

A lot of literature is available on this accident and its causes. Besides technical analyses, an interesting publication of IRSN focuses on the human and organisational factors [IRSN 2015]. The short and medium term consequences for health and the environment have been assessed too by many organisations including [UNSCEAR 2013], [WHO 2013]. A regular update on environmental impact is given in [IAEA 2015]. The RIHSS[1]-group of the art. 31 EURATOM Group of Experts decided to organize on 18 November 2014 a scientific seminar looking back at the accident [Seminar 2014]. The Belgian Association for Radiological

1 RIHSS: Research Implications for Health and Safety Standards, a Working Group chaired by Patrick Smeesters, Belgium, in the framework of the art. 31 EURATOM Group of Experts, http://europa.eu/eu-law/decision-making/treaties/pdf/consolidated_version_of_the_treaty_establishing_the_european_atomic_energy_community/consolidated_version_of_the_treaty_establishing_the_european_atomic_energy_community_en.pdf

Protection BVS-ABR invited me to reflect on ethical issues based upon the presentations given during the seminar for its scientific meeting held in Brussels on 19 June 2015.
This paper is the written synthesis of the points presented during my presentation at this seminar. As my background is in nuclear physics, radiation protection and nuclear safety, and not in ethics, the points raised here have to be considered a "common sense approach to ethics". The approach was to highlight a few issues related to ethics in each presentation of the seminar, and to give my personal considerations on this. This paper as such does not aim for exhaustiveness on all ethical aspects of such complex accidental situations leading to long term consequences; furthermore, this text is not at all normative. The goal is to focus on some aspects in the hope that the reader forms her/his own opinion on the points raised, and can make positive use of these opinions.

INTRODUCTION

The seminar organized by RIHSS brought renown experts together (speakers, art. 31 Group of Experts, a few guests per member state of the EU, representatives of international organisations). The speakers covered each an aspect of the accident and its consequences; as chair of the seminar I had the opportunity to stimulate questions and discussion. This paper is based on the notes taken on that occasion, and the slides which are available in [Slides 2014]. It doesn't include comments on the Belgian contributions to this seminar (via Patrick Smeesters, one of the speakers and Hans Vanmarcke, one of the members of the discussion panel), as both contributed as well to the BVS-ABR scientific seminar as to the Annals.

The remainder of this paper refers to the topics covered in the seminar, selects one or two issues, and my personal reflection on these issues. Several of the presentations went further that the points selected.

The accident – presentation by Richard Wakeford

Richard Wakeford described the accident evolution, starting from the natural ones (earthquake, tsunami) and the nuclear ones (in the various reactors). He came to the conclusion that one should never forget that accidents can happen and raised of course the question whether this accident was avoidable or not. He also stressed the difficulties in comparing natural and industrial disasters.
As regards this latter point, many people still have the perception that natural disasters can be considered as 'bad luck' or an 'act of God', which

are old concepts in safety analysis. Industrial or man-made accidents should be avoided thanks to a positive safety culture, enhanced by an integrated management system promoting continuous improvement. However, in many cases, the borderline between natural and man-made disasters may be very fuzzy, certainly if siting is considered. We refer to the work of [Rossignol et al., 2014] in this respect. Many natural disasters such as flooding often are enhanced by human interventions in the environment.
Referring to the historic earthquakes and tsunamis at the East coast of Japan, it is obvious that the design of the power station should have anticipated future events of similar or higher severity. Was this negligence? Economic pressure? Inadequate distribution of knowledge or responsibility? Were the safety authorities aware or not? Were they accepting to take the risk?
The ethical issues for me are linked to whether the decisions on siting and design were a matter of negligence, or a risk taken on purpose because of economic reasons? And the role of the regulator in this decision process (independence, competence).
In the aftermath of the accident and within Europe a series of 'stress tests' were imposed on the operators. This certainly was a good initiative. But a few years later, the discussions on 'how safe is safe enough?' and 'How much safer must the nuclear be as compared to other risks?' (for health or for society) have led to fully different answers in the various countries. This point merits further study. To my modest opinion, the concepts of risk are too often brought without sufficient nuance, and 'acceptibility of risk' of course is a mixture of 'real risk' and 'emotion and policy decisions', not facilitating objective discussions. The decision of policy makers to base policy on acceptability or on 'real risks' certainly includes ethical aspects.

Effects on thyroid cancer – Peter Jacob

Peter Jacob presented a very scientifically sound synthesis of the prognoses for thyroid cancer for the next decades. One of the messages of his presentation is that an estimate of thyroid cancers to be expected, e.g. based upon the knowledge after Chernobyl, is not trivial at all, due to large differences in occurrence of thyroid cancer not linked to the accident in both areas. The lifetime excess rate for thyroid cancer for females exposed to 20 mSv as an infant is around 0,3 %. The excess of cancer may be detectable after 50 years, and is not expected to be detectable in the first 20 years.

In itself, this is good news of course: the fewer cases, the better. From a scientific point of view, monitoring and follow-up certainly is interesting. But is this monitoring helpful to the people who lived the accident (and their families)? This really is an ethical issue: who is helped by the monitoring programme? The people themselves? The authorities (showing their responsibility)? Or the scientists (allowing improving their models). What is best: earlier detection and reassurance, or is the psychological harm larger than the potential benefit? To me, the focus should be on the anticipated benefit for the people involved. If they can be helped better if more information is available, let's support this. But if the harm is only beneficial to science or authorities, even at the detriment of the people exposed, we should not support a large monitoring programme. If the benefit to the population is too low, return to normality should be the major ambition.

Exposure and doses – Stephanie Haywood

Stephanie Haywood elaborated on the exposure of the population and the assessment of doses. She showed considerable differences according to time and position of predominant pathways (plume irradiation, inhalation, external exposure by ground-shine, ingestion), and of isotopic composition (iodine or long-lived isotopes such as Cs-134 and Cs-137). She clearly mentioned that the focus in the beginning was on protection of the people, not on precise measurements for post-accident exposure assessments. This was enhanced due to the loss of many vital systems for monitoring, even loss of electricity, in the immediate aftermath of the accident.

