

IRPA North American Workshop on the Ethical Dimensions of Radiological Protection

Sponsored by the Health Physics Society, the Canadian Radiation Protection Association and the Sociedad Mexicana de Seguridad Radiologica, held in Baltimore, Maryland on July 17-18, 2014, following the 59th Annual Meeting of the Health Physics Society at the Hilton Baltimore hotel.

Basic Principles of Biomedical Ethics: Reflecting upon what's happening in Fukushima

Chieko Kurihara,
Member of TG94, Ethics of radiological protection, ICRP
Senior Researcher, Regulatory Science Research Program,
Research Center for Radiation Protection;
Quality Assurance and Standardization Section,
Planning and Promotion Unit, Molecular Imaging Center,
National Institute of Radiological Sciences (NIRS)



- 1. Consideration of principles of biomedical ethics and radiological protection (RP)**
- 2. Workshop products and cross cultural considerations of ethical/RP principles**
- 3. Ethical consideration of actual issues happening in Fukushima**
- 4. Discussion and conclusions**

1. Consideration of principles of biomedical ethics and radiological protection (RP)

2. Workshop products and cross cultural considerations of ethical/RP principles

3. Ethical consideration of actual issues happening in Fukushima

4. Discussion and conclusions

Belmont Report (1979, United States)

A: Boundaries Between Practice & Research

● Practice

- designed solely for the well-being of an individual patient

● Research

- designed to test an hypothesis to generate generalizable knowledge, for the merit of future patients

B: Basic Ethical Principles

● Respect for persons

- Autonomy, self-determination
- Protect those with diminished autonomy

● Beneficence

- Nonmaleficence
- Maximize benefit, minimize harm

● Justice

- fairness in distribution of risk of research and benefit of research results

C: Applications

- Informed consent
(information, comprehension, voluntariness)
- Surrogate consent
- Avoid undue influence

- Risk-benefit assessment

- Selection of subject (Avoid to involve vulnerable people in risky research; and to provide benefit of research results to wealthy people)

Autonomy

Basis of the principle

- “**Respect for person/Autonomy**”, derived from “**human dignity**” (Kant), regarded as “absolute value”. (Common for people of Buddhism, Confucianism, Islam, but description of the way to realize the virtue seems to be various.)
- States have an obligation to promote **human rights** and **freedoms**, derived from human dignity (UN Declaration of Human Rights; International Convent on Human Rights, concluded through debates among people of various religious, cultural background).
- “**Informed consent**”, derived from “autonomy”, elements of which are information, comprehension, voluntariness; may be individual-, family-, or community-based, up to culture and/or situation.

Autonomy

Discussion around the principle

- Questions concerning to “human dignity”: (1) How about the people **incapable** of autonomous decision-making?; (2) How about human **fetus, embryo**? (3) How about the **animal rights, animal welfare, and environment**?
- Belmont report and other international ethical norms respond to the questions: (1) “Persons of **weak autonomy** and people under **undue influence (vulnerable populations)** stand to **additional protection (surrogate consent** ; system to avoid undue influence) ; (2) (3) rights or welfare of human fetus and embryo; or animal are still controversial in bioethics; meanwhile, RP already covers animal and environments.
- Ethical consideration on genetic research generated the idea of “**right NOT to know**” as well as “right to know”.

Autonomy

Ethical principle and RP system

- ICRP recommendations mentioned about **decision-making** issue, in Pub. 109, for emergency, 111, for existing, at the level of state, community, individual person; considering not only scientific issue, but also social, cultural, and individual preference. We need considerations more in depth in light of human dignity, human right, autonomy, in various cultural contexts.
- Difficulties remain in community-based decision-making in disintegrated communities (compulsory evacuation).
- You need more considerations about additional protection of vulnerable populations, in the context of, e.g., (1) State/ community based decision-making of acceptance of NPP; (2) Elderlies/children's decision-making of evacuation (emergency)/returning (existing).

Beneficence

Basis of the principle

- “Beneficence” and “Nonmaleficence” in (Hippocratic Oath)
“Maximize benefit, minimize harm” (justification in RP).
- Application of this “beneficence” principle is “risk-benefit assessment”. (optimization in RP).
- Risk-benefit assessment should be scientific evidence-based; but decision-making inevitably includes social, cultural, and individual preference (autonomous decision-making at the level of state, community, individual person).

Beneficence

Discussion around the principle

- There is a criticism to “beneficence” among bioethicists, as it may lead to **paternalism**. (Benevolence “Jin” in Confucianism “Jihi” in Buddhism: precious concept, but sometimes regarded as paternalistic).
- Some of bioethicists emphasis “**right of taking risk**”. This double-edged concept may be used as excuse for the sake of “risk acceptance”.
- There have been debates between people of views of **deontology** and **utilitarian** in balancing “human rights” and “risk-benefit assessment”.
- In many cases insufficient or improper scientific knowledge management has caused confusion.

Beneficence

Ethical principle and RP system

- 3 principles of RP seemed for me to be mainly included in this “beneficence”.
- A problem of RP seems to be the culture of too-much focusing “risk-minimization” so that sometimes “more than minimal risk” may not be sufficiently informed to stakeholders.
- Another problem of RP is the trend to analyze radiation risk independently, without comparing/integrating with other risks of health, before considering socio-economic, cultural issues.

Justice

Basis of and discussion of the principle

- Aristotle described 2 categories of justice:
 - **distributive justice** (Belmont Report);
 - **corrective justice** (Compensation).(May different description in Islamic)
- In the latter half of 20th century, Rawls, Harbaramas, Sen have developed the idea of “justice” toward the directions of more protection of vulnerable populations (people of poverty); whereas other theoreticians have advocated toward the directions of “**libertarians**” (rich country’s democracy).

Justice

Ethical principle and RP system

- Site location of NPP and nuclear waste disposal.
- **Resource-poor** communities accept NPP and/or waste disposal, induced by economic “**undue influence**” (subsidy, working opportunity: undue influence? Justifiable reward to taking risk?). Benefit is shared equally by the nation.
- Some of the people enjoying benefit (at the sacrifice of resource-poor communities) are reluctant to accept the evacuees and/or food-shipping from Fukushima.

