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In cooperation with ICRP and IRPA

Ethical consideration of radiological protection: Learning from Fukushima

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National Institute of Radiological Sciences (NIRS)

1. Introduction

2. Consideration of ethical principles related to radiological protection (RP)

3. Ethical consideration of actual issues happening in Fukushima

4. Conclusions

Areas of today's presentation

- **Exposures situations**
  - Planned
  - Emergency
  - Existing
- **Categories of exposures**
  - Occupational
  - Medical
  - Public : present and future generations
  - Fauna and flora (Biota)

Revised from Presentation by Jacques LOCHARD

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Related disciplinary areas

(natural science)

- Biology, radiology, physics
- Epidemiology, clinical epidemiology
- Radiological protection (applied science)

(social science)

- Philosophy, ethics
- Political philosophy, political science, economics, publi policy studies
- Science and technology studies (risk communication, consensus development, regulatory science)
- Applied ethics (technology ethics, bioethics)

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Bioethics as Super-disciplinary (Kimura R, one of the founders of bioethics)

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Presentations by RP experts on ethics underlying RP system

Meta-ethics

Normative ethics

Consequentialism (also called teleological ethics)

Utilitarianism	**Optimization**	collective ethics	prudence
Deontological ethics	**Limitation**	individual rights	dignity
Virtue ethics	**Justification**	vigillance, fairness	justice

Autonomy
Beneficence
justice

Applied ethics (Radiological protection system)

prudence….. LNT model, ALALA, acceptability/trelability

justice……. restrictions on individual doses, dose constrains

dignity……. Consent (105), self protection (111), stakeholder engagement (103)

From related field

Regulatory science and public policy studies (IAEA); RP, ethics, and Asian philosophy

Science studies (post-normal science) ; bioethics (human subject protection)

Discussions of WS at KINS

Why people so fear radiation?

Mandatory evacuation, ethical?

Social media

More ethics, not only communication

Radiation and atom bomb

Environment, human & animal welfare

WS products

Communication

Well-being

Acceptable/tolerable risk

Interdisciplinary collaboration

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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

- "Autonomy", derived from "human dignity" (Kant), regarded as "absolute value", one of the 4 or 3 principles of bioethics (Beauchamp & Childress; Belmont Report).
- States have an obligation to promote human rights and freedoms" , derived from human dignity (UN Declaration of Human Rights; International Convent on Human Rights).
- "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 behavior?; (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.
- Difficulties remain in community-based decision-making in disintegrated communities.
- 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" (Hippocratic Oath) and "Nonmaleficence" in Beauchamp & Childress are combined in 1 principle "beneficence" in "Belmont Report". Principle of beneficence includes "Nonmaleficence" and "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. Some of bioethicists emphasis “right of taking risk”. This is double-edged concept to be used as excuse.
- 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 assessment has caused confusion.

Beneficence

Ethical principle and RP system

- 3 principles of RP seems to be mainly included in this “beneficence”, and you need more considerations about other values. (My previous presentation)
- 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 informed to stakeholders. (My previous presentation)
- 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 (Nicomachean Ethics):

  distributive justice (Belmont Report);

  corrective justice (Compensation).

- 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; whereas other theoreticians have advocated toward the directions of "libertarians".

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.
- Selling NPP to some countries (1) resource-poor countries; (2) rich countries, but with wide gap between rich and poor.

"Prudence", related to "justice" principle, may work for considerations embracing these complicated situations.

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３．Ethical consideration of actual issues happening in Fukushima