Moreover, she stressed that there may be a tendency to consider only the last accident for guiding the preparedness in future. The Fukushima accident is being considered normative for future accidents. The reality is that one should not forget to prepare for all types of accidents, as a future one will certainly be different from Fukushima or Chernobyl, and hopefully be better in terms of severity and mitigation of consequences.

From an ethical point of view, I would mention three points worth elaborating:

1. There may be a tendency of over- and under-stressing consequences of the accident for policy reasons, depending whether one wants to enhance, stabilize or shut-down nuclear energy production. It is important that the link between opinions and facts is maintained

at all levels of policy making, including the work of UNSCEAR, IAEA, ICRP, EU,…. and national levels. The information and the conclusions taken from the information should be as objective as possible, explaining what is known, uncertain or unknown; what is likely, unlikely or certainly not the case.

2. There is a lot of attention to consequences of accidents in chemistry (e.g. the entire Seveso legislation) – at least in Europe – and in nuclear (in most parts of the world). Yet, this is not necessarily the case for other industries and societal introductions of technology. The same is trough for assessment of consequences of routine operations and releases. This of course has to do with the acceptability of risk issue expressed above. One could certainly safe more lives with the same amount of money now spent to very rare events. An old but still very inspiring paper on this issue is [Tengs et al., 1995].
3. There is also a discussion on priority setting in accidental situations. The request of fast decision making for mitigating the accident and/or for protecting the people and the environment may leave too little time for optimal monitoring programmes for adequate dose assessments or for optimal communication. The dose assessment programme can maybe be covered up by post-accident monitoring (retrospective dosimetry) based on biological samples e.g. in the RENEB project [RENEB], or even electronic components as available in mobile phones or bank cards or via apps [Van Hoey et al.,2015]. These studies certainly need further attention and support. The communication issue is important for the psychological and emotional status of the population afterwards. It is obvious that the real emergency staff should focus on accident mitigation and avoiding immediate harm; communication people should indeed prepare for the aftermath. This transition is not trivial at all. Honesty and ethics are important in this; uncertainty unfortunately is an enemy of good policy in these situations.

Practical Health Risk Assessment – Linda Walsh

Linda Walsh elaborated on the assessment of health risk, and took five important lessons for improving this. Focussing on ethics and on reassuring the population being victim of the accident, she suggests that communication experts would be associated to radiation protection scientists and public health experts to address the members of the public in the affected area. Of course, their trustworthiness is important.

From an ethical point of view, a major point she raised: information and reassurance: how open should one be? Should one focus on objective information or on the reassurance? Translated: from a 'scientific and objective jargon' to a 'psychological and subjective jargon'? To my modest opinion, both approaches can be applied depending on the mind-set of the people addressed, the major objective being helping the people to continue their lives the best way possible. One vital, primordial comment however needs to be made here: one should never lie to the people! Nuance, simplification, not telling all details, … are beneficial. Lies are ethically not correct and will even not be effective on very long terms, as loss of credibility of the actors involved is a major issue with adverse effects for everybody.

A second point she raised is how to assess and communicate difficult concepts and very uncertain figures. How do the people consider potential dose, non-attributable cancers, statistical excess risks that epidemiology will never be capable demonstrating unless major scientific/medical evolutions take place in the next decades? And how to deal with these as compared to other risks and confounding factors such as smoking, alcohol consumption, perturbed food patterns etc.? To my opinion, the ethics involved here is to adapt communication to the level that is adequate for the people involved, to show empathy, and to avoid over-interpretation of data.

Worker dose – Jean-René Jourdain

Jean-René Jourdain presented the data on exposure of the workforce involved during the emergency situation, and for the first years in the clean-up work. He showed that the number of persons involved is increasing over time, that six people had doses above 250 mSv, but that there is some uncertainty given some lack of data in the very beginning (1 dosimeter per group of people instead of one per individual; no adequate monitoring data for internal contamination) given the very difficult situation the workforce had to work in. Considering this, I would not claim that the exposure of the workforce leads to many ethical considerations. The major issue is to be better prepared for adequate dosimetry in all circumstances.

During the debate however, Gilbert Eggermont raised the point that in the aftermath of the accident people intervened that were hired by 'suspect' companies and not having appeal to the normal practice of monitoring of

workforce in the professional world. If this is the case, this is of course an ethical point of attention: one should provide adequate protection to all staff involved, also in the clean-up phase of an accident. There is an important role here for regulators and controlling organisations and for the public authorities in general. And also for the professional organisations involved. If this statement is proven, international organisations should at least mention this, condemn this and yet try making an effort to assess orders of magnitudes of exposures of the people involved.

Emergency preparedness and strategy – Ulrike Welte

Ulrike Welte explained the new approach in Germany as proposed by the SSK [SSK 2014]. The major lesson she raised is that accidents can happen, will be different from the previous ones, and that preparedness needs being enhanced. In Germany this has led to a new assessment of emergency planning zones. In Belgium, various organisations are working also on advice and/or the modification of the radiological and nuclear emergency plan. I suppose the outcome of this exercise will be topic of future sessions of the BVS-ABR.

It is certainly positive to make improvements to the emergency preparedness system after a major accident. However, one should not forget either to focus on prevention of the accident. Stress test exercises and improvement plans are probably (this means if both the studies and the implementation plans are adequate) more effective than putting too much effort on preparing response. The major ethical issues for me are: focus on prevention is better than focus on response; secondly: which residual risks can one still accept? Too restrictive risk anticipation may certainly be blocking progress and welfare of the population. One could refer e.g. to traffic, genetically modifying foodstuffs, use of many additives in the food industry, etc.