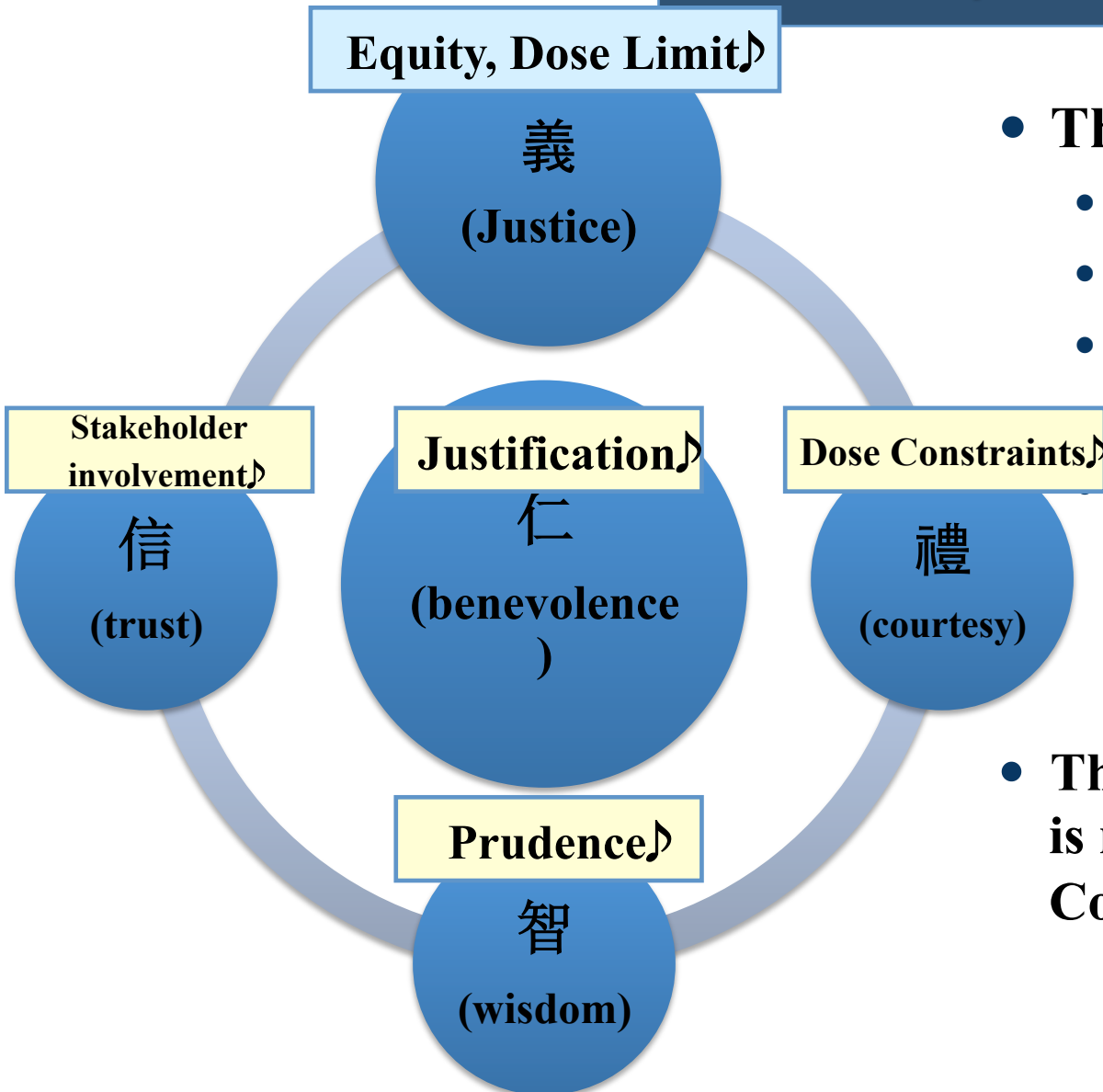
1. Consideration of principles of biomedical ethics and radiological protection (RP)

2. Workshop products and cross cultural considerations of ethical/RP principles

3. Ethical consideration of actual issues happening in Fukushima

4. Discussion and conclusions

The value system of Classic Confucianism



- **The five virtues:**
 - Benevolence
 - Righteousness/justice
 - Courtesy (Propriety, Manners)
- Wisdom
- Sincerity/trust

- **The traditional ethics in China is mainly derived from Classic Confucian thought.**

Courtesy of Mr. Senlin Liu, ICRP C4
& slightly modified by K. Cho, ICRP C4

Permitted to quote from the presentation slide by K Cho, at the 1st European Workshop on the Ethical Dimensions of the Radiological Protection System, 16-18 December 2013, Milan, as a part of the summary of 1st Asian Workshop on the Ethical Dimensions of the RP System, 27-28 August 2013, Daejeon

Final Comments on future steps

- Problems in the Fukushima accident were **mainly in implementing the RP system**, rather than in weaknesses of the system itself.
- RP experts had not embraced **the human dimension** of the implementation of the system.
- **If the ethical basis is clarified** then it would help clarify what the objectives of the system really are.
- **Eastern philosophy**, despite having no numerical values, may offer solutions to ethical issues in the RP system.
- Concept of **wellbeing and dignity** is worth exploring further and called for interdisciplinary research with bioethics including comparison studies.

Summary of the European Workshop

Important principles found in 3 groups discussions

- 1) Courtesy for **dignity** and **autonomy**, in the sense of respect for individuals and ensuring stakeholder engagement.
- 2) Benevolence for **beneficence** and non-maleficence, to maximise benefits and minimise harm
- 3) **Justice** mainly to cope with intergenerational issues and less advantaged individuals, equity, solidarity, proximity,
- 4) **Wisdom** for **prudence** and precaution , in a wide view
- 5) **Honesty, transparency**, accountability, shared vigilance to lead **trust**
- 6) **Wellbeing** in reference to the WHO concept.

(For each, associated to the values of classical Confucianism)

Most important: Dignity

Ethical values in implementing the system; Vigilance; Justification; Deliberation and democratic process

Important message:

- The ICRP RP system is well-constructed itself, however, social, ethical values should be more considered for its implementation.
- For the most important value, **dignity, protection of vulnerable population (e.g. children, elderly) should be emphasized.**



Organized by Marie-Claire Cantone,
University of Milan

My findings through Asian, European WS

Aug 27-28 2013 Dec 16-18 2013

Principles of bioethics

“Georgetown Mantra”

Dignity Autonomy Informed consent Human right Well being	Beneficence Do no harm Minimize risk Risk-benefit assessment	Justice Equity Fairness Transparency Accountability
---	---	--

Kurihara C. Research ethics and radiological protection: Reflecting the discussion at the Japanese Society of Radiological Technology Meeting. Japanese Journal of Radiological Technology. 2011; 67(6): 683-90.

Before the Asian WS

It seemed that 3 of RP principles are all related to Beneficence of bioethics, especially “too much prudence” (minimize risk) cause distrustfulness.

