

Report

**ICRP's Second North American Workshop on
'The Ethical Dimensions of the System of Radiological Protection'**

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List of participants

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Introduction

This workshop was part of a larger series of ICRP-workshops with the aim to spell out the ethical foundations of the system of radiological protection. ICRP has established Task Group 94 (TG 94) to develop a publication on the ethical foundations of the system of radiological protection, aiming to consolidate the basis of ICRP's recommendations, to improve the understanding of the system and to provide a basis for communication on radiation risk and its perception. This workshop series is intended to contribute to the work of TG 94. Earlier workshops were held in Daejeon (Korea), Milan (Italy), Baltimore (USA), and Madrid (Spain). This was the second North American workshop, and probably the second last, which will be held in Fukushima City (Japan) June 2-3.

The workshop started with a general overview of ICRP's recent efforts to revise its recommendations, provided by ICRP Vice-Chair, Jacques Lochard. Kunwoo Cho & Chieko Kurihara, respectively the Chair and a member of TG 94, presented an overview of the work of their TG on the Ethics of Radiological Protection until now. There were four additional keynote talks, given by Stephen Gardiner (Revising the Principles of Radiological Protection), Sheila Jasanoff (Imagines of Risk and the Ethics of Radiation Protection), Friedo Zölzer ("Common Morality" Approaches for the Ethics of Radiological Protection) and Behnam Taebi (Bridging the Gap between Social Acceptance and Ethical Acceptability). The rest of the time was spent in an interactive discussion by the participants with the aim of contributing to the ongoing work of TG 94. The full program of the workshop could be found here: <http://www.icrp.org/docs/Harvard%20Workshop%20Second%20Announcement.pdf>

In the interactive session, the key issues were collected and reviewed. A great portion of the discussion was devoted to two efforts. First, to identify and categorize the key ethical issues and second, to sum up some of the key challenges that we have in this categorization and in understanding the meaning of each of these ethical issues. In the following we will briefly review the key issues of the discussions in this workshop, and present some recommendations as well as some open questions for TG 94.

Question 1: Could the system of RP help us assess the desirability of a certain technology?

More specifically, the question was posed if the system of RP could assist us in assessing the desirability of risky technology that involves ionizing radiation, compared to alternatives that do not involve radiation. The question was presented for two specific areas of application; i.e. i) nuclear energy as a potential source of energy and ii) choosing among medical alternatives.

As regards nuclear technology, it is very unlikely that the system of RP could facilitate making a choice between nuclear energy and its alternatives. Such decisions involve many more considerations than only questions of RP. The ICRP-system of RP does not aim to accommodate such comparisons.

As regards medical applications, the Justification Principle serves as the gatekeeper. However, it only provides a net positive benefit threshold. How to choose the best of all available alternatives is probably beyond the scope of RP. The question remains as to whether justification within RP should help with choosing between medical alternatives and modalities. Here we need to distinguish between therapeutic and diagnostic procedures.

- Therapy – There are often different treatment methods. For instance for prostate cancer, the physician can consider external beam radiotherapy, brachytherapy, surgery, chemical castration, etc. Each method has advantages and disadvantages. The ultimate treatment decision should have a more holistic context, not limited to radiation considerations.
- Diagnostics – Again, there are different diagnostic techniques for a variety of medical situations. For instance, in case of chest pain, various imaging techniques (functional versus anatomic) could be considered such as stress echo cardiography or nuclear stress testing. The physician needs to compare and balance radiation risk and risk associated with invasive procedure. Again, the conclusion is that choosing a diagnostic method involves broader considerations than only.

Indeed, using radiation in medicine is – in principle – justified, since it clearly has benefits for the patient. However, the question of whether a certain procedure is justified often comes down to the judgment of medical professionals.

The bottom line: the answer to the question above is: sometimes, mostly at the lowest level.

Notes for TG 94: Please consider the following two publications in this regard.

- ICRP 103 paragraph 205 ‘beyond responsibility of radiation professionals’
 - ICRP 105 paragraph 667 (medical use of IR) ‘account for all available information’
- In other words, this idea is already included; the RP system facilitates the consideration and use of alternatives.