An issue for me is the lack of harmonization among EU countries; the decision in many EU countries to proceed with revisions of their emergency preparedness without consultation of the neighbouring countries certainly doesn't help harmonizing, and the role of the EC seems rather week in this domain. Yet, one can mention recent progress obtained via HERCA and WENRA [HERCA/WENRA].

Concluding comments

Referring to the comment made during the symposium by Maria del Rosario Perez, representative of the World Health Organization, stating that health is more than absence of disease, but rather refers to human well-being. As such, the social disruption and the psychological impact of an emergency situation have to be taken into account more than they were in the past, not substituting for radiation effects either.

A major issue, not solved till now in emergency response, is an adequate policy for dealing with waste. The history has shown that mankind invents solutions on the spot (trenches in Ukraine, a temporary storage in Goiania, much local storage in packaging material around Fukushima). This point deserves more attention, as it impacts both radiologically and psychologically. A better mechanism for the transition from crisis situation to post-accident is a prerequisite for achieving this. The French CODIRPA approach [CODIRPA] may be inspiring.

The main conclusion is that the victims should be more in the focus, not the policy of a country or an industry or a pressure group. The same is through for medical monitoring programmes: they should according to me mainly serve the victims, not the scientists.

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ETHICAL ISSUES IN THE SYSTEM OF RADIOLOGICAL PROTECTION

Patrick Smeesters
MD, Radiation Protection Advisor (hon)
Federal Agency Nuclear Control, Belgium,
Chairman of the BVS/ABR
Chairman of Art 31 RIHSS WP
Alternate Belgian Representative in UNSCEAR

1. Context

In December 2013, the Italian and French Societies of Radiation Protection in cooperation with the International Commission on Radiological Protection (ICRP) and the International Radiation Protection Association (IRPA) organized the First European Workshop on the Ethical Dimension of the Radiological Protection System. On 4 to 6 February 2015, a Second European Workshop on the same topic was organized in Madrid jointly by the Spanish Society of Radiation Protection (SEPR), the Italian Association for Radiation Protection (AIRP), the French Society of Radiation Protection (SFRP) and the UK Society for Radiological Protection (SRP), in cooperation with ICRP and IRPA. I have been invited to give during this second workshop two presentations about theoretical issues regarding ethics on the one hand in the nuclear sector and on the other hand in the medical sector.

2. The international genesis of the System of Radiological Protection: harmonization and club-effect

Current regulation in radiation protection of the population is mainly elaborated through a sequence of stages, beginning with scientific research, followed by global evaluations by organisations like the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) or the BEIR (Biological Effects of Ionizing Radiation) Committee of the US National Academy of Sciences, this process ending in recommendations

by the International Commission on Radiological Protection, up to now the leading group in the field.

All or part of these recommendations are then generally transposed into European directives, setting the mandatory safety objectives for the European Union (EU) Member States, and into the international Basic Safety Standards (BSS), jointly sponsored by the International Atomic Energy Agency (IAEA), the International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the Pan American Health Organization (PAHO). At the EU level, according to the Euratom Treaty, the directives are adopted by the Council (with qualified majority), on a proposal from the European Commission (EC). To elaborate these proposals, the EC is assisted by a group of independent scientific experts referred to in Article 31 of the Euratom Treaty.

This international genesis gives guarantees of validation and consolidation and obviously favours harmonisation but, on the other hand, entails risks of inbreeding, political influences and "pseudo"- consensus ("club-effect"): it is much more comfortable and safe to follow this (impressive) herd.

Despite this international genesis, it is not always easy to obtain unanimity between the experts and, at a later stage, between the States. This is, at least partly, because recommendations and subsequent regulations always include value judgments and because, even within the scientific evaluations, some ethical issues are often deeply interwoven. The importance of these fundamental value judgments is increasingly recognized these last years.

3. Ethical *grounds at the basis of* the ICRP Radiological Protection System: classic views and new reflections

ICRP also is currently showing increasing interest in explaining and justifying on ethical grounds its Radiological Protection System and has created a Task Group dedicated to this topic. Such awareness is welcome, all the more so since ICRP is still considered being the world reference in radiological protection recommendations.

The current Radiological Protection System is built on three pillars: justification, optimization and dose limits. A classic ethical lecture of the

justification principle links it to utilitarian ethics: do globally more good than harm (collective approach).The same is true for the optimization principle: try to maximize good vs harm. On the contrary dose limits can be linked to deontological ethics (individual approach): be sure that no individual is unduly harmed, this unduly character being evaluated by comparison with parallel « acceptable » (or accepted) situations. Dose constraints are based on the principle of equity between individuals, as they are fixed on the basis of comparisons with similar situations and right to access to the benefit of good practice.

All the system includes some consideration of precaution. The justification and the optimisation principles, and even the harm evaluation lying at the basis of the choice of dose limits, are based on the fact that there is serious and plausible evidence that stochastic effects can be induced by ionizing radiation even at low dose of radiation and that the probability of these effects being induced increases proportionally to the dose (as this relation is considered to be linear in the low dose range, the expression "Linear, No-Threshold" or "LNT "hypothesis" is currently used to describe the paradigm at the basis of the radiation protection system). Let us note by the way that this description as "Linear, No-Threshold" can be misleading as it only applies to the low dose range. The risk estimates underpinning the Radiological Protection System are in fact based on the risks observed at moderate to high doses divided by a factor taken as being 2 (the Dose and Dose Rate Effectiveness Factor: DDREF). The dose effect relation that is used in radiation protection is in reality not linear but linear-quadratic.

The ALARA approach consisting of taking preventive measures to limit the induction of uncertain but serious and plausible effects, while not forbidding the practice, could then be considered as an early application of the precautionary principle.

The justification principle could also be related with the principle of responsibility (banning of some unjustified practices or consumer products, such as radioactive toys; strong protection of pregnant women, etc.).