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- Logistics
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- Evacuation and returning
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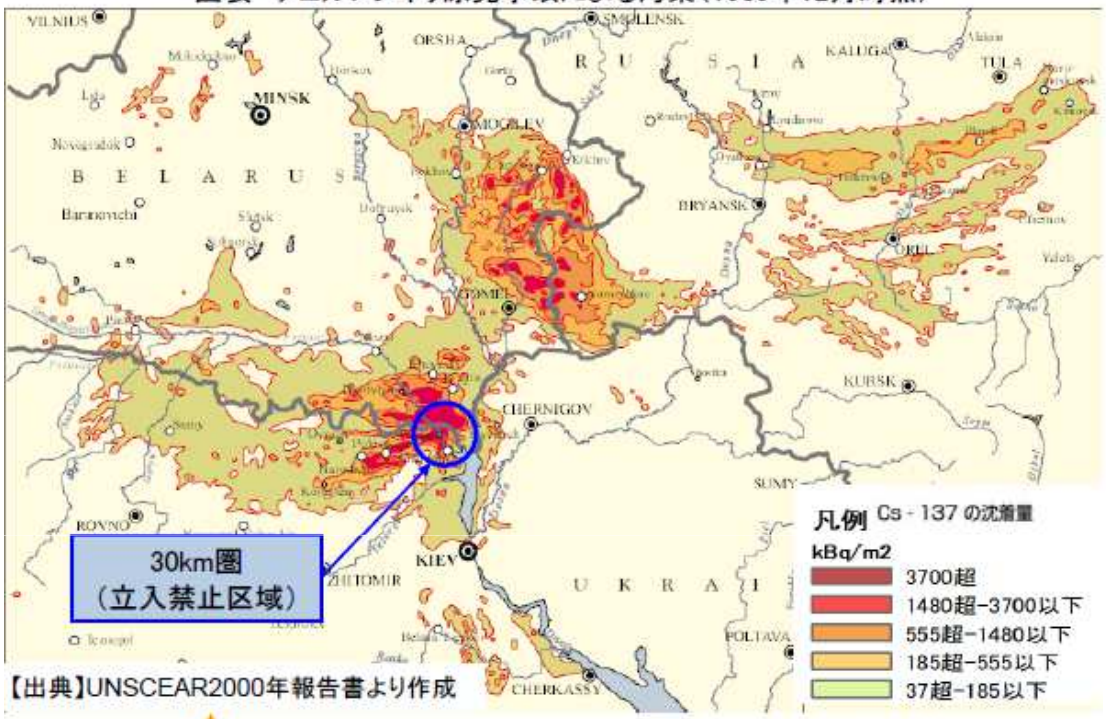
Characteristics

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.

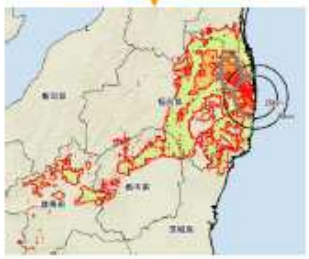
Characteristics

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）

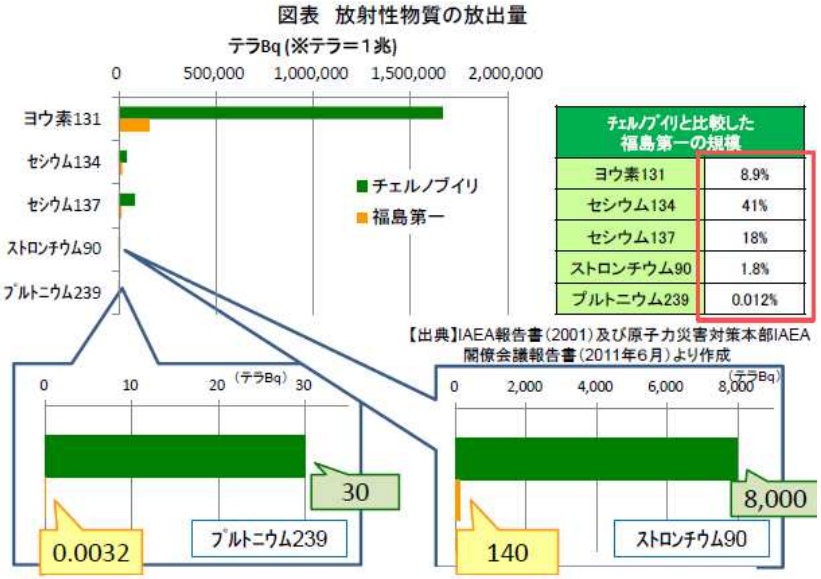
【出典】文部科学省発表資料（2011年11月）より作成

図表　汚染地域の面積

汚染濃度（kBq/㎡）	汚染地域の面積（㎢）		
	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

３．**Ethical consideration of actual issues happening in Fukushima**

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Logistics

Fundamental problems

- Investigation Commission under the National Diet concluded this accident to be a human-disaster, lacking necessary preventive measures, because of cozy alliance among government, industries, and scholars.

  It is not merely resulting from natural disaster.

  ("NP Village" "Myth of safety")
- IAEA's Standards and ICRP's recommendations have not been sufficiently implemented in domestic regulations.
- Lack of logistics in repair of facilities, evacuation, examination and medications, elimination of contaminated land, assessment of health effects, etc. have caused the fundamental distrustfulness of public .

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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.

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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.
- Still now in one elder care facility 64 elderly people stay 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).