Justification
Optimization
Limitation
RP principles

My findings through Asian, European WS

Aug 27-28 2013 Dec 16-18 2013

RP principles

Principles of bioethics

“Georgetown Mantra”

Justification

Optimization

Limitation

Dignity
Autonomy
Informed
consent
Human right
Well being

Beneficence
Do no harm
Minimize risk
Risk-benefit
assessment

Justice
Equity
Fairness
Transparency
Accountability

At the end of European WS

I found that all the RP principles can/should be related all the bioethics principles, i.e., all the ethical principles should be implemented in RP system and actual situations.

My findings through Asian, European WS

Aug 27-28 2013 Dec 16-18 2013

RP principles

Principles of bioethics

“Georgetown Mantra”

Justification

Optimization

Limitation

Dignity
Autonomy
Informed
consent
Human right
Well being

Beneficence
Do no harm
Minimize risk
Risk-benefit
assessment

Justice
Equity
Fairness
Transparency
Accountability

At the end of European WS

I found that all the RP principles can/should be related all the bioethics principles, i.e., all the ethical principles should be implemented in RP system and actual situations.

Bioethics as “Supra-interdisciplinary”

By Kimura R, one of the world founders of bioethics (engaged in the creation of G. Mantra)

-Bioethics as a prescription for civic action: The Japanese interpretation. *The Journal of Medicine and Philosophy*. 1987; Reidel Publishing Company. pp.267-77.

My findings through Asian, European WS

Aug 27-28 2013 Dec 16-18 2013

RP principles

Principles of bioethics

“Georgetown Mantra”

Justification

Optimization

Limitation

Dignity
Autonomy
Informed
consent
Human right
Well being

Beneficence
Do no harm
Minimize risk
Risk-benefit
assessment

Justice
Equity
Fairness
Transparency
Accountability

At the end of European WS

I found that all the RP principles can/should be related all the bioethics principles, i.e., all the ethical principles should be implemented in RP system and actual situations.

Bioethics as “Supra-interdisciplinary”

By Kimura R, one of the world founders of bioethics (engaged in the creation of G. Mantra)

-Bioethics as a prescription for civic action: The Japanese interpretation. *The Journal of Medicine and Philosophy*. 1987; Reidel Publishing Company. pp.267-77.

Seeking for common ground with other various religious, cultural background.....

ICRP Special Session: "**Ethical Dimensions of the Radiological Protection System**", May 14, 2014, Kuala Lumpur Room, Malaysia, In: The Fourth Asian and Oceanic Congress on Radiation Protection (AOCRP-4), Chaired by: Christopher Clement, Azleen binti Mohan Zain



Implementation of IAEA-BSS;
Bases of human dignity,
human rights, equality,
freedom, in the sense of
modesty and neutral.

Nation must combat liberalism and human rightism

Threat: It's a way of thinking that goes against Islamic teaching, says PM (Prime Minister of Malaysia) New Straits Times May 14, 2014

PRIME NEWS

'Nation must combat liberalism'

THREAT: It's a way of thinking that goes against Islamic teachings, says PM

T.N. ALAGESH
Kuantan
news@nst.com.my

"HUMANRIGHTISM", a liberal way of thinking that places human rights and secular law above religion, has to be addressed swiftly as it is against Islamic teachings, said Prime Minister Datuk Seri Najib Razak.

He said such a way of thinking, which had been accepted as a new way of thinking, was being spread rapidly in Malaysia. He said it was a threat to Muslims, as it rejected Islamic teachings. (Those who subscribe to such liberal thinking) do everything, claim to be Muslims, but they do not follow Islamic teachings.

"This a deviant (way of) thinking and a threat, which is dangerous to

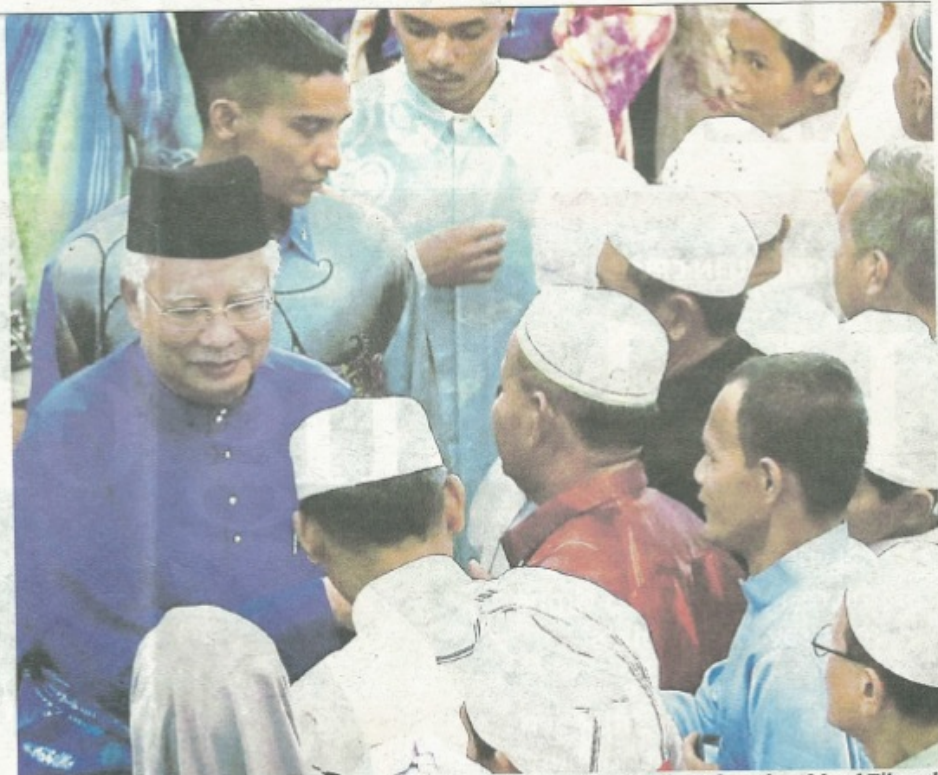
Najib said this in his speech at the opening of the 57th national-level Tilawah Al-Quran competition, themed "Wasatiyyah Tonggak Kesatuan Ummah" (Moderation is the Pillar of Muslim Unity), at Dewan Jubli Perak here last night.

Present were Najib's wife, Datin Seri Rosmah Mansor, Menteri Besar Datuk Seri Adnan Yaakob, Minister in the Prime Minister's Department Datuk Seri Jamil Khir Baharom and state Mufti Datuk Abdul Rahman Osman.

Najib said Malaysia was an Islamic country and that Islam played a vital role in uplifting *maqasid syariah* (the implementation of syariah based on the Quran and Sunnah).

He said the government prioritised the rights of every individual, regardless of skin colour or religion.

