"Ethical Dimensions of the Radiological Protection System"
ICRP Special Session, 10:30-12:30 May 14, 2014
Kuala Lumpur Room, Level 5, Putra World Trade Centre (PWTC)
IRPA Regional Congress, The Fourth Asian and Oceanic Congress on Radiation Protection (AOCRP-4), May 12-16, 2014 at PWTC, Kuala Lumpur, Malaysia

Ethics and radiological protection:
Learning from Fukushima and Asian perspective

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Planning and Promotion Unit, Molecular Imaging Center,
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1. Consideration of ethical principles related to radiological protection (RP)
2. Workshop products to consider ethical principles and RP
3. Ethical consideration of actual issues happening in Fukushima
4. Discussion and conclusions

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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	C：Applications
●**Respect for persons** ・Autonomy, self-determination ・Protect those with diminished autonomy	○Informed consent （information, comprehension, voluntariness） ○Surrogate consent○Avoid undue influence
●**Beneficence** ・Nonmaleficence ・Maximize benefit, minimize harm	○Risk-benefit assessment
●**Justice** ・fairness in distribution of risk of research and benefit of research results	○Selection of subject (Avoid to include 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". (For the Islamic people, description may be different but has the common essence?)
- States have an obligation to promote human rights and freedoms, derived from human dignity (UN Declaration of Human Rights; International Convent on Human Rights; implication of freedom may be various up to culture).
- "Informed consent", derived from "autonomy", elements of which are information, comprehension, voluntariness.

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 week 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.（Confucianism “Jin” is precious concept, benevolence, 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 democratism).

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". 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.

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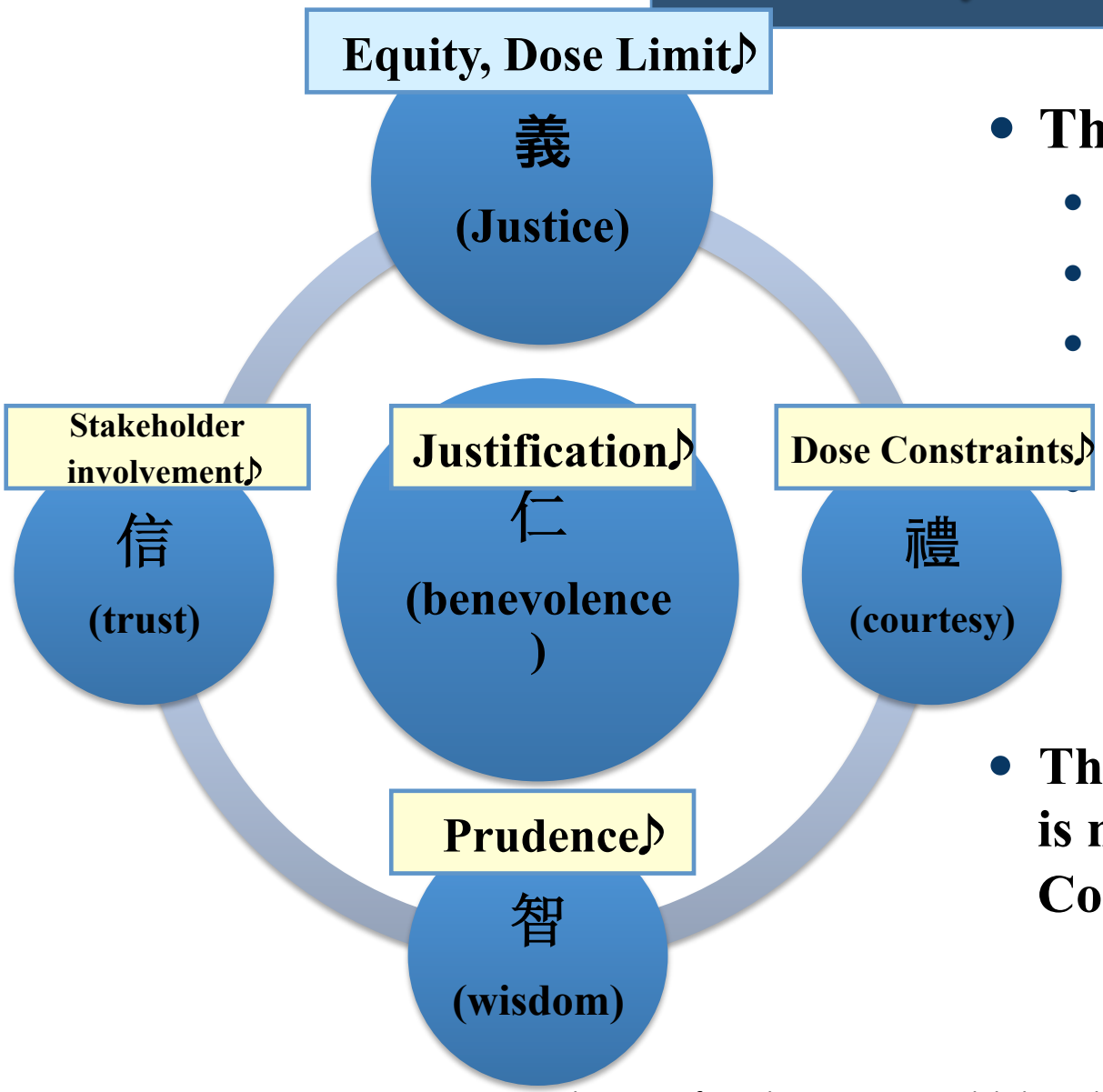
The value system of Classic Confucianism