Difficulties in decision-making

- Some of bioethicists criticized mandatory evacuation, considering other health impact resulting from evacuation; others emphasize the risk of low dose radiation effects. Decision-making of returning must be on 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; "

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.

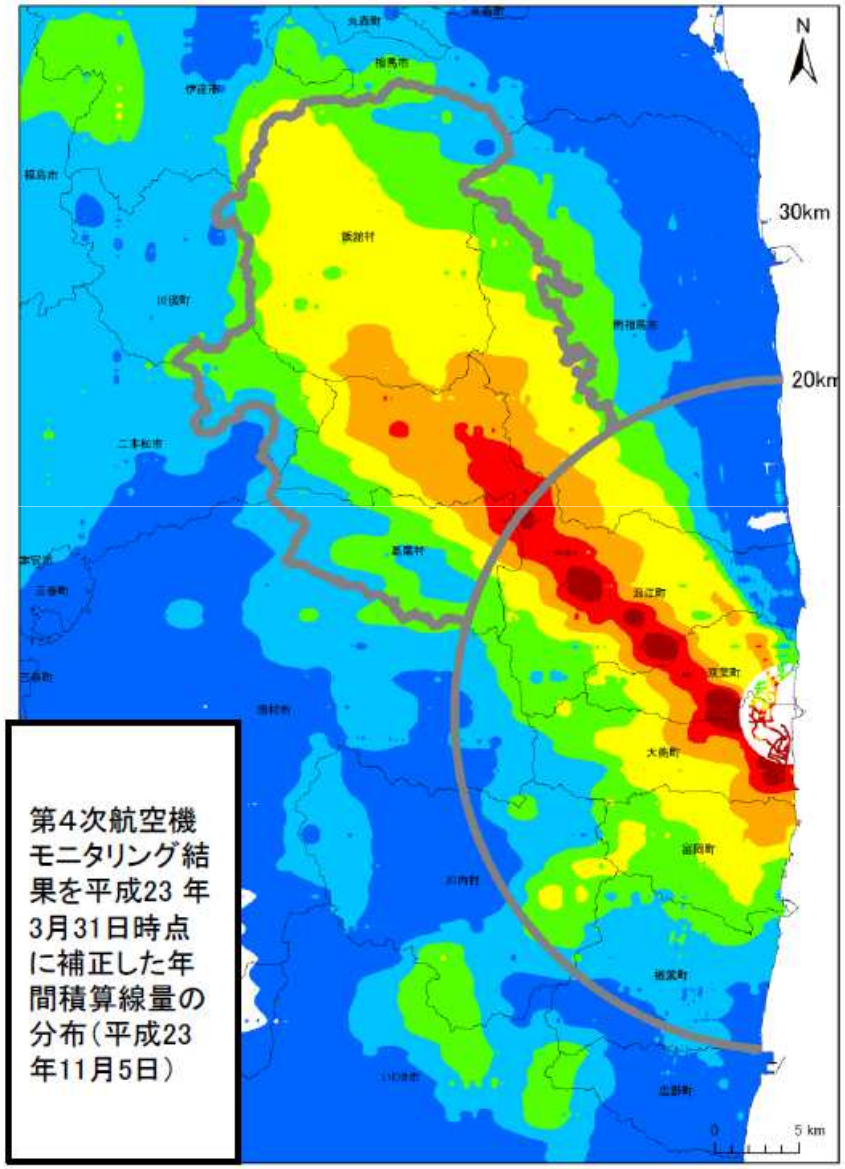
Nuclear Regulation Authority. Basic principles for returning (draft, Nov 20, 2013)

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.