Twenty-eight male and 13 female reciters from various states and the



Prime Minister Datuk Seri Najib Razak meeting the people after officiating the 57th national-level Tilawah Al-Quran competition in Kuantan yesterday. Pic by Luqman Hakim Zubir

Najib: Big revenue gains from GTP, ETP

KUALA LUMPUR: Prime Minister Datuk Seri Najib Razak yesterday

introduced to spur progress in Malaysia, with the aim of achieving

we are on the right track to achieve this aspiration," said Najib in a Face-

More non-Western religious, cultural perspective should be included in our consideration of RP and ethics.

Buddha in Temple in Kamakura, with
Taiwaneese psychiatrist, psychologist (his
wife)



Recent discussion on informed consent

PET brain imaging study involving elderly subjects, planned to compare brain tissue after the death of the subjects. Should this objective be clearly explained at the first IC process?

Western: “must be”

Asian: “may be sometimes difficult; can be explained after the inclusion of PET imaging study.”

In Taiwan, Human Research Act to cover whole human research was developed reflecting on the research “insufficient” informed consent about the real objective of the genetic research to identify the characteristic of minority people. “This is the issue of equality.”

- Fundamental ethical principles (human dignity, human right, beneficence, justice, equality..) would be common in the world people.
- Also RP principles (justification, optimization, minimization) would be robust and common for all, like ethical principles.
- However, description of these principles and implementation in real life (especially in cases of emergency and existing situation) may be very much different, so we have to be careful about these diversity.

- 1. Consideration of principles of biomedical ethics and radiological protection (RP)**
- 2. Workshop products and cross cultural considerations of ethical/RP principles**
- 3. Ethical consideration of actual issues happening in Fukushima**
- 4. Discussion and conclusions**

2. Ethical consideration of actual issues

happening in Fukushima

Topics discussed at the
Milan Workshop

- Characteristics
- Logistics
- Communication
- Evacuation and returning
- Compensation
- Survey and research
- Conflict of interests
- Future perspectives

2. Ethical consideration of actual issues

happening in Fukushima

- Characteristics

- Logistics

- Communication

- Evacuation and returning

- Compensation

- Survey and research

- Conflict of interests

- Future perspectives

Topics discussed at the
Milan Workshop

Focuses of today's
discussion

2. Ethical consideration of actual issues

happening in Fukushima

- Characteristics

- Logistics

- Communication

- Evacuation and returning

- Compensation

- Survey and research

- Conflict of interests

- Future perspectives

Topics discussed at the
Milan Workshop

Focuses of today's
discussion

Briefly mention these
topics in Discussion
part

Characteristics

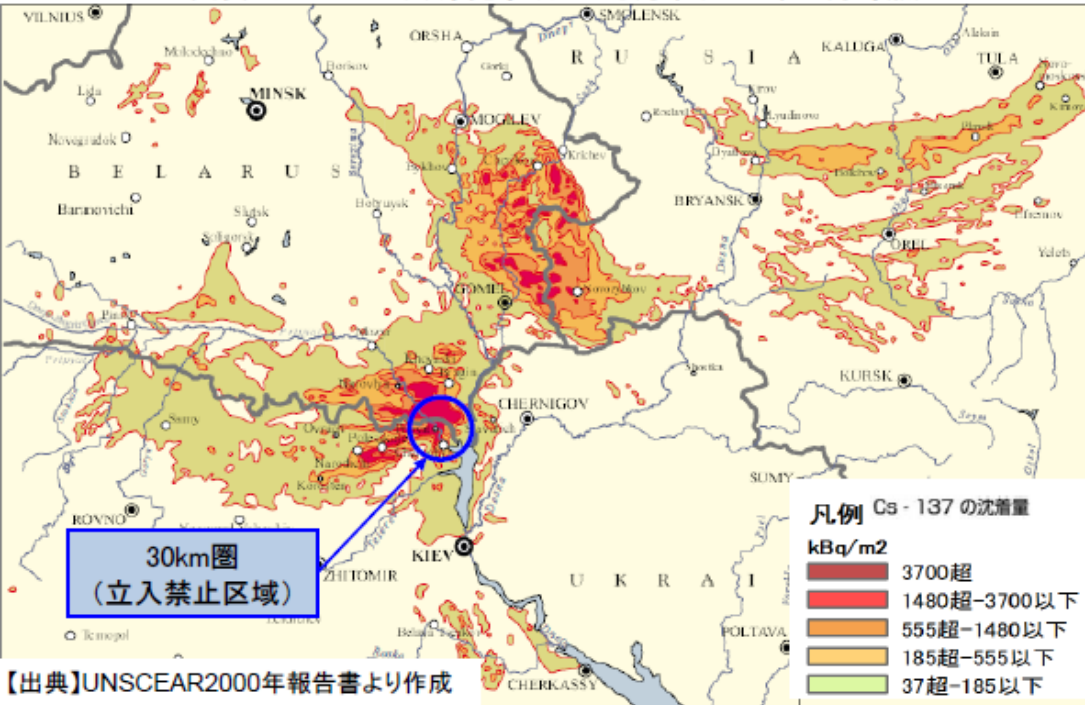
FUKUSHIMA NPP Daiich Accident:

“Level 7” accident,
caused by natural disaster,
25 years after Chernobyl
and first experience of
such high level of disaster
in the era of “social media”
and in a matured democratic,
free and open society,
with experiences/memories
of Hiroshima, Nagasaki.



Characteristics

図表 チェルノブイリ原発事故による汚染(1989年12月時点)

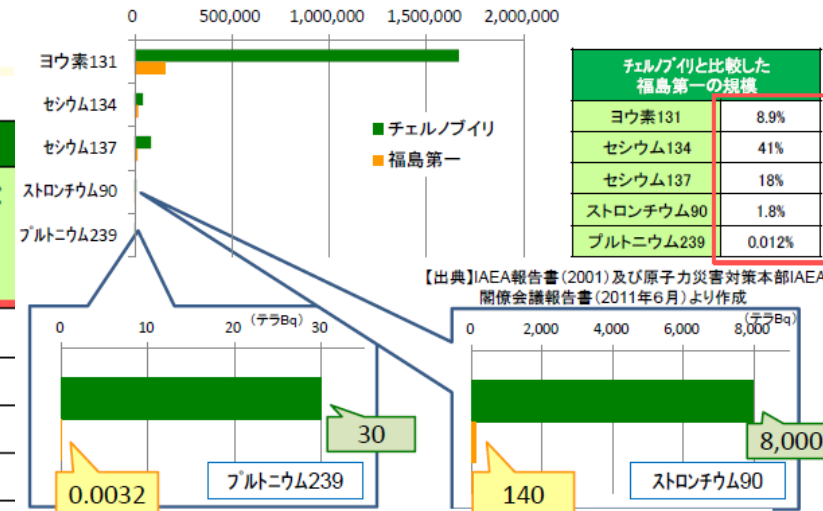


Comparison of contamination with the case of Chernobyl

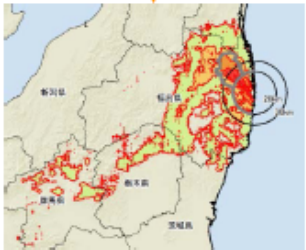
図表 汚染地域の面積

汚染濃度 (kBq/m ²)	汚染地域の面積(km ²)		
	チェルノブイリ 原発事故	東電福島 第一原発 事故	チェルノブイリと 比較した 福島第一 の規模
> 1,480	3,100	200	6%
555 - 1,480	7,200	400	6%
185 - 555	18,900	1,400	7%
37 - 185	116,900	6,900	6%
合計面積	146,100	8,900	6%