As reminded by C. Clement, Scientific Secretary of ICRP, during the Madrid Workshop, the ethical lecture of the Radiological Protection System is in fact complex and underlying values may be conflicting. So utilitarianism alone ignores justice and uncertainty and deontology alone

ignores potential collective consequences of decisions. As a result there is frequently a need to balance conflicting values.

The way forward ICRP currently proposes is searching for the existence of internationally widely accepted values and to see how these values are or may be used in practical situations (societal, occupational, medical, environmental, wastes, …).
Four main ethical principles seem currently to be widely shared: Dignity (linked to autonomy), Beneficence, Non Malevolence and Justice. These were proposed as framework for biomedical ethics by Beauchamp and Childress and are assumed to be rooted in a "common morality", which is not relative to cultures or individuals because it would transcend both.
Other widely accepted principles mentioned during the Madrid workshop are: Prudence, Concern for the underprivileged, Equity (including intergenerational equity), Honesty, Empathy, Participation, Transparency and Accountability.

4. Ethical *issues within* the Radiological Protection System itself and its application:

The discussions during the Madrid workshop were focusing on the "application" of the Radiological Protection System and the identification of values (or conflicts of values) that are at stake in various types of practical applications.

Unfortunately practically no consideration was given to ethical issues in the value judgments and the choices that were made within or are inherent to the current system itself. I tried to highlight some of them during the workshop, as explained hereafter.

First, the right implementation of the Radiological Protection System inherently supposes a day to day effort and implication of the persons in charge, but elements such as right education and training, possible misinformation or conflicts of interest frequently jeopardize the *efficiency* of the system.

Secondly, the ethical justification of the system inherently supposes taking *due account* of the « harm » from exposures, but what about scientific updating regarding the evaluation of this harm? Do we have to wait for 100 % certainty before changing anything and why?

Thirdly, there are more or less hidden ethical choices *within* the Radiological Protection system, such as the degree of taking into account of epistemic uncertainties (uncertainties related to lack or insufficiency of knowledge) and the level and consistency of use of the precautionary principle.

Finally, regarding the choice of values "widely accepted internationally", elements like "club" effect for the experts involved or conflicts of interest can play an important role. Are stakeholders outside the field duly consulted?

4.1. The efficiency of the system rests on the day to day implication of the persons in charge

In the ICRP Radiological Protection System, dose limits are justified by considering them as "just tolerable" exposures and have to be complemented by optimisation processes and by the use of source or task related dose constraints. Such a system is mainly oriented to providing sufficient means in order to maintain the exposures ALARA (As Low As Reasonably Achievable), rather than to just verifying the conformity with a standard.
It is more an Anglo-Saxon approach (obligation to implement means) than a French one (obligation to obtain results).

The effective implementation of the Radiological Protection System therefore supposes an effort, a motivation and a day to day implication of the persons in charge.
Various factors can nevertheless jeopardize the effectiveness of the system, among which conflicts of interest play an important role: optimization is expensive and minimizing the risks is an easy way to escape from these costs and from reproaches.

Radiological protection and its scientific rationale are also often insufficiently or erroneously explained during education and training. Frequently the risk of radiation induced effects in the low dose range (less than 100 mSv) is minimized or even denied by the teachers themselves. A common wrong and misleading statement is that LNT and ALARA are only a "prudent" approach and that they don't have "any scientific basis", while there are in reality a lot of scientific (biological, biophysical and epidemiological) evidences underpinning the system. The content of the course is also often not up to date and the continuous education is frequently inexistent. This

contributes to explaining why the obsolete concept of harmless "maximum permissible dose", where dose is considered as a "credit" that can be used to manage the work planning, is still largely present.

This situation is worsened in many work environments where radiological protection culture is practically absent and, unfortunately, the medical field is also often concerned by this lack of radiological protection culture. A practical consequence of this faulty culture is the frequent absence of any ALARA procedure and the persisting distrust and brake regarding the use of dose constraints.

Finally the protection of women of reproductive capacity is also often inadequate. This is worsened since abdomen dose limits have been replaced by mandatory information. The problem is that the provided information is often wrong or out of date.

4.2. Harm and scientific updating

There must be a continuous loop linking Policy with Research and Development.

Research produces continuously new data. These new data have to be evaluated and validated, and their potential implications discussed, leading, the case being, to changes in regulation or policy or to specific guidance or indicating new research needs or priorities.

A fundamental ethical question is then how much evidence is considered necessary for updating the system. Do we have to wait for 100% certain evidence or do we follow a precautionary or a prudent approach if "sufficient" evidence is available? An important point is that this "sufficient" character depends also, although partially, from the difficulty or detriment of the possible remedial actions.

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 some lack of vigilance and responsiveness regarding "early warnings" that were already described many years ago.

Why were radiation induced cardiovascular effects "recognized" so late? Is it due to a too slow "digestion" of new scientific results by the existing assessment organizations? Does it come from a resistance to cognitive dissonance or to change of paradigm (the distinction between stochastic

and deterministic effects vanishing to some extent)? Probably all of this but there is also frequently, in the current scientific world, some misuse of the evidence-based approach, with an excessive focus on the necessity of obtaining hard evidence or 100% certainty (focus on avoidance of false positives regarding causal relations) and an insufficient focus on the need to avoid also false negatives (risk of dismissing real risks).

There was also a wrong comprehension of precautionary approaches, considered a priori as being costly and difficult to implement. Yet, regarding radiation induced cardio-vascular effects, precautionary measures were and are easy to take: adaptation of radiotherapy protocols (breast cancer); management of cumulative high diagnostic exposures or use of dose constraints to limit cumulative (or lifetime) organ doses of workers.

Before the ICRP Seoul revision of the recommendations regarding protection of the lens of the eye and of the organs of the circulatory system, the regulators have been facing a difficult ethical issue (that could happen again in the future).
On ethical grounds, could they wait for changes of the ICRP recommendations and of the BSS before acting and taking practical protective measures for the lens of the eyes?
Should they currently wait for ICRP and IAEA taking seriously into account the risk for the circulatory system before acting?