（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



第4次航空機モニタリング結果を平成23 年3月31日時点に補正した年間積算線量の分布（平成23年11月5日）

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

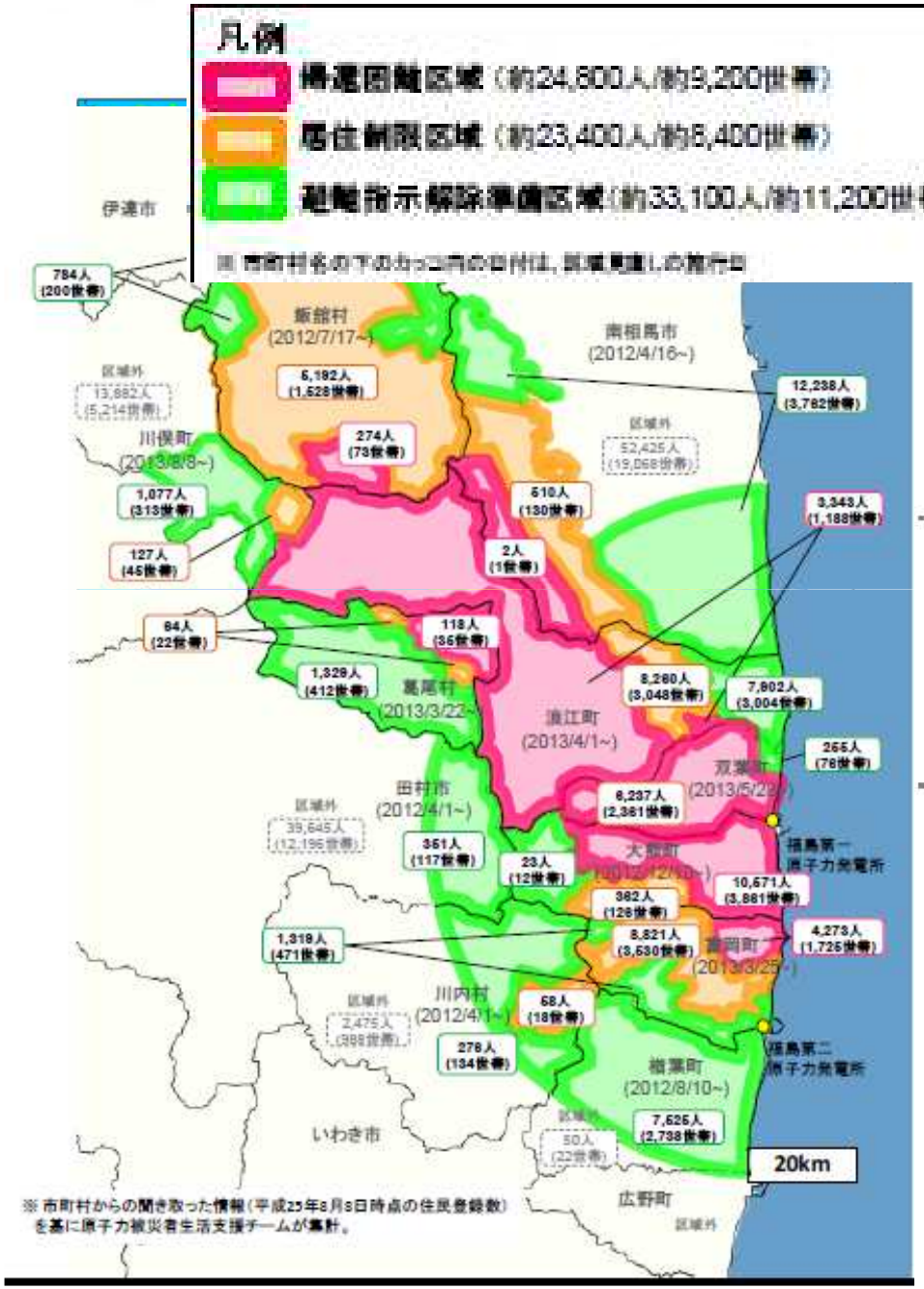
20-50mSv
→ 居住制限区域

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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→ 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

	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)

３．**Ethical consideration of actual issues happening in Fukushima**

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Compensation

- Nicomachean Ethics-corrective ethics:
  If the loss of A is resulting from the fault of B,
  B should compensate this loss of A.
  (liability, fault/non-fault, causal relationship)
- If the loss is resulting from some activities
  for public interests, compensation may be
  granted through public framework,
  by public expense.

Compensation

Objectives of NP disaster compensation law

- Protection of victims of NP disaster
- Promotion of NP business

＊ Unlimited liability of compensation

<u>Advisory committee of government established the guidelines to define the range of compensation:</u>

(First, April 2011, additions until January 2013)

Costs associated to evacuation

Physical, psychological harm

Loss/limitation of business or work

Damage resulting from harmful rumor

Damage resulting from radiation exposure

individual　individual　business organizations

(voluntary evacuation)

原子力損害賠償のご請求・お支払い等実績

Nov 15, 2013

平成25年11月15日現在

	個人	個人（自主的避難等に係る損害）	法人・個人事業主など	
ご請求について				
ご請求書受付件数（延べ件数）	約505,000件	約1,297,000件	約218,000件	
合意状況について　※1				
合意いただけた件数（延べ件数）	約465,000件		約191,000件	
合意いただけた金額	約1兆2,695億円		約1兆4,792億円	
本賠償の状況について				
本賠償の件数（延べ件数）	約440,000件	約1,285,000件	約188,000件	
本賠償の金額　※2	約1兆1,769億円	約3,526億円	約1兆4,302億円	
これまでのお支払い金額について				
本賠償の金額　※2			約2兆9,597億円	①
仮払補償金			約1,502億円	②
お支払い総額			約3兆1099億円	①+②