- **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.

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Summary of the European Workshop

Organized by Marie-Claire Cantone, University of Milan

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.

Summarized from the" draft" report of the 1st European Workshop on the Ethical Dimensions of the Radiological Protection System, 16-18 December 2013, 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"

RP principles	Principles of bioethics		
Justification	Dignity	Beneficence	Justice
Optimization	Autonomy	Do no harm	Equity
Limitation	Informed consent	Minimize risk	Fairness
	Human right	Risk-benefit assessment	Transparency
	Well being		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 principles and practice.

My findings through Asian, European WS

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RP principles

- Justification
- Optimization
- Limitation

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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.

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

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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

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Topics discussed at the Milan Workshop

Focuses of today's discussion

2. Ethical consideration of actual issues happening in Fukushima

- Characteristics
- Logistics
- Communication
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Topics discussed at the Milan Workshop

Focuses of today's discussion

Briefly mention these topics in Discussion part

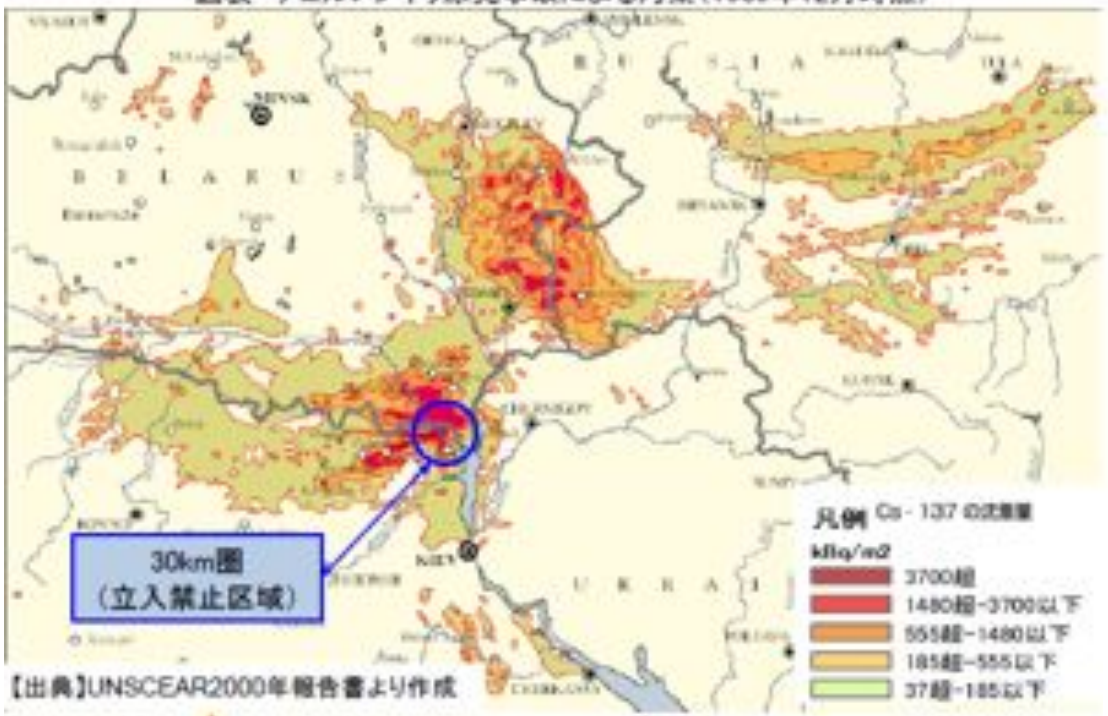
Characteristics

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）



【出典】UNSCEAR2000年報告書より作成

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）

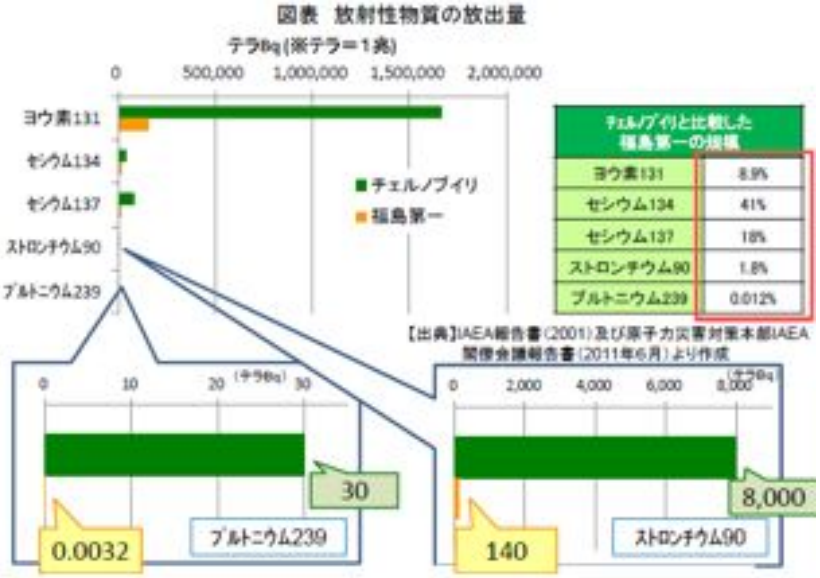
【出典】文部科学省発表資料（2011年11月）より作成

図表　汚染地域の面積

汚染濃度（kBq/㎡）	汚染地域の面積（km²）		
	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％

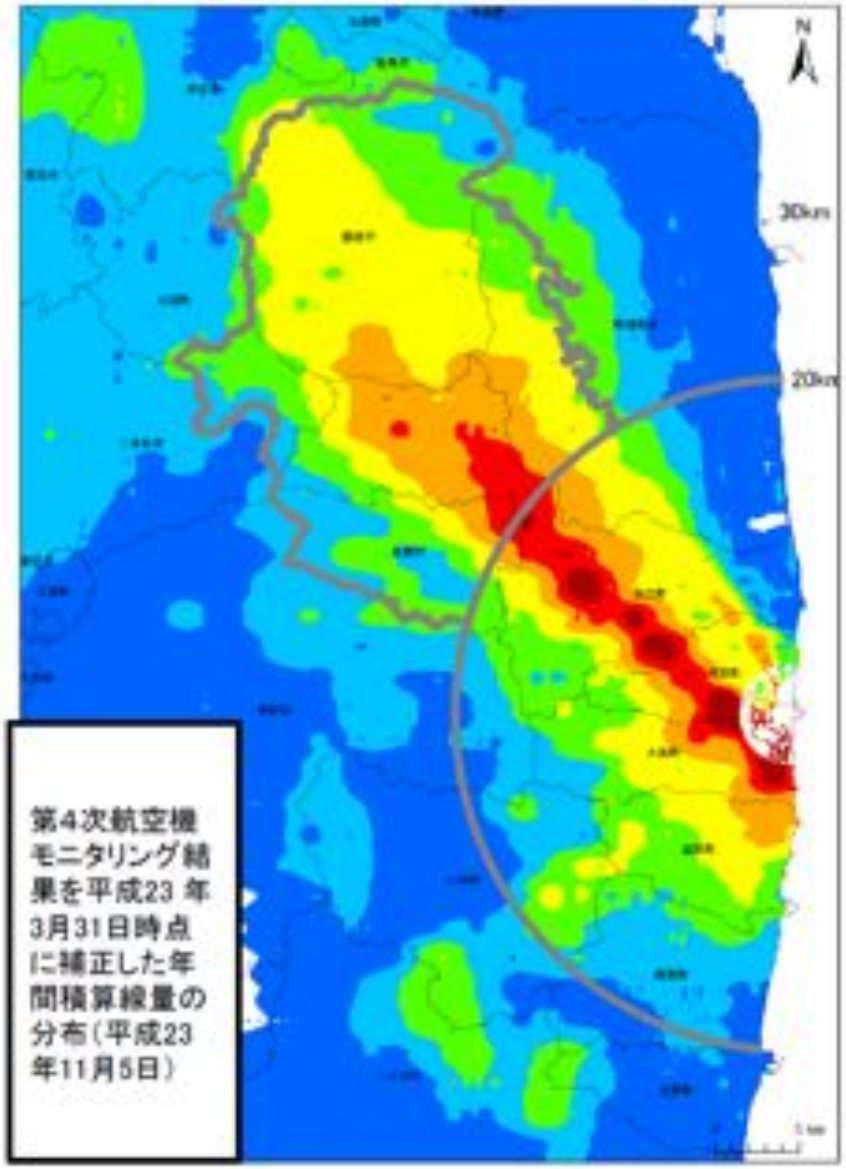
Comparison of contamination with the case of Chernobyl

図表　放射性物質の放出量



【出典】IAEA報告書（2001）及び原子力災害対策本部IAEA閣僚会議報告書（2011年6月）より作成

（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.

