

IRPA North American Workshop on the Ethical Dimensions of Radiological Protection

“Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom.” L. S. Taylor, 1956

The International Radiation Protection Association is pleased to announce the first North American Workshop on the ethical dimensions of the radiological protection system. This workshop, sponsored by the Health Physics Society, the Canadian Radiation Protection Association and the Sociedad Mexicana de Seguridad Radiologica will be held in Baltimore, Maryland on July 17-18, 2014, immediately following the 59th Annual Meeting of the Health Physics Society at the Hilton Baltimore hotel, 401 West Pratt Street. The Workshop will begin at 1:00 pm on Thursday, July 17, and conclude at 5:00 pm on Friday, July 18. Registration information is available on the IRPA web page (www.irpa.net).

IRPA has been requested by the ICRP to support the latter's initiative on the philosophy, and in particular the ethics of radiological protection. Consequently IRPA has organized a series of international workshops on the ethical dimensions of radiological protection in order to gather comments, experience, and suggestions from its Associate Societies that will support the development of a guidance document. (This process was successfully used to develop the IRPA Guidance Document on Radiation Protection Culture.) Workshops have already been held in Asia (Daejeon, Korea) in August 2013, and Europe (Milan, Italy) in December 2013. These workshops featured presentations on the subject from various perspectives, followed by breakout sessions to develop suggested positions on the various issues. The ICRP has created Task Group 94 under Committee 4 (Application of the Commission's Recommendations) to develop an ICRP publication on the ethical dimensions of the radiological protection system, and a draft for review is planned to be completed by the end of 2015. The input from IRPA will be an important contribution to this document, representing the views of the global radiation protection profession.

Some issues that have emerged from the first two workshops are that although the ethical foundations of the ICRP principles of Justification, Optimization, and Limitation are consistent with the major Western philosophical traditions including utilitarian ethics (Hume), deontological, or duty ethics (Kant), and virtue ethics (Aristotle), and with the Eastern philosophical traditions of Confucianism, there is no clear and comprehensive description of the ethical basis for the radiation protection system that can be applied globally. An issue that emerged from the Fukushima Dai-Ichi nuclear power plant accident is that in a given situation, especially an emergency, ethical principles can be in conflict. Although the assumption of the linear no-threshold model is based on the virtue of prudence, its application may lead to violations of the principles of respect for personal autonomy and dignity. It may also result in the imposition of a real risk of premature death to avert a potential risk, such as occurred in the evacuation of elderly and ill persons from the fallout zone. This appears to have violated a fundamental principle of medical practice: first, do no harm. On the other hand, if this population were not evacuated, would the rights of caregivers to avoid an involuntary potential risk be violated? Obviously such questions are not easy to answer.

Six hours of continuing education credit (2 per half-day) have been granted by the ABHP for attendance. Breakout sessions are scheduled to focus on the areas of regulations, medical applications, and public communications. However, other topics may be added to or replace these if attendees desire. IRPA Treasurer and HPS Past President Dick Toohey is the coordinator for this workshop, and may be reached by email at either retoohey@comcast.net or treasurer@irpa.net. There is no registration fee.

The program for the North American Workshop is as follows:

Thursday, 17 July:

1:00 Welcome and Introduction	R. Czarwinski, IRPA
1:30 Introduction to the Ethical Foundations of the RP System	J. Lochard, ICRP
2:00 The Ethics of RP: Philosophy, Values, and Practical Challenges	C. Clement, ICRP (Presented by R. Toohey, IRPA)
2:30 Basic Principles of Biomedical Ethics	C. Kurihawa, NIRS
3:00 Break	
3:30 Ethics of RP in Medicine	R. Vetter, Mayo Clinic
4:00 Ethics of RP in Public Communications	R. Johnson, RSCI
4:30 Standards of Professional Responsibility for CHPs	E. D. Bailey, AAHP
5:00 Assignments and Goals for Breakout Sessions	R. Toohey, IRPA

Friday, 18 July:

8:30 Continental breakfast	
9:00 Breakout Sessions (Medicine/Public Communications)	Session Leaders
10:30 Break	
10:45 Breakout Sessions	Session Leaders
12:00 Lunch (on your own)	
1:30 Reports of Breakout Sessions	Session Leaders
3:00 Break	
3:30 Development of Conclusions and Recommendations	R. Toohey, IRPA
5:00 Closing of Workshop	R. Toohey, IRPA

MEDICAL Discussion Group report:

The primary issues in medical applications of radiation are considerations of worker dose to the practitioner vs. patient care, risk communication to both workers and patients, and stakeholder engagement in Medicine.