By the way, the problem was tackled in the last EU BSS (need of optimisation of organ doses) but without being really highlighted, although the linked challenges are important.

4.3. Taking into account of epistemic uncertainties and use of precaution.

There are more or less hidden ethical choices within the Radiological Protection system, such as the degree of taking into account of epistemic uncertainties (uncertainties related to lack or insufficiency of knowledge) and the level and consistency of use of the precautionary principle.

4.3.1. The question of irradiation in utero can be used as a first example.

The risk from in utero irradiation is currently regarded with more optimism than previously, and, even if the ICRP and the BSS ask for a protection of

the child to be born, in planned exposure situations, being comparable with that provided to for members of the public, "threshold" figures, like the emblematic 100 mSv numerical value, are frequently presented as "the" break-point criterion in emergency planning, post-accidental situations or medical exposures.

Yet, even without speaking about the risk of radiation-induced childhood leukaemia after irradiation in utero at low dose, there are a lot of radiobiological data asking for more prudence also for non-cancer effects in the low dose range.

After irradiation during the pre-implantation period, generally considered as safe with regard to the radiation-induced risks, non-lethal congenital malformations have been induced in animals, particularly (but not only) in those with a genetic predisposition to specific congenital malformations or with genetic disorders in the pathways of DNA-repair.
Moreover, during the zygote-stage (about 1 day), there could be no threshold dose for the radiation-induction of congenital malformations in genetically predisposed animal strains.

After irradiation during the organogenesis, more congenital malformations have also been induced in animals with genetic disorders. There are similarities with the effects of chemical agents.
In these cases, the cause of the congenital malformations may not be an increased loss of cells (classic deterministic effect) but rather the persistence of un-repaired or mis-repaired DNA-damaged cells ("teratogenically damaged cells").

Now, in humans, the same genetic susceptibilities probably exist: there are indeed families showing clusters of spontaneous congenital malformation. There are also in humans many genes implicated in the DNA-damage response and involved in the genetic susceptibility to cancer induction by irradiation; if the mechanisms are similar (persistence of mis-repaired DNA-damaged cells), it is plausible that human genotypes leading to cancer-proneness are also associated with a genetic susceptibility to the radiation-induction of congenital abnormalities (or more subtle tissue dysfunctions).
Due to genetic susceptibilities, there could then be for some individuals a higher risk of radiation-induced malformations (or dysfunctions) or lower thresholds (or even no threshold at day 1?) and this risk could also

exist during the "safe" periods of pre- and early post-implantation (when women are not aware of being pregnant). Although frequently assumed to be low, the frequency of these individuals is not known.

This raises doubts about the "definite" and generalized character of the 100 mSv threshold dose for lethal, developmental or other detrimental effects (other than cancer) after irradiation during the first trimester of pregnancy, currently applied as a practical criterion. As an example, this numerical value is presented by ICRP in its Publication 103 as a "true dose threshold" for congenital malformations. This could be an unjustified simplification.

On the basis of the precautionary principle, does this not require cautiousness in the medical field, particularly for high dose examinations, including those performed during the pre/post implantation stage, in women not aware of being pregnant? The application of the ten-day rule (planning the non-urgent examination within the ten days following the beginning of the menstruation), whenever the abdominal dose could be significant, would largely reduce these problems.

There are still many other uncertainties regarding the effects of irradiation in utero: radiation effects on gene expression, subtle effects or long term effects of Nervous Central System 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 currently not considered as a priority and there are no or few budgets allowed.

When looking at the potential implications of all these new data, a basic question is how much scientific evidence is needed before the scientific community feels it is necessary to apply the precautionary principle. A related question is to know if the various stakeholders (besides the experts) would need the same amount of evidence before recommending precautionary action.
A linked issue is that the underlying ethical choices (management of uncertainties and precaution) made within the recommendations for radiological protection are not visible and transparent, neither for the exposed persons nor for the various decision-makers.

Incomplete and unbalanced information is then given to the individuals concerned.

4.3.2. Radiation induced hereditary effects: typical epistemic uncertainties

Another clear example of ethical choice within the System of Radiological Protection is related to the management of the risk of radiation induced genetic risk.
Radiation-induced genetic risk (risk of hereditary effects in the descendants of irradiated parents) was in the past considered prominent, on the basis of a large number of animal experiments. Reassuring observations in the descendants of the Japanese A-bomb survivors, together with increasing concern about the radiation induction of cancers, led to a decreased interest in the genetic risk, including in the budget devoted to research.

The way international committees currently deal with the radiation-induced genetic risks raises concerns. Since the last UNSCEAR report on this topic (2001), and particularly since the last ICRP recommendations, there is a tendency to more and more neglect the radiation-induced genetic risks. This issue is particularly relevant for exposures in childhood as possible effects will have a" full" chance to arrive. Let us remember in this respect the old concept of "genetically significant doses".

New genetic risk coefficients recommended by ICRP consider exposure and genetic risk for two generations only - the equilibrium value used in ICRP 60 being judged to be of questionable scientific validity because of the unsupported assumptions necessary on selection coefficients, mutation component and population changes over hundreds of years. As a result, the risk associated with gonadal dose is now estimated to be around 20 cases per 10,000 people/Sv, rather than around 100 cases in ICRP 60 (previous recommendations).
But there are three fundamental issues: is the total radiation-induced genetic risk really lower than we thought in 1990? Is the genetic risk limited to the two first generations? Do we know enough to draw final conclusions?

Let us begin with the first point: is the (total) genetic risk lower than we thought 15 years ago?
Although this is not said explicitly in the above-mentioned ICRP documents, it is the message that everybody understands. The new risk

coefficients for radiation-induced hereditary diseases are lower and they are presented as a global estimation of the genetic risk from radiation. In fact they are lower because only two generations are now considered, but they are nevertheless compared with the previous risk coefficients that were estimated at equilibrium.
When evaluated on comparable bases (risk for the first generation, for 2 generations, …) , the genetic risk is not reduced, as obvious when comparing the UNSCEAR 2001 Report with the previous UNSCEAR Reports of 1988 and 1993.
The sharp decrease of the genetic risk coefficient recommended by ICRP is based only on its choice to take now the effect on the generations over the second as being zero.