図表 放射性物質の放出量
テラBq (※テラ=1兆)



両図を同縮尺
で記載



図表 東電福島第一
原発事故による汚染
(2011年11月時点)

Communication

Fundamental problem:

- Lack of timely, valid information disclosure by Government and TEPCO caused fundamental distrust to them of people.
- Lack of logistics of government and knowledge of people about the standards/recommendations of IAEA, ICRP. (or lack of trust to them because of criticisms about the relationship with NPP or Nuclear arm industries)

Expansion of knowledgeable lay-experts:

- Knowledgeable lay-experts, learning from anti-nuke experts (of fundamental anti-nuke (weapon) society), have been communicating about radiation risk, making use of social media, many of them having their own Geiger counters.

Communication

Most prominent communication gap:

- Reference level

1mSv/y → 20-100 mSv/y (emergency)

→ 1-20mSv/y (existing)

Criticism: Why highest (20mSv) in 1-20mSv?

- Radiation risk in low doses and LNT model

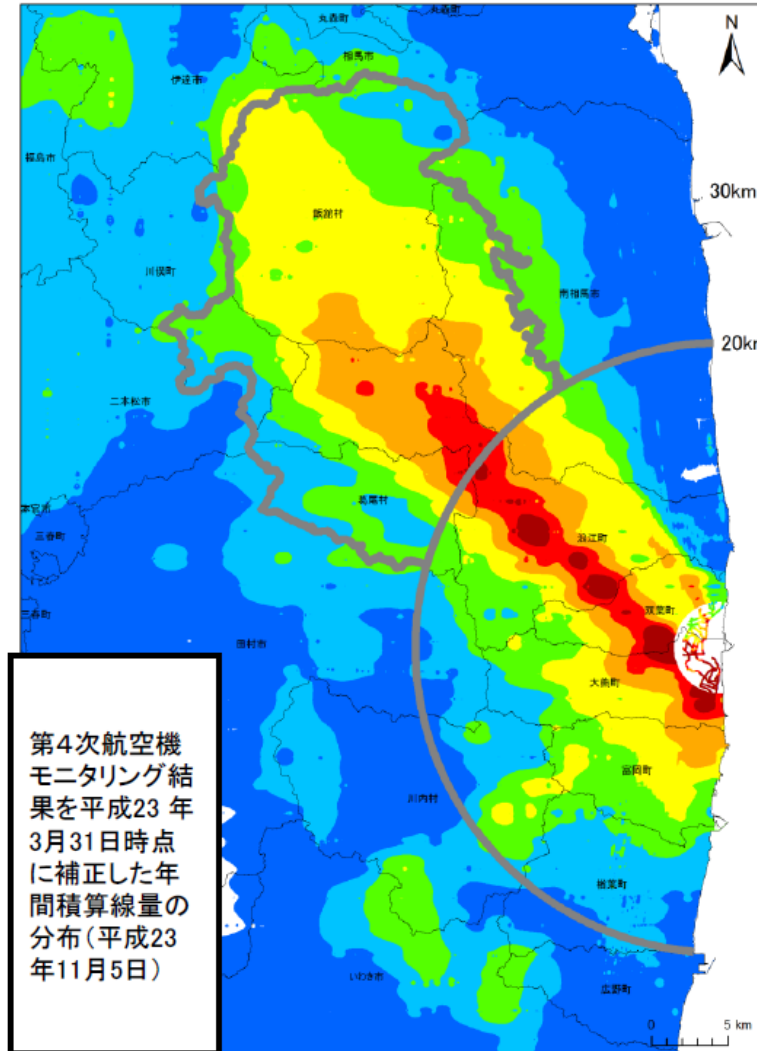
Never ending pros & cons

< 100mSv

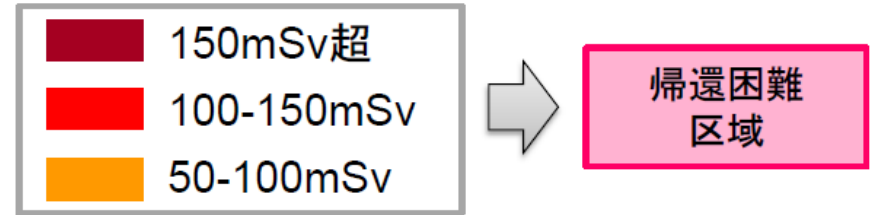
RP specialists, including NIRS, have been criticized by not only anti-nuke activists, but also by epidemiologists, ethicists.

Evacuation and returning

(参考) 空間線量から推定した年間積算線量に応じた3つの区域への見直し



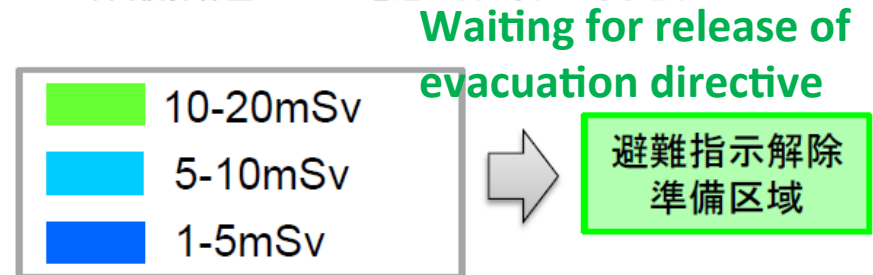
The districts with zones more than 50 mSv/y are designated where people should not return.