150mSv超
100-150mSv
50-100mSv
→ 帰還困難区域

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

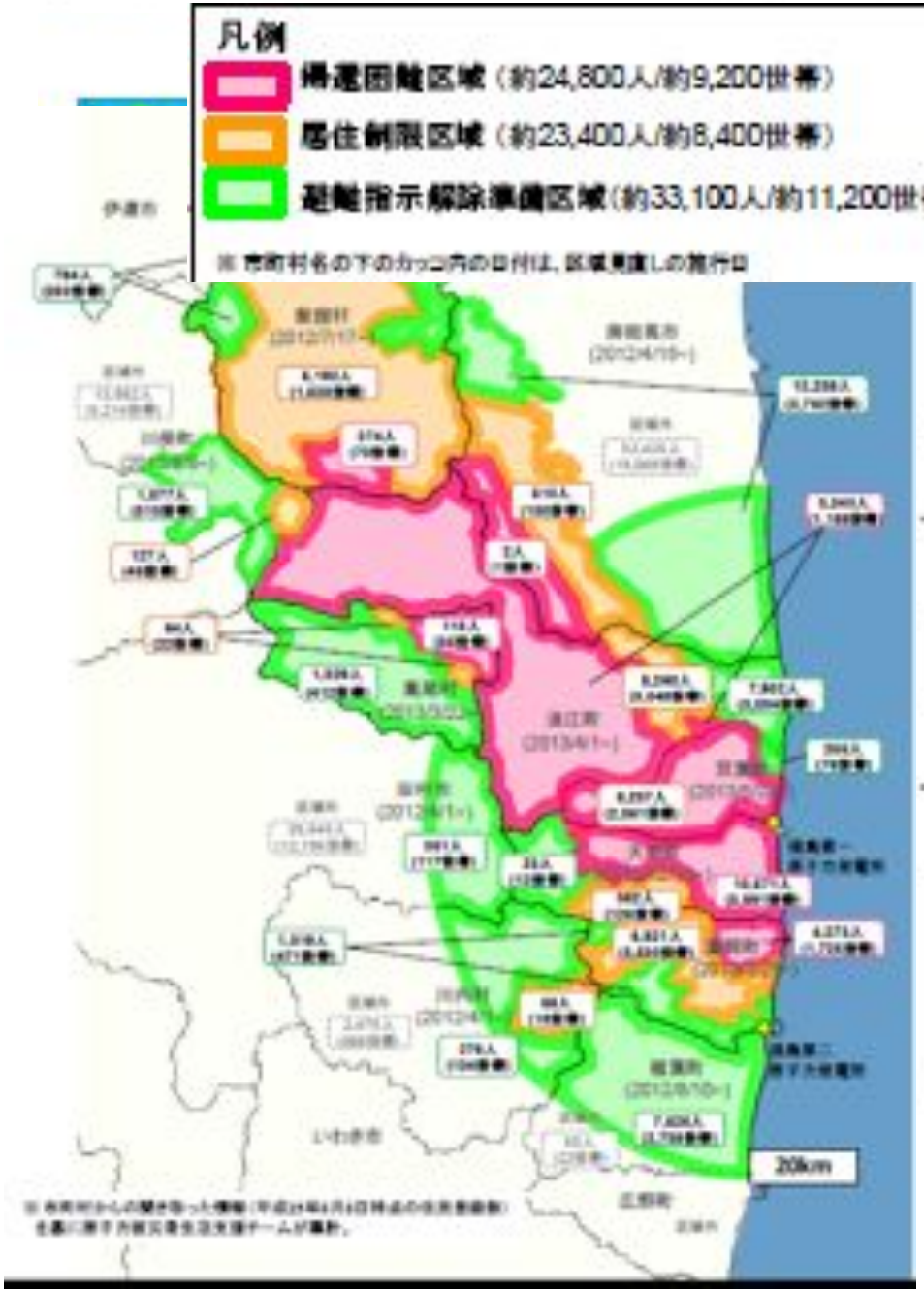
20-50mSv
→ 居住制限区域

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

10-20mSv
5-10mSv
1-5mSv
→ 避難指示解除準備区域

(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.