Now the second question: can we say that the genetic risk is "practically" limited to the two first generations?
The above-mentioned ICRP documents strongly suggest this. They support this view by radiobiological data suggesting that a major contribution to the genetic risk comes from multigene deletions that are compatible with viability and express themselves essentially in the two first generations by multi-system developmental abnormalities (in analogy with naturally-occurring microdeletion syndromes). This kind of radiation-induced effects can be seen as congenital abnormalities and will indeed rapidly disappear in the next generations due to selection effects. Besides these particular effects, ICRP incorporates also in its risk estimates the radiation-induction of autosomal dominant and X-linked diseases and of chronic multifactorial diseases, but it restricts here too its estimation to the two first generations. To justify this, ICRP underlines the numerous uncertainties involved in the estimation of the long term genetic risk. So the equilibrium value of ICRP 60 is now judged to be of questionable scientific value because of the "unsupported assumptions on selection coefficients, mutation components and population changes over hundreds of years".
In fact the "short term" hereditary effects are not limited to diseases in the two first generations. When the chronic multifactorial diseases are left aside (as it was the case in the UNSCEAR Reports of 1988 and 1993), the "equilibrium" risk coefficients are not significantly influenced by population changes over hundreds of years, but mostly by the selection effect for the most important component, i.e. the autosomal dominant/X-linked diseases, and this equilibrium is obtained after 5 to 6 generations

(UNSCEAR Report 2001, figure V, p. 40). From a public health perspective, it would be by far more acceptable to take explicitly all the autosomal dominant/X-linked diseases into account, up to 5-6 generations, as it was done in the past.

Finally, do we know enough to draw final conclusions?
Considering the ”numerous uncertainties” involved 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 ignoring the possibility of significant long term risks.
In reality, the uncertainties regarding the radiobiological mechanisms are still important. Research teams are still struggling with things like non-targeted effects, transgenerational genomic instabilities, modifications in gene expression, etc, all playing possibly a role in the genetic risk.
Among the radiobiological issues having a potential impact on the evaluation of the radiation-induced genetic risk, there is the question of the mutations in tandemly repeated DNA loci (TRDLs such as minisatellites).

Minisatellite mutations are generally considered as pure markers of exposure without health significance. Some of these mutations are nevertheless « associated » with various health disorders. Although this does not mean that they are the causative factor, it remains that the role of the minisatellites is still largely unknown.
Other issues related to the complexity of the genome machinery are new data regarding transgenerational mutagenesis. Transgenerational mutagenesis has up to now been observed only in animals but, using the expression of Bridges during a 2006 Seminar, « lack of human evidence does not mean evidence of lack of effect » and, if such effects would occur in human beings too, they would have wide implications.
Possible differences in genetic changes between external and (chronic) internal exposures are another important issue, for instance in situations like the post-Chernobyl contaminations. After all, the vast majority of human data are currently based on follow-up of populations after external exposures (Life Span Study, radiotherapy studies).

The basic question is whether we know enough about possible long term radiation-induced genetic effects to close this matter and to conclude now that the effect on the generations over the second is negligible.

The current approach (initiated by ICRP but now practically generalized, including in the new UNSCEAR Children report) regarding radiation-induced genetic risk evokes ethical questions. Giving authoritative messages suggesting that the genetic risk is of lower or no concern, while minimizing possible long-term effects, is a position opposite to the application of the principle of precaution (understood as recommending measures of precaution or prevention to avoid plausible but uncertain detrimental effects). Due to their scientific authority, organizations like ICRP or UNSCEAR influence the societal and regulatory actors that have actually to decide on the necessity to apply or not precaution or prevention measures.

4.3.3. Other ethical choices within the Radiological Protection system

Many other ethical choices are present and more or less hidden within the System of Radiological Protection. Let us give two last examples.

First, regarding cancer risk, a lot of new data are suggesting a DDREF lower than 2. Is a DDREF of 2 still justified? Is "1 =2 in radiological protection" 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.

Secondly, the radiation-induced cancer risk (ERR: Excess Relative Risk) is significantly higher for women than for men while the Excess Absolute Risks (EAR) are equivalent.
But does this (current!) equivalence of the Excess Absolute Risks fundamentally change the ethical issue posed by the difference in relative risks?
And should we favour equivalence of limits, as the ICRP did, or equivalence of risks?

4.4. 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 and value judgements (RISCOM).
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.
Unfortunately stakeholder involvement is currently often just a façade. The invited stakeholders and experts coming from outside the nuclear world are very few and their opinion often considered as irrelevant and hardly taken into account.
Without really looking outside the field of the "nuclear" stakeholders, this concept of "values widely accepted internationally" and its unavoidable corollary of "widely accepted arbitration between conflicting values" could be just a kind of expression of self-satisfaction.

5. Synthesis and conclusions

Recommendations and subsequent regulations about the Radiological Protection system always include value judgments. Even within their underpinning scientific evaluations, some ethical issues are often deeply interwoven. The importance of these fundamental value judgments is increasingly recognized these last years, including by the International Commission on Radiological Protection.

The way forward ICRP currently proposes is searching for the existence of internationally widely accepted values and to see how these values are or may be used in practical situations (societal, occupational, medical, environmental, wastes, …).

The discussions during the Second European Workshop on the Ethical Dimension of the Radiological Protection System (Madrid 2015) were focusing on the "application" of the Radiological Protection System and the identification of values (or conflicts of values) that are at stake in various types of practical applications.

Unfortunately practically no consideration was given to ethical issues, value judgments and choices that were made *within* or are *inherent* to the current system itself.