----- 5年経過してもなお、年間積算線量が20mSvを下回らないおそれのある地域 -----

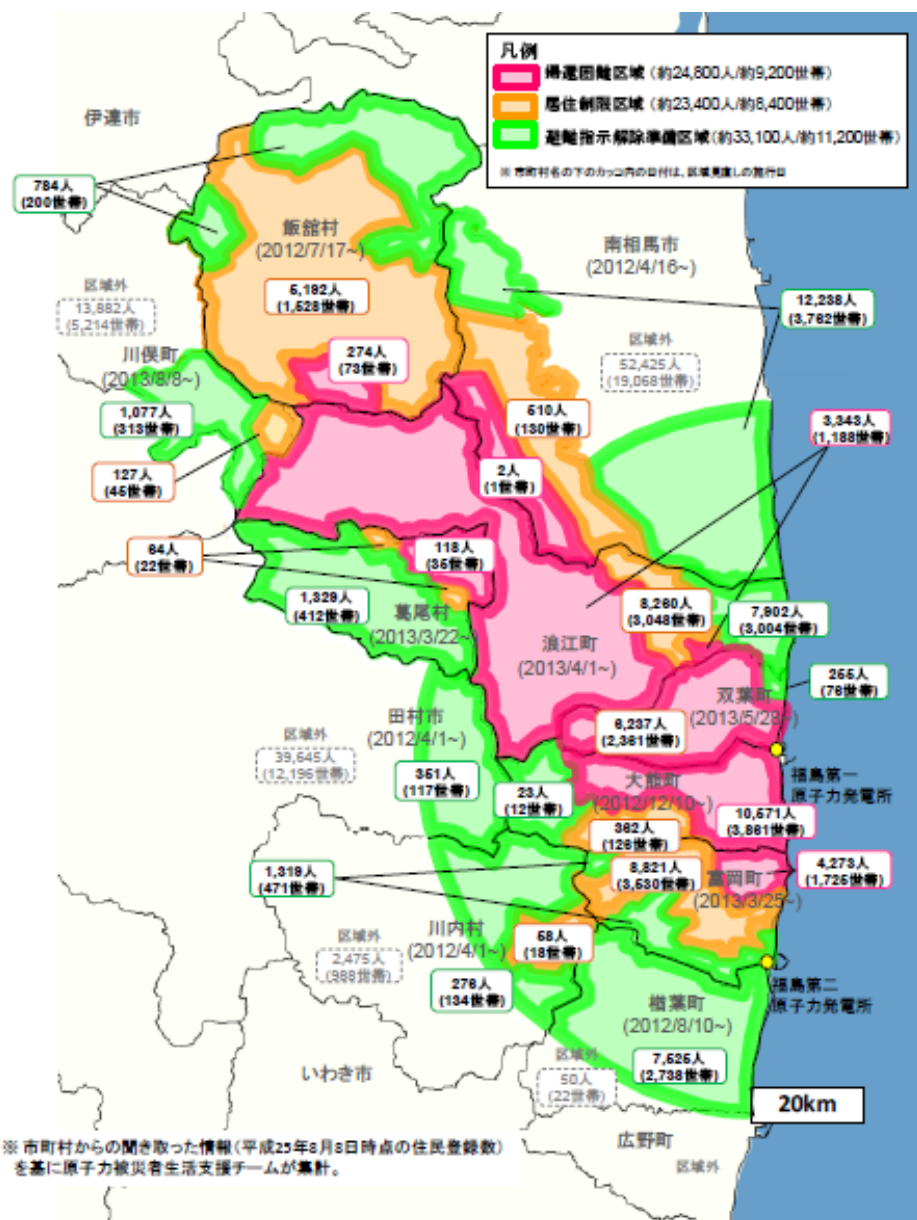


----- 年間積算線量が20mSvを超えるおそれがある地域 -----



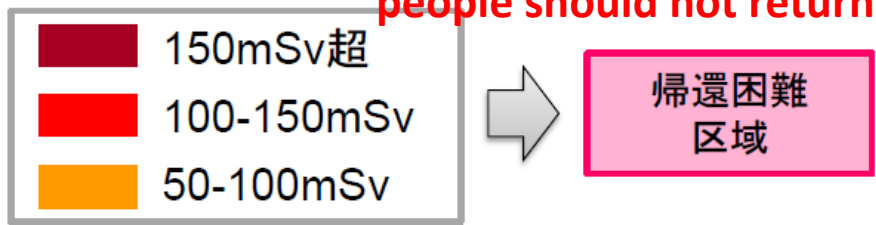
Evacuation and returning

(参考2) 避難指示区域の見直し後の各区域の人口及び世帯数



Total: 81,300 evacuees

people should not return.



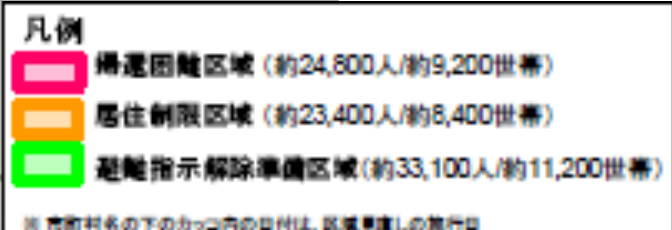
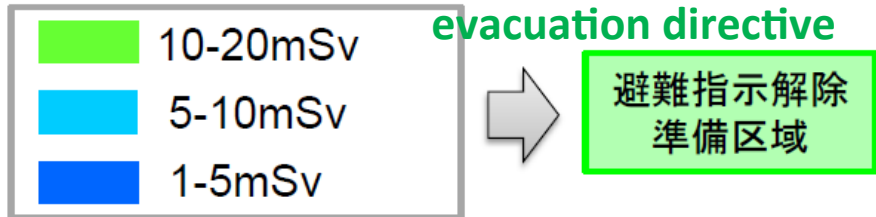
5年経過してもなお、年間積算線量が20mSvを下回らないおそれのある地域

Restricted residential area



年間積算線量が20mSvを超えるおそれがある地域

Waiting for release of evacuation directive



Evacuation and returning

Lack of logistics

- SPEEDI (System for Prediction of Environmental Emergency Dose Information), developed by the MEXT since 30 years ago; Discrepancy between evacuation plan and data from SPEEDI, which caused more distrust of people.

Vulnerable groups: Elderlies

- Cast away: At the hospital/facility for dementia, 50 of 438 have died being left in the hospital; in the process of evacuation; at the evacuation center.
- “Unnecessary evacuation” of caregiver happened because of some misinformation.
- Now in one elder care facility 64 elderly people stayed in a village where most of 6,000 people have left.

Evacuation and returning

Vulnerable groups: Pregnant women

- Japan Society of Obstetrics and Gynecology stated that pregnant and nursing women of radiation dose 50mSv do not necessary to have preventive iodine medication. (Mar 16, 2011) Still now fear about the impact on fetus.

Vulnerable groups: Children

- According to the Fukushima prefectural survey, among 226,000 children (18+ at the time of accident) 59 were assumed to have thyroid or other cancer, during these 3 years (2011-13). Overestimation? They have been continuing the study.
- Many of the people argue that 20 mSv/y standard is not acceptable for children.