Question 2: What is the main aim of the new publication that TG 94 is preparing?

The new publication has two key objectives: firstly, to clarify the ethical basis of the system of RP, and secondly, to bring awareness about the ethical aspects of RP to both the interested public and RP professionals. RP is traditionally difficult to understand for non-experts because of the high level of jargon. Furthermore, the fact that ethics is an integral part of the day-to-day practice of radiation practitioners is not sufficiently acknowledged. This publication aims to bring awareness by presenting a lay-persons summary that would be accessible to a large group of practitioners from different academic and professional fields as well as to the general public. With this publication, ICRP aims to communicate the “whys” of the system with the public and professionals as well as to help strengthen the basis of the recommendations. This new publication may eventually have a significant impact on the next basic recommendations of ICRP (i.e. an as yet unplanned revision of ICRP Publication 103).

The ICRP mission statement is to promote RP for the public good and, more specifically, to protect people and the environment without unduly limiting the benefits of the use of radiation. Ethics should be incorporated as an established part of practice and training in RP. ICRP can incentivize this process with this publication, but also by encouraging their members to include ethics as an integral part of their training. The forthcoming publication could serve as a baseline of knowledge with the opportunity for more in-depth study.

Question 3: What are the key values and principles in the system of radiological protection?

The group followed a tripartite model, or an imaginary triangle with three levels, with on the top level values (i.e. key ethical issues that we have reasons to hold paramount), on the mid-level principles (i.e. principles that we derive from those values – the existing ICRP principles of Justification (JP), Optimization (OP) and Dose limitation (DL) belong to this category – and the lowest level of tools, procedures and guidelines that are very specific and relevant to the daily practice of radiation practitioners. The process of connecting the values with the principles and, consequently, tools and procedures, is what is called the process of *specification* in applied ethics (a term used by Beauchamp). The group has further tried to identify if an important ethical issue should be a part of this tripartite model. Alternatively, important ethical issues need to be included in ICRP's Code of Ethics (<http://www.icrp.org/docs/ICRP%20Code%20of%20Ethics.pdf>) – that mainly regulate the daily practice of ICRP as an organization – or in the IRPA Codes of Ethics (<http://www.irpa.net/members/IRPA%20Code%20of%20Ethics.pdf>) that “are intended to aid [RP professional] in maintaining a professional level of ethical conduct related to radiation protection.” Some of the procedural values, for instance would better fit in the codes of ethics rather than on the list of values and principles discussed in the upcoming publication.