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100-150mSv
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10-20mSv
5-10mSv
1-5mSv
→ 避難指示解除準備区域

The total death toll: 15883; missing: 2651
Fukushima death toll: 1606; missing 207
Additional related death in Fukushima:
761 ; 380, mainly resulting from evacuation

Communication

Fundamental problem:

Lack of knowledge, even in medical experts, or in politicians

- Extreme case: Radiation exposure disease is contagious (by delivering particles?)

- Lack of knowledge about the standards/ recommendations of IAEA, ICRP. (or lack of reliance 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, have been communicating about radiation risk, making use of social media, many of them having their own Geiger counters.

Communication

<u>Most prominent communication gap:</u>

- 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

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.

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.
- 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 this study.

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.

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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.

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	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

Reconstruction Agency August 21, 2012

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
- NNH-ef/NNH-rlnt:

  Odds radio of evacuation vs radiation (OER)

Evacuation and returning

- Substantial number of elderly people have died because of evacuation.
- Evacuation plan was based on the worst scenario of explosion of radiation and length of “out of control” situation of broken NPP.
- 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?

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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.
- We should not compromise to maintain the goal of “Do no harm (harm zero)” principle but should not have an assumption of “risk zero” situation.
- 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.

Considering vulnerable populations…

- Sometimes Asian leaderships fail to inform the fact to people from the philosophy of benevolence (“Jin”).
- 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.
- 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.
- It may be effective to reconstruct already existing ideas of RP from view of bioethics ("Supra-interdisciplinary") analyzing in depth Fukushima experience.
- Remaining question: concept of ethical principles, e.g., "dignity" for people of Islamic, Buddist Hindu...

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	- Sources not controllable, - Actions disproportionately disruptive - Actions on the exposure pathways (not on the source)	- Dose reduction - Individual information on radiation risk and the actions to reduce doses - Assessment of individual doses
1 à 20	- Benefit from the situation rather than from the exposure - Action on the source or on the exposure pathways	- General information to reduce doses - Training, individual assessment of exposure (planned exposure situations)
< 1	- Indirect or societal benefit - Action on the source that can be planned in advance	- General information on the level of exposure - Periodic checks on exposure pathways and level of exposure

ICRP publication 62

Categories of risk and corresponding levels of benefit

Level of risk	Risk category	Corresponding effective dose (adults, mSv)	Level of social benefit
trivial	Ⅰ（～10^{-6}）	＜0.1	minor
Minor to intermediate	Ⅱa（～10^{-5}）	0.1−1	intermediate to moderate
	Ⅱb（～10^{-4}）	1−10	
moderate	Ⅲ（～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)

Organ or system	Single dose	Annual and total dose
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

Fejka R. 2010 US-SNM Annual Meeting

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.

Brenner, et al. *PNAS* 2003.

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

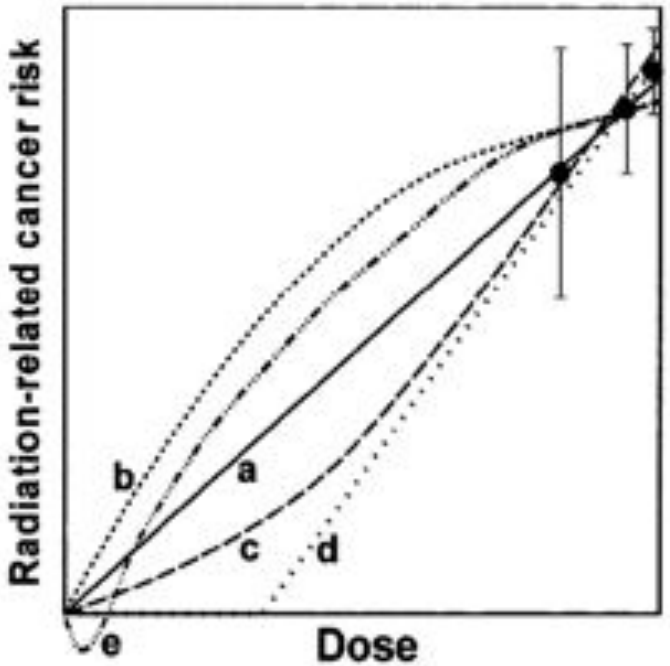
- 50-100 mSv：no established evidence of an increase of risk for radiation less than 100 mSv
- LNT（Linear No Threshold）model

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。