Difficulties in decision-making

- Decision-making of returning is in difficult balance between protections of 2 vulnerable groups (elderlies VS children, fetus).

Evacuation and returning

UN Human Rights Council, Special Report 27 May 2013

“Formulate a **national plan** on evacuation zones and safe limits of radiation by using current scientific evidence, based on human rights rather than on a risk-benefit analysis, and reduce the radiation dose to less than 1mSv/year; “

Also call for Conflict of Interests disclosure of Nuclear Regulation Authority

Reply of Japanese government ICRP also recommends that the transition from an emergency exposure situation to an existing exposure situation should be managed by keeping exposures as low as reasonably achievable, taking into account economic and societal factors as well as the distribution of doses and benefits resulting from the implementation of the protection strategies.

Nuclear Regulation Authority. Basic principles for returning (draft, Nov 20, 2013)

100mSv> : Difficult to demonstrate additional risk, international recognition, though special consideration is necessary for children, pregnant.

20mSv> : minimal requirement; long-term goal: 1mSv;

Government should provide additional protection and supports for the people.

Evacuation and returning

UN Human Rights Council, Special Report 27 May 2013

“Formulate a **national plan** on evacuation zones and safe limits of radiation by using current scientific evidence, based on human rights rather than on a risk-benefit analysis, and reduce the radiation dose to less than 1mSv/year; “

Also call for Conflict of Interests disclosure of Nuclear regulation Authority

Reply of Japanese government ICRP also recommends that the transition from an emergency exposure situation to an existing exposure situation should be managed by keeping exposures as low as reasonably achievable, taking into account economic and societal factors as well as the distribution of doses and benefits resulting from the implementation of the protection strategies.

This April the government partially resolved mandatory evacuation but some of the information disclosure of survey results of radiation dose of related area was delayed because of the estimated radiation dose was higher than expected, although lower than 20 mSv.

Nuclear Regulation Authority. Basic principles for returning (draft, Nov 20, 2013)

100mSv> : Difficult to demonstrate additional risk, international recognition, though special consideration is necessary for children, pregnant.

20mSv> : minimal requirement; long-term goal: 1mSv;

Government should provide additional protection and supports for the people.

	Total	Age		
		<20	21-65	65<
Total	1632	4	168	1460
Iwate	193	0	24	169
Miyagi	636	1	77	558
Yamagata	1	0	1	0
Fukushima	761	0	61	700
Ibaragi	32	3	4	27
Saitama	1	0	1	0
Chiba	3	0	1	2
Tokyo	1	1	0	0
Kanagawa	1	0	0	1
Nagano	3	0	0	3

**380/761
Associated
with NPP
related
evacuation**

Evacuation and returning

We need the comparison of the risk associated with evacuation (mortality at least 380/83,100, 0.46%) and risk associated with radiation according to LNT model, along with duration.

- NNH-ef: Number needed to harm of evacuation-Fukushima
- NNH-rlnt: Number needed to harm of radiation-LNT model
- $\text{NNH-ef}/\text{NNH-rlnt}$:
Odds ratio of evacuation vs radiation (OER)

Evacuation and returning

- Substantial number of elderly people have died because of compulsory evacuation.
- Evacuation plan was based on the worst scenario of explosion of radiation and length of “out of control” situation of broken NPP.
- Returning plan has still now been in difficulties because of uncertainty of risk of radiation, not only difficulties of balancing between protections of 2 vulnerable groups (elderlies VS children, fetus); but also well-being of children living apart from homeland OR returning to low dose contaminated area (small but existing risk).
- Social factors (not only radiation risk) to make unable people to return have been more and more increasing.

Evacuation and returning

- Question: Whether or not evacuation and returning planning was well-constructed previously to the accident, estimating health risk of evacuation, considering worst scenario, considering most vulnerable populations not only children but also elderly?
- “Although the LNT model is based on the virtue of prudence, its application may lead to violations of the principles of respect for personal autonomy and dignity. ...This appears to have violated a fundamental principle of medical practice: first, do no harm. “ (quoted from the announcement of this WS)

Evacuation and returning



Impact on decision-making of people whether or not to accept restarting operation of NPR.

Fukui District Court accepted the arguments of residents to stop restarting operations of Ohi NPR, concerning the risk of violation of personal rights of residents within 250 km.

Because personal rights of residents is superior to the freedom of economic activities to generate electricity (including workers' rights of choice of employment?).

Evacuation and returning



Impact on decision-making of people whether or not to accept restarting operation of NPR.

Imagine the worst scenario where compulsory evacuation in 250 km is ethically justifiable

Fukui District Court accepted the arguments of residents to stop restarting operations of Ohi NPR, concerning the risk of violation of personal rights of residents within 250 km.

This rights of residents is superior to the freedom of economic activities to generate electricity (including workers' rights of choice of employment?).

- 1. Consideration of principles of biomedical ethics and radiological protection (RP)**
- 2. Workshop products and cross cultural considerations of ethical/RP principles**
- 3. Ethical consideration of actual issues happening in Fukushima**
- 4. Discussion and conclusions**

2. Ethical consideration of actual issues happening in Fukushima

- Characteristics
- Logistics
- Communication
- Evacuation and returning
- Compensation
- Survey and research
- Conflict of interests
- Future perspectives

Briefly mention these topics in Discussion part

Considering vulnerable populations...

- RP community has discussed and implemented community-involvement/empowerment issue under the principle of autonomy, dignity; however, we need more “capacity development” of community-based decision-making, in advance to accident, considering science-based comparison between radiation risk and health risk associated with evacuation.
- Especially in Asian or probably also in African countries, community decision-making (involving not only children but also elderly; keeping religious life style) is very much important, comparing Western people emphasizes individual decision making.
- More open-minded talk of RP specialists about the radiation risk and scientific findings could promote capacity development of community.

Considering vulnerable populations...

- In the process of the revision of the Declaration of Helsinki (World Medical Association's ethical standard of clinical research), the president of WMA (female physician, Uganda) avoided too much benefit for the community of research subjects, which may cause "obedience syndrome" and deleted the related sentences from the draft Declaration, and emphasized importance of "capacity development", which leads to autonomous decision-making of resource poor community.

It's time to revise Pub. 62, responding recent research ethics discussion!

- For the community to accept NPP, capacity development is crucial both before and after the accident, including consideration about the alternative energy.
- Too much compensation before and after accident would cause "obedience syndrome" of resource poor community and jeopardize their decision-making capacity.