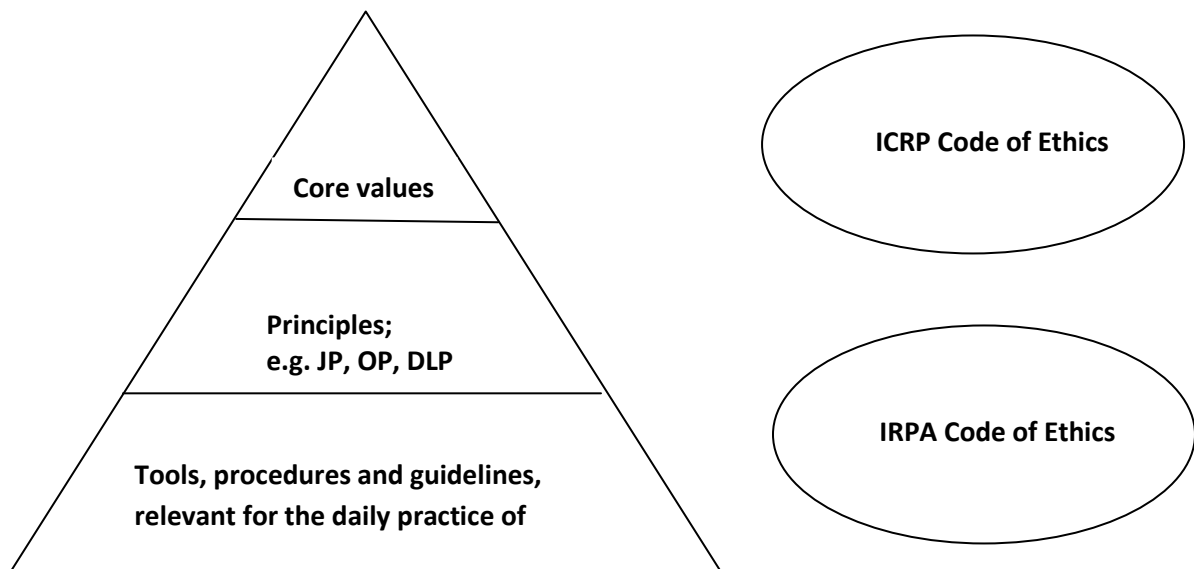


Figure 1: The categorization of the ethical issues raised by the group into the five categories listed

The Task Group has identified four /five key values, depending on whether we refer to beneficence/non-maleficence as two separate values or one central value. These values will be listed below, with ethical issues and considerations that the group connected to them listed under each value.

Core value 1: Dignity

- Dignity (core value) captures a lot of elements associated with procedural ethics
 - The Preamble of the UN's Universal Declaration of Human Rights (<http://www.un.org/en/documents/udhr/>) already emphasizes that “recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world”.
- Inclusiveness in decision-making for those who are exposed to potential risk

- Duty to inform
 - Specify complete and accurate information regarding risk (transparency)
 - To what extent should this be applicable in all circumstances? E.g. dental x-rays
- Empowerment
 - e.g. training of workers, restoring dignity after an accident, radon in homes
- Awareness: inform people, characterize the situation
 - It is for the sake of awareness and empowerment that there is a right-to-know
 - Existing procedures recommended by the RP system: stakeholder involvement, informed consent (implicitly implied is right to know), right to know (does not include consent)

Core value 2: Prudence

- Wider meaning: reasonableness, narrower meaning: precaution
 - Idea of careful deliberation
 - Collaborative? Covered in inclusiveness
 - Should prudence be a principle? (in addition to the existing three)
 - Precautionary principle (according to the Wingspread definition): “Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” The bottom line: sometimes it is wiser not to act.
 - ICRP 103: LNT model prudent basis
 - Para 36: LNT best practical approach; refers also to precautionary principle
 - Maybe prudence should be considered as a core value and precaution as a descriptor
 - Wisdom is discussed under ‘Prudence’, but ‘wisdom’ a virtue rather than a value.

Core value 3: Justice

- Intergenerational justice, although it could be mentioned under non-maleficence too
- Procedural justice: Participation
- Spatial distributive justice: Equity? (Equity, or rather avoiding inequity, is used in earlier ICRP-publications. Perhaps it is commendable to follow that language.)
 - Equity in ICRP: limit inequity in dose distribution; identify those in tail of distribution and bring them in the lower range of dose. Hence, according to this definition, avoiding inequity is putting justice into practice.
- Corrective justice?
 - Compensation for (a) wrong doing or (b) risk exposed to (e.g. paying citizens to drill on their land in shale gas mining)
 - Compensation doesn’t have to be legal/monetary fines
 - Word choice “compensation” (some believe that it has an association of doing something wrong for which one compensates) or “added value” as some nuclear waste management organizations have chosen (again other believe that added value give an inappropriate positive twist to compensation).
- Accountability: a notion of responsibility at the individual level
 - Who is responsible? (moral)
 - Who is liable? (legal)
 - Who is accountable?
 - Responsibility is already in the ICRP Code of Ethics
 - Something correlated with prudence? Component of reasonableness?

Core value(s) 4 (and 5): Beneficence versus non-maleficence

The group had a long discussion about the question as to whether i) these two values need to be acknowledged as two separate values, ii) they need to be considered together as one key core value, or iii) only beneficence should be acknowledged as a key value. Some of the participants believed that non-maleficence is a conservative and very limiting value. It could be easily misinterpreted that every activity that brings any kind of harm should be banned. This is not helpful in the daily practice of RP. However, as with medical ethics, in RP non-maleficence could best be interpreted in conjunction with beneficence. The radiation imposing practice is recommended because there is a net benefit (JP), but the non-maleficence warns us about potential harms. The group did not come up with a consensus opinion and wish to leave this as an open question for the TG.