The hospital area where radiation exposure is a primary concern is the fluoroscopy laboratory, i.e., interventional radiology, including interventional procedures, coronary angiography, and angioplasty. Except for some PET radiochemistry laboratories, nuclear medicine and radiation oncology practices do not result in high worker exposures.

Most people in the interventional radiology suite are not highly exposed, but those who are exposed can be highly exposed. The eyes are particularly difficult to protect; worker time in the laboratory can be 8 or more hours per day; photons can “wrap around” protective lenses due to scattering; and specialists in certain procedures are in high demand. Regulations do not allow worker exposure limits ever be deliberately exceeded. However, the group suggested that it would be ethical, if tissue reaction limits are not exceeded, that the stochastic limit be raised, but only if the worker (i.e., the interventional radiologist) signs an informed consent (or similar) document. The procedure may be related to a life saving treatment or extend the life of the patient, which justifies raising the stochastic limit of the radiologist if he/she is informed and willing. Could that also apply to others in the suite, such as nurses, technologists, and anesthesiologists? That is not so clear, as they could be under “coercion,” i.e., trying to keep their jobs to agree to a raised exposure limit.

In general, a “fixed, defined limit is appropriate in any situation where the stakeholder cannot give informed consent” (e.g., public exposures, or subordinate workers.)

So how much of an increase could be ethical? Any new (raised) limit should still be protective of tissue reaction effects. The increased risk should remain comparable to risks in hazardous industries such as construction, mining, agriculture, but be less than risks in extremely hazardous occupations, such as space travel. The limit should also consider previous exposure and age. The dose limits for emergency responders based on activity (lifesaving, property protection, etc.) could be used as a model. Should we change the risk equation from risk of mortality to risk of injury? Hospital employees have a low mortality risk but a high injury risk, e.g. nurses have a high risk of needle sticks and back injuries. Can this exception through informed consent be applied to other occupations, e.g. industrial radiography? Could evacuation be voluntary in an emergency situation, i.e. could evacuees choose their own action level? What about early return to an evacuated area? Could people choose their own risk level for returning to their homes?

Is it ethical to have different limits for different professions? If so, can we allow professions to set their own limits (perhaps as long as an “upper bound” limit is not exceeded)?

How do we maximize autonomy and minimize coercion? Should a physician receive a financial incentive for treating more patients, which results in exceeding the regulatory radiation worker limit? Does the system of RP have the right to limit autonomy in order to limit coercion?

Can we ethically limit release of radioiodine therapy patients? Yes, because of public health concerns. Instructions are given to released patients on limiting exposure to members of the public (e.g. avoid public transport) but are not enforceable; should the hospital provide the service needed (e.g., transportation home) and fold the cost into the cost of the procedure? Government has the right to overrule individual autonomy to protect public health as in the quarantine of patients with infectious diseases. Some studies suggest that 95% of patients follow release instructions, but 5% do not. We can

maximize the autonomy of the patient by using patient-specific dose rate calculations rather than the administered/retained activity; but we also need to look at cohabitants. What about the public? There is implied informed consent for all kinds of hazards, e.g. vehicle accidents, and the person seated next to you on the bus may have influenza. Second-hand tobacco smoke is not regulated everywhere. In general, restrictions placed on autonomy are commensurate with risk.

Both the treating physician and the patient have a duty to the public to minimize risk, by providing and following release instructions to minimize public exposure. In tort cases, there are three elements of neglect: actual harm (non-maleficence), duty owed (prudence), and proximal cause (patient not following instructions.)

Should limits protect the most vulnerable? Who is that? It is the elderly for tissue reaction effects, and children for stochastic effects. Ataxia-telangiectasia patients are the most sensitive to radiation effects, but comprise a very small number of people; some genotypes, e.g. BRCA1,-2 positive or other genetic indicators are similarly more sensitive. An annual exposure limit of 1 mSv, divided by the hours in year (8,766) and multiplied by the hours of exposure presents a negligible risk.

In the United States stakeholder engagement is built into the regulatory process, through the Advance Notice of Proposed Rulemaking (ANPR), public comments and hearings, stakeholder meetings, etc. Consumer groups also follow the process of rulemaking closely. Societal and cultural differences in other countries may limit this process elsewhere.