So the right implementation of the Radiological Protection System inherently supposes a day to day effort and implication of the persons in charge (ALARA spirit), but elements such as right education and training, possible misinformation or conflicts of interest frequently jeopardize the efficiency of the system.

In addition, the ethical justification of the system inherently supposes taking due account of the «harm» from exposures, but what about scientific updating regarding the evaluation of this harm? Do we have to wait for 100 % certainty before changing anything or do we follow a precautionary or a prudent approach if "sufficient" evidence is available? Too often, scientific updating is too late by lack of precautionary spirit.

Last but not least, there are more or less *hidden* ethical choices *within* the Radiological Protection system, such as the degree of taking into account of epistemic uncertainties (uncertainties related to lack or insufficiency of knowledge) and the level and consistency of use of the precautionary principle. Examples are to be found in the management of irradiations in utero, of radiation-induced genetic risks or of differences in sensitivity to radiation effects between men and women.

The "fathers" and users of the Radiological Protection System try to rest on values widely accepted internationally, but their "consensus" could be biased by a club-effect due to the lack of independent fora and to the poor implication of the "weak" stakeholders and of experts "outside the field", whose expertise is unfortunately often considered with arrogance.

The risks arising from the exposure of the population to ionizing radiations are making part of the current societal concerns, together with issues like GMO, dioxin or global warming.
All these issues are dealt with in an international context where economic and political interests are at stake and present large uncertainties regarding their consequences that require considering the possible application of the precautionary approach.
Now, as regards radiological protection, there is a paradoxical evolution: although the uncertainties on health effects are still present and are even

growing, the application of the precautionary principle seems to be decreasing in the international organizations coping with this matter.
Scientific vigilance, deontology and responsible decision-making, including unavoidable value judgments, are necessary at all levels and scientific advisors and regulators cannot allow themselves to « wait for instructions » from international organisations but have to take their own responsibilities.

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ETHICAL CONSIDERATIONS ON FUKUSHIMA

Contribution of G. Eggermont
former president of BVS/ABR,
Invited Expert EU Scientific Seminar Art 31 Group

Brussels, June 19, 2015
Panel Discussion:
Personal Views on the Ethical Lessons from Fukushima

1. A nuclear accident similar to Fukushima can happen in Europe in the coming years

An accident with low probability and high societal consequences is possible and could hit densely populated areas with complex socio-economic and traffic infrastructures. (Eg2013, VM2014, SF2015)

Are we prepared?

- Internal emergency management was reconsidered by the operators in stress tests

- External emergency planning and post accidental management was not yet reviewed. It still only considers small distances and short term radiological consequences

Germany has set up an ethical commission. Concern on major accident consequences in densely populated areas was given political expression (Et2011). As a result Germany is reducing nuclear energy gradually to phase out and is preparing stricter criteria for emergency measures over longer distances (www.ssk.de).
In **France** the regulator, ASN (AS2012), launched post accidental strategy reflexion for improving long term preparedness.

2. Each major nuclear reactor accident was complex with a lot of unforeseen elements

The history of past accidents learns that nuclear risk assessment did not fully integrate:

- **human error** (Harrisburg); the engineer approach in PSA developments in MIT had neglecting social science indicators on human behavior and interaction
- **management reliability** (Chernobyl); safety culture was no issue up to 1986
- **nature and regulatory independency** (Fukushima); earthquake experience and tsunami history had indicated safety measures, they were postponed due to poor watchdog culture.

What is not yet considered now? How complete and creative is in our scientific risk assessment approach?

Accidents beyond design are real. Accident sequences such as a pressure vessel rupture can occur as studied by the EC reactor Safety R&D and EU FISA conferences. Metallurgic uncertainties could increase such risks. Pressure vessel rupture could be fatal also for the protection provisions in the Belgian safety in depth approach. Loss of coolant can lead to melt through in supporting structures as was faced by Russia during the Chernobyl crisis.

Moreover we are not paying full attention to the vulnerability of spent fuel pools in the older reactors where protection for external impact is weak. Fukushima has learned that fuel pools in combination wit a reactor accident can seriously aggravate accidental consequences and complicate emergency management and long term waste water management.

Do we consider growing uncertainty of ageing in post accidental perspective?

- Recent plant life extension (PLEx) authorisation approaches in Belgium did not yet consider safety concerns of that nature.
- Such concerns were given attention in the pioneering past (underground rock siting Chooz1)
- APS recommendations in the seventies(Le1975) as expressed in new EPR Gen III reactor projects

Why are we only considering atmospheric dispersion for accident management

A spread of radioactivity in ground water considering the hydrogeology near river Schelde in Antwerp could be a crucial gap in our prospective exercises.

New European safety design has put forward new safety provisions for GEN III EPR (sand bed technology) taking serious core melt down into soil into account. For extending life of older reactors, such as Doel 1 &2, Belgian FANC did not require such measures, as they were considered too expensive by Electrabel.

3. Nuclear safety requires periodic independent evaluation also of the regulator

After Fukushima the **potential impact of nature** was seriously reconsidered with a structured stress test approach in Europe. This was extended to other vulnerabilities such as terrorism. Inspired by the financial crisis it was organized through self evaluation by operators, supervised by regulators. It leads to action plans for improvement and to exchange in the feedback of experiences. On site emergency plans were revised as well. Some worst case scenarios were omitted.

An external independent review of the accident in Japan demonstrated that not only nature was the cause of the accident but also the revolving doors between operators, regulators and policy makers which had postponed safety measures (such as mandatory dike heights in risk zones against flooding) (Wa2013).

"*safety criteria are only adequate when they are implemented*"

The role and independency of regulators in Europe was however not considered by an impartial body. Peer review of stress tests was organized at EU level with interesting results. ENSREG (European Nuclear Safety Regulators Group; 2015 http://www.ensreg.eu) organised with the EC three stakeholder conferences, one with the end results. They pointed out the lack of attention for external emergency planning and long term management of nuclear calamities in Europe. Divergences of conformity of Member State were not specified in a transparent way. Civil society was only involved in a structured way in some countries. No full transparency could be organised on the feedback of terrorism risk for safety provisions.