Conclusions

- The RP recommendations already contains many of well-constructed ideas and procedures to protect people and environment; however, there are something missing from view of health science and bioethics, including religious, cultural studies.
- Now we should reconstruct (or revisit) already established ideas of RP from view of bioethics (“Supra-interdisciplinary”) analyzing in depth Fukushima experience.

Back up

(自分の参考のため)

ICRP Publication 103 – Table 5

Band of projected dose (mSv/an)	Characteristics of the exposure situation	Radiation protection Requirements
20 à 100	<ul style="list-style-type: none"> - Sources not controllable, - Actions disproportionately disruptive - Actions on the exposure pathways (not on the source) 	<ul style="list-style-type: none"> - Dose reduction - Individual information on radiation risk and the actions to reduce doses - Assessment of individual doses
1 à 20	<ul style="list-style-type: none"> - Benefit from the situation rather than from the exposure - Action on the source or on the exposure pathways 	<ul style="list-style-type: none"> - General information to reduce doses - Training, individual assessment of exposure (planned exposure situations)
< 1	<ul style="list-style-type: none"> - Indirect or societal benefit - Action on the source that can be planned in advance 	<ul style="list-style-type: none"> - General information on the level of exposure - Periodic checks on exposure pathways and level of exposure

Categories of risk and corresponding levels of benefit

Level of risk	Risk category	Corresponding effective dose (adults, mSv)	Level of social benefit
trivial	I ($\sim 10^{-6}$)	<0.1	minor
Minor to intermediate	II a ($\sim 10^{-5}$)	0.1–1	intermediate to moderate
	II b ($\sim 10^{-4}$)	1–10	
moderate	III ($\sim 10^{-3}$ 以上)	>10*	substantial

* To be kept below deterministic thresholds except for therapeutic experiments.

- Repeated participation should be avoided
- Expert(s) should be included in research group, ethics committee

International Commission on Radiological Protection. ICRP Publication62: **Radiological Protection in Biomedical Research**. Adopted by the Commission in November 1992. *Annals of the ICRP Pergamon Press Ltd.* 1993.

Radiation dose limits of RDRC

Radiation dose limits under which use of radioactive drugs for research are considered and effective by the US Code of Federal Regulations (21CFR361.1)

<u>Organ or system</u>	<u>Single dose</u>	<u>Annual and total dose</u>
Whole body; Active blood-forming organs; Lens of the eye; Gonads	3 rem (=30mSv)	5 rem (=50mSv)
Other organs	5 rem (=50mSv)	15 rem (=150mSv)

21 CFR 361 - Prescription Drugs For Human Use **Generally Recognized As Safe And Effective** And Not Misbranded: Drugs Used In Research: Sec. 361.1 Radioactive drugs for certain research uses.

Allowed: investigating human physiology, pathophysiology or biochemistry

Not allowed: Safety, Efficacy, Diagnostic, Therapeutic, Clinical trials, Patient management
firs-in-human, more than defined number of subjects, etc.

2009: 76 RDRCs, 628 protocols, 3297 study subjects

Discussion concerning the risk of low dose radiation exposure (1)

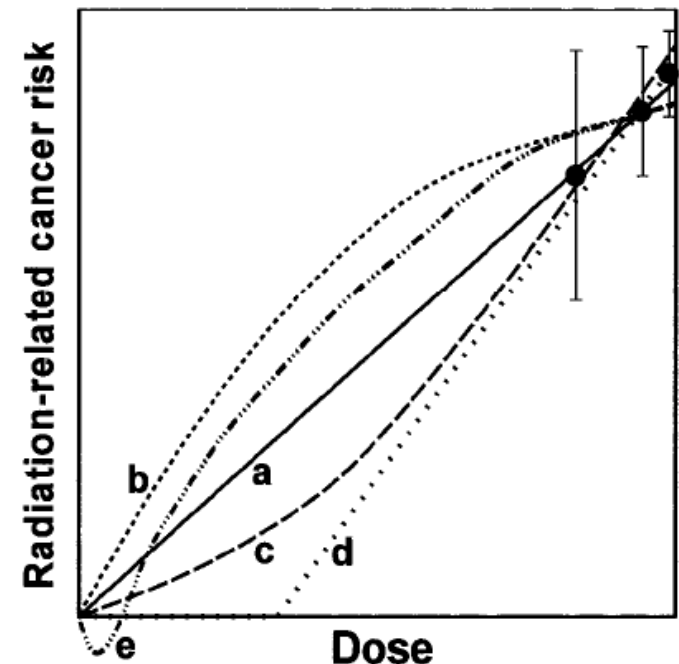
- Reasonable evidence an increased cancer risk
acute doses $>$ 5 mSv.
- Good evidence an increased cancer risk is
acute doses $>$ 50 mSv.
- Reasonable evidence an increased cancer risk
protracted doses $>$ 50 mSv.
- Statistically significant evidence an increased cancer risk
protracted doses $>$ 100 mSv.

Discussion concerning the risk of low dose radiation exposure (2)

- 50-100 mSv : no established evidence of an increase of risk for radiation less than 100 mSv
- LNT (Linear No Threshold) model
ICRP, NCRP, ICRP, NCRP, UNSCEAR,
the BEIR Committee

possibility of low risk
due to low dose

Sometimes too much sensitive.....
Sometimes too much aggressive.....



Wall, et al. BJR 2006.; Brenner, et al. PNAS 2003.

③リスク：疾患発生率と不利益

放射線のリスクは平均的な健康成人についてのもので、リスクとは、当該線量の被ばくによってもたらされうる、①致死的な種々のがんの発生率、②致死的ではない種々のがんの重み付けをされた発生率、③子孫に起こりうる重篤な遺伝性疾患の発生率、これら①②③の合計で表される不利益（デトリメントと呼ぶ）、と説明される。

ICRP は放射線防護の目的では「LNT（Linear Non-Threshold）モデル」を採用しているので、倫理委員会や被験者に対し、がんのリスク増加に言及する場合には、100mSv を超えない線量においてはがんのリスク増加の疫学的証拠は得られていないことも、あわせて説明が必要である。

④リスク：年齢・健康状態による違い

子どもが対象である場合の不利益は成人の 2~3 倍、50 歳以上の高齢者が対象者である場合の不利益は若い成人の場合の 1/5 から 1/10 であるとみなし、重篤な、または末期の疾患に罹患している患者の場合の不利益はさらに低くなる、と説明される。これは、ICRP の提唱する実効線量はあくまで代表的な成人のモデルで計算されたもので、各個人のリスクを評価する指標ではないことによる。一般的な放射線防護のための規制では、このような年齢や個人による差を考慮して、最もリスクが高いと考えられる集団に対しても安全な基準が採用されているが、被験者を特定する研究の場合には、対象となる研究の目的と被験者の選択において、個別の評価が必要である。