— Tolerability (of risk) and reasonableness:

- To establish what is reasonable/tolerable have to go through balancing core values
- Tests of tolerability, reasonability should be formulated as a tool? As a way of applying principles
- Various ICRP publications exist on how to consider reasonability (early on, this was cost-benefit analysis)
- Reasonableness: inherent in optimization, Tolerability: inherent in limitation
- Need to be defined such that help people to act
- Reflection of the core values at the level of the principles, but still empty because it doesn't mean anything practically
- Leave as open the question to how to make 'useful' for practitioner
- Still up to RP professionals of a different kind to look at what is tolerable

Question 4: Should aesthetic values be included in the publication?

Over the last couple of years, radiographic pictures of humans have been used as art in various instances. The question is: to what extent should the new publication say something about the ethical desirability of such practice? The value at stake is 'respect for autonomy,' or in the spirit of the TG presented values, 'dignity'. Traditionally, one can say that only the use of radiation (x-ray) for medical purposes or for some industrial or security related screening (such as in airports) is justified. Perhaps, this issue relates more to conduct of practitioner in cases where x-ray use is restricted (e.g. In Japan you need to have a license to expose humans to radiation).

Question 5: How can the proposed system with values and principles be helpful in assisting practitioners? A case study: stress first versus stress only tests.

The case study was provided by Andrew Einstein (many come up at the American Society of Nuclear Cardiology meetings). This report does not aim to provide a detailed account of the case study. Rather, a very brief representation of the case is discussed, after which we will review some key ethical issues. Technical aspects of stress first versus stress only are considered in ICRP Publication 120.

Patients often visit physicians with chest pain or shortness of breath, indicative of coronary artery disease (which is the leading cause of death in the US and likely worldwide, 17 million people die worldwide from CAD). Benefits of improved cardiovascular prevention, diagnosis, and treatment (including use of ionizing radiation) have really led to a net benefit in public health and saving millions of

lives. The most common of the associated diagnostic tests is the nuclear stress test. A nuclear stress test involves a radiopharmaceutical taken up by the myocardium, which is then imaged and assessed. Initially the radiopharmaceutical is administered at rest and reflects different areas of the heart. The radiopharmaceutical will be administered again under stress, theoretically showing reduced blood flow to part of the heart under stress compared to that at rest. This comparison can reflect ischemia. Patient can get stint, etc.

There are two types of these tests: SPECT and PET. SPECT is the most common as cardiac PET is more difficult. PET radiopharmaceuticals have shorter half-lives than SPECT. Of the different protocols in SPECT, the most common radiopharmaceutical is Tc-99m (80% of 15-20 million nuclear med procedures performed worldwide), with a half-life of about 6 hours.

There are two different methods (with each a different protocol) for obtaining cardiac images.

- Method A: Most common protocol is a single day low dose, high dose Tc-99m protocol. The patient is injected with a modest dose of Tc-99m (~370 MBq) under rest conditions. The patient will rest 45 min to let the blood be redistributed and taken up in heart. SPECT images will then be obtained. The test will be repeated under peak stress conditions. Since the original radiopharmaceutical dose can “shine through” into your new stress images, a higher dose will be injected (~3-4X initial injection). The patient will be put on treadmill or bicycle. The second set of SPECT images will be taken and compared with the rest images. 75% of all stress tests performed this way.
- Method B: Stress test images will be obtained (370 MBq, treadmill right away) first. The benefit of this method is that if these images are normal, no rest images are needed. The physician needs to be there to interpret images. As it happens, often the rest test is needed.

Considerations:

Medical insurance pays more for doing method A (two injections) than method B (only one injection). Method B is much less commonly used; method B has more hands on, the physician has to be there in the middle of the day, etc. The great benefit of method B for the patient is that he/she will be exposed to less dose if no rest images would be needed.