Is our regulator impartial and always fully independent from operators?

- Potential conflicts of interests for operators becoming regulators are evaluated differently in France and Belgium.

- Experts can as well advise operators and consider related authorization procedures as member of the regulatory advisory board.
- Is transparency organized when lobby groups such as the Nuclear Forum are influencing public servants in regulatory bodies?
- Could more risk awareness been organized using RISCOM conditions for transparency?

4. Each major nuclear accident in the future will have international consequences of radioactivity contamination

Are we organized for a major nuclear accident at the relevant European level?

Safety criteria are not yet harmonized for European nuclear power reactors. A European operational nuclear safety authority not yet exists. Free networking (ENSREG, HERCA, etc.) of more than 25 regulators has improved bilateral exchange.

Emergency planning is still a member state competence with varying action criteria not yet harmonized at EU level. Ulrike Welle from German SSK clearly stated at the Luxemburg Seminar that the nuclear emergency approach should only be allowed to differ from state to state for specific local aspects.

Long term accident management only becomes mandatory from 2018 on (BSS).

Harmonization of insurances is still lacking in Europe and post Fukushima EC policy intentions were postponed.

Few ethical attention is given to warnings from international prospective research that environmental accidents could generate in future a new kind of migration and have financial consequences that small member states cannot afford.

5. The last nuclear accidents have created a huge nuclear waste management problem

Ukraine is facing a large solid waste problem in a permanently evacuated area but Fukushima faced a huge liquid waste problem on site never met before in nuclear history neither in accident planning. Moreover the cleaning and decontamination of houses and former living areas created

waste quantities as important as for normal operation of a whole production park over decennia.

How to prepare for such a nuclear waste problem in Europe where each MS has to plan its own future waste management policy?
Can NIRAS ONDRAF integrate such exercises?
Control measurements for waste could be taken up in emergency management and for long term post accident planning, at least at the European support level as it could happen in a densely populated region where rehabilitation cannot be excluded in principle.

6. Specific emergency actions are not yet reviewed since Fukushima

The happening of Fukushima early in spring has limited the food contamination to a reasonable level which could be controlled in international trade. It partly explains the difference in contamination with Chernobyl. Nevertheless the noble gas source term was similar and not so well expressed in dose estimations. Instructions to shelter in Japan in order to protect for noble gas clouds as well for iodine exposure were not well controlled in function of time and will require more adequacy.

How to organise actions in general up to a realistic level of 100 km and more?

The Belgian Health Council already proposed following German studies and HERCA options to improve iodine prophylaxis (HG2015), which was far from successful in Japan.
Evacuation strategies should also be reconsidered to face in a realistic way European and Belgian conditions. Specific attention should be given to the impact of traffic congestion as well on direct intervention efficacy in the plant as on evacuation ability.
The interaction of new social media on citizen behavior in crisis situations needs particular attention and requires even more than before to build confidence and trust in experts and authorities.

Are we coherent in our emergency preparedness?

Our focus on long term radiological consequences of small doses in emergency planning has neglected the socio economic impact of a major nuclear accident on a contaminated region. The socio economic structures in Belgian emergency planning are not yet implemented. Moreover the international traffic function of some of our major reactor site areas

(Antwerp, Calais) could be disturbed over long periods in case of a Fukushima alike accident scenario.

7. The dose to plant and intervention workers in Japan was essentially given to temporary workers with large uncertainties

Dosimeters were shared among workers at Fukushima which increased uncertainty on potential effects particularly for those with reduced follow up capacity. It contrasts with the UNSCEAR and IAEA haste to minimize health effects of the accident.

The clean-up operations also require numerous external workers with challenges for training, monitoring and medical follow up which should be considered in European actions.

8. Conclusion - How to prepare a more precautionary approach?

A nuclear accident will happen in Europe in the future. Crisis management will be complex full of uncertainties and ambiguities. The interaction with the workers and the public will depend on trust and confidence built up in advance.

In such a case only precautionary approaches can be successful. They require a participatory approach of civil society in nuclear safety policy and siting criteria and a fortiori in emergency planning and accident management.

Emergency preparedness is only the first objective in nuclear crisis management. It requires a more realistic scope for measures such as iodine prophylaxis and evacuation taking into account the vulnerability of densily populated areas such as Antwerp. Fukushima has confirmed a potential long term duration of contamination in large areas. This requires a policy for transition and long term measures with at least a strategy for prolonged perturbation of a region.

Value judgments differ for experts and the general public and cause a lot of ambiguity in particular if return conditions are not accepted and liability not fully guaranteed for victims. Perception seems not only determined by fear or cancer but also by concern for family, future, animals etc. and is shaped by (a lack of) trust building and controversies in the past.

Risk communication during intervention and even more during long term rehabilitation is crucial and requires structuring of transparency such as put forward by the RISCOM model (An2008).

The participatory dimension needs to be structured for the public in the region around nuclear plants. Local committees of information, coordinated at national level and supported by independent expert advice should be organised. Participatory approaches were successfully set-up in Belgium for nuclear waste disposal siting but not yet for reactor decision making. In France it was already legally structured(CLI-ANCLI (Association Nationale des Comités Locaux d'Information)). The Committees were associated in the EU reactor stress tests. A first initiative to organize cross border meetings at the Belgian West Coast was abandoned by FANC despite efforts of the European Nuclear Transparency Watch and support of ASN.

A revision of nuclear crisis management with a feedback of the lessons of Fukushima and other experiences is required. The feasibility of emergency measures should be demonstrated for complex densily populated areas. A reconsideration of safety criteria for nuclear power plants is recommended at periodic safety revisions of the regulator in particular when safety problems occur which can cause or increase risk for major accidents (such as pressure vessel rupture) and for beyond design accident consequences.

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