Exceeding a limit must be fully justified and demonstrated to be unavoidable. How could it be implemented in practice? Would it also require enforcement of dosimeter wearing to record the increased exposure? If an option exists to exceed the regulatory limit, motivation for not wearing the badge is decreased. Although a financial reward may exist for exceeding the limit, the motivation is often the ethical requirement of providing the best therapy to the patient. Recording and record maintenance of previous exposure is very important in the context of permission to exceed the limit.

Use of informed consent would add flexibility to the RP system: patient informed consent is needed for radiation exposure; emergency responders are under consideration for informed consent, but not considered for other occasions. The Fukushima Dai-ichi nuclear power plant accident showed that people could stay in contaminated areas with informed consent. We have to look very carefully at other situations to ensure that coercion by financial incentives does not interfere with informed consent.

Regulatory implementation could be extremely difficult; it is easier if there is a clear conflict between not exceeding the dose limit and saving (or prolonging?) life. A change to allowing limit exceedance via informed consent would introduce variability and inconsistency; can it be extended to other areas where worker exposure is not so clearly linked to life-saving?

There is always a problem when comparing RP with other occupational safety issues: generally there is a very different level of risk involved than with electrical safety, working at height, etc. Conditions of urgency or unavailability of resources also change things. Standards for some occupational risks are actually mandated at a lower level than RP, so comparison with other industries may not be so bad.

We need to pay attention to total risk; higher risk limits in an emergency situation reflect an exceptional situation; is it really transferable to a non-extraordinary situation?

In the United States the old occupational exposure limit of 3 rem/quarter and the 5(N-18) system (where N is the worker's age in years) allowed this flexibility; current defined annual limits do not.

There has been no discussion in developing the RP system of differences between medical practice and other occupations; because of consideration of patient benefit and risk vs. practitioner benefit and risk, we need to take a look and revisit the situation. The medical ethic of patient care will always take precedence over the ethic of worker RP. We are trying to apply a system developed outside the medical system to it; the limits are so far below the level of demonstrable effects that they are not comparable to risks from not treating the patient.

In the United States, if it is absolutely necessary to exceed limit the public dose limit in the care of a hospitalized family member treated with radioiodine, the hospital can call NRC or state regulator for an exemption. An exemption request has probably never happened with patient release. However, it has been considered for certain caregivers/relatives of critically ill patients.

Communication Discussion Group report:

Preamble: believing that workers and the public have a right to know about rad risks and to understand radiation and the principles of radiation safety, the group recommends that:

1. Communication must be clear and understandable in the common language
2. Communication should facilitate informed decisions by institutions and individuals
3. Communications should include science, values (ethical, social, political and cultural) and experience
4. Communications should convey prudent and reasonable options for action
5. Communications should occur early and preferably before an incident
6. Communications should explain the benefits of options
7. Communicators should be a resource to help people make informed decisions
8. Communicators should hear and reflect concerns, fears and feelings
9. Communications should be truthful, accurate, open, impartial, and honest, and tell what we know and also what we don't know.
10. Communications should recognize and respect differences
11. Communications should foster rapport and help develop trust
12. Communications should convey the prevailing standards
13. Communicators should provide a service to different publics, groups and organizations
14. Communications should be low cost or free
15. Communications should bridge from cause to effect

Discussion:

In general, the RP expert is not the decider, but rather helps deciders to make informed decisions. Communications start with the prevailing current circumstances and reality of the situation.

The objectives of a communications effort cannot include building trust, because that can only be built over a long period; trusting does not necessarily include agreeing with us. However, the communications effort helps to develop trust, and if poorly done, can destroy trust.

Communications must assist people to make decisions; it is much more than just risk communication focused on data. One aim is to enhance the RP culture that focuses on safety; risk communications is only a part of the whole. We have put too much focus on the risk; we need to increase focus on protection methods, self-help, and empowerment. We must provide actionable information.

Who is the public? The public is anyone who is not an RP specialist. We must target communications to the target group and tailor messages to the audience's level of wealth, education, etc.

The ethical principles of dignity and autonomy apply to generate the public's "right-to-know"; communications should provide the public the skills to apply RP principles to self- and community protection.

Communicating probabilities usually doesn't help, especially very small probabilities; in fact, risk acceptance is usually independent of the probability. In Japan people want to know the risk probability of 10-20 mSv exposures; RP experts may say the risks are too small to be of concern, but people do not understand. Some experts think a 20 mSv exposure is too risky for children, and dueling experts increase anxiety.

Do we understand cultural issues (including religion) well enough to incorporate them effectively in RP communications? Probably not, but efforts such as the recent environmental ethics conference in Budweis, Czech Republic are improving our understanding.