Method A vs B: about 12 mSv vs 3 mSv (whole body)

Patients can undergo this test several times (sometimes on the order of a dozen or more)

- Non-Maleficence/beneficence
 - Method B should be preferred from the point of view of ‘non-maleficence’ (limit harm) as well as ‘dignity’ of patients. Yet, this method requires more time, the physician will receive less money and it will take away more time of physician from other patients.
 - Some would argue, RP not a paramount value at levels below 100 mSv. This is not sound reasoning and exactly what the value of non-maleficence would argue against
 - Test for good of the patient, limit harm as much as you can
- Prudence
 - Some would say no evidence for effects below 100 mSv (12 and 3 mSv considered equal) and thus no harm done (weak epidemiological evidence)
 - But prudence would choose B (in terms of patient), as A is 4X more risky (using LNT) (precaution)

- Prudence rebuttal to organizations that say no evidence at low doses etc.
- Most efficient for health care system? Prudence may choose A; doctor gets to see more patients, financially better for clinic
- Dignity
 - Interest of single patient
 - Patient not offered “menu” for A and B
 - Strike right balance in informed consent; is it really possible to give ALL information?
 - Getting away from the patriarchal system of doctor always knows best, as doctor interests might not always align with the best interests of the patient
 - Making citizens aware of different aspects of the problem – awareness
- Justice
 - Equity: fairness to compare radiation and non-radiation field. What is applicable in other fields of medicine? For example, chance of cancer vs chance of complication from surgery twenty year old woman (cancer risk greater) vs 80 year old man
 - Maximize use of resources for the greatest number of patients, etc.

Question 6: Should the publication address environmental protection as an ethical value?

When it comes to environmental protection, one can distinguish between the protection of the environment for the sake of people (an anthropocentric approach) or the protection of the environment for its own sake (a non-anthropocentric approach). The ICRP doesn't specifically say if it follows the anthropocentric or non-anthropocentric approach in protecting the environment. Current publications distinguish between protection of flora and fauna (not air, water, soils, etc). In environmental philosophy a different categorization is more common, namely, animals (individual animals versus species), plants and ecosystems. This issue needs to be included in the publication but not much new effort will be needed because other recent ICRP publication already addresses this issue.

Question 7: Should the publication talk about the radiation impact of the military practice or radiation protection in the nuclear security debate?

It is beyond the ICRP mandate to discuss whether or not to use (or to produce) nuclear weapons. This is a highly politicized discussion in which radiation protection will probably be a very minor issue. The IAEA treatment of the issue of security for nuclear materials has evolved in recent years. Similar to earlier developments in which ICRP fundamental thinking about safety has affected the IAEA's Fundamental Safety principles, the new publication on ethics of radiation protection could add something to the IAEA's the fundamentals of nuclear security, an issue fully in development at the IAEA. Here is a link to the IAEA's nuclear security publication series: <http://www-ns.iaea.org/security/nss-publications.asp>

Final thoughts, reflections and some recommendations

Here are some remaining thoughts, reflections and recommendations that were raised by the workshop participants.

- It should be considered to include a few case studies in the publication.
 - Case studies proved to be very helpful in discussing the ethical issues at hand.
 - Case studies include practical, integrated examples and they illustrate the interactions of ethical values and principles. They can help practitioners to understand what values mean to their daily practice.
 - Case studies could also help communicate with the general public.
- Ethics should be included in the training of practitioners. See also the recommendation under Question 2 (The aim of this publication).
- In a future event, it is advisable to organize at least one public event in conjunction with this kind of specialized workshop. Also in this workshop a public event would have been warmly welcomed by the Harvard Kennedy School community. This is in line with the aim of the publication to communicate with the general public (or with people outside the practice of radiation protection).
- The TG should aim to have a very accessible *executive summary*. Extended philosophical discussions may make the publication less accessible, so that perhaps any elaborated philosophical discussion could be shifted to an appendix.
- It is advisable that some thinking of the TG would be presented at different radiation protection or applied ethics conferences. For instance the biennial Society for Philosophy of Technology conference in Shenyang (China) in July 2015 would be a great place for such exercise: <http://spt2015.neu.edu.cn> . Another opportunity is the 3rd Symposium on Ethics of Environmental Health that Friedo Zölzer is planning to organize in Budweis (Czech republic) in September 2016.