# of claims

# of consensus

※1 自主的避難等に係る損害については、合意書は発送しておりません。

※2 仮払補償金から本賠償に充当された金額は含んでおりません。

3 trillion Japanese Yen total amount, already granted

Compensation

- Hot discussion on the share of expenditure for compensation between TEPCO (Tokyo Electric Power Company) and its stock holders (may cause increase of electricity bill) AND government (tax charge)
- Compensation should be provided as much as possible, however, too much compensation may impair self-sustainability of the disaster victims. (beneficence)

Experience of Declaration of Helsinki: Representatives of resource-poor countries raised objections to excessive benefit sharing, to avoid “dependency syndrome”.

- When and how they stop granting compensation?

Compensation

Critical issue in near future related to RP

- To what extent damage resulting from radiation exposure should be compensated?
- How should be the decision-making of granting compensation?

- Retrospective/Prospective epidemiological survey?
- LNT model?
- Situation-based probability?
- As a remedy?

３．**Ethical consideration of actual issues happening in Fukushima**

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- **Survey and research**
- Conflict of interests
- Future perspectives

Survey and research

- Any research/survey should be conducted compliant with domestic/international laws, regulations and ethical principles.
- There must be claims against research/survey without providing medical care. ("guinea-pig" claims, historically since Hiroshima, Nagasaki)
- However, Compromised scientific validity because of ethical considerations may cause biased research results, which cause health damage.
- It may be necessary to develop international consensus of research strategy at the time of emergency. (More in depth of Pub 111 "radiation monitoring and health surveillance")

Survey and research

- Declaration of Helsinki and CIOMS guidelines have discussed in these 20 years about the research in "resource-poor setting" and for "vulnerable population".

  Responding to health needs

  Post-trial access: fair-benefit, reasonable access

  (Avoid "dependence syndrome")

- Some additional points to be considered, based on the experiences of Hiroshima, Nagasaki, Chernobyl, and Fukushima:

  - Balancing among science, ethics, support, and self-satisfaction of the researcher/supporter

  - Findings about vulnerable population may cause discrimination toward the vulnerable population.

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Conflict of interests

UN Human Rights Council, Special Report 27 May 2013

"Ensure disclosure of members of the Nuclear Regulatory Authority of their association with the nuclear power industry"

Reply of Japanese government

The website of Prime Minister's Cabinet Secretariat [http://www.cas.go.jp/jp/genpatsujiko/info/proposals.html] provides information (in Japanese) on the past and present association of the NRA Chairperson and Commissioners with the nuclear industry which was uploaded on the Cabinet Secretariat's website on 26 July 2012 prior to their appointment, taking into account the resolution made in the Environment Committee of Japan's House of Representatives. In this regard, this draft sentence should be corrected to "Public disclosure of past or present association with the nuclear industry was required and made prior to the appointment of its Chairperson and Commissioners." Furthermore, in this regard, paragraph 80 (b) should be corrected in due course.

Conflict of interests

- Long history and substantial amount of criticisms toward conflict of interests among NPP related companies, government, scholars. This has been main cause of public distrustfullness of RP system.
- Background: suspicious about the relationship between NPP and Nuclear armament.
- In the area of medical research, COI disclosure has been becoming routine practice, through substantial debates on the scientific misconducts and biased research results, resulting from COI between doctors and drug companies.

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Future perspectives

RP system can become more credible for the people when it can share future perspectives with people, even though some of which is not the issue of RP.

Reconstruction

- People-centered (humanistic) reconstruction (with dignity)
- Criticisms of “reconstruction without humanity”; “Greedy capitalism at the cost of Fukushima victims”

Energy problem

- Direction to go ahead:

  “NPP Zero” (abolish NPP) and alternative energy

  NPP sales to Middle East , attaching RP system beyond the hard experience of Fukushima

Nuclear disarmament

- Finally, RP community should prepare the answer to the questions whether nuclear armament (nuclear deterrence) is ethically justifiable or not. (Learning from WMA’s statement.)

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4. **Conclusions**

Conclusions

- The RP recommendations already contains many of necessary ideas and procedures to protect people and environment; however there are something missing from view of health science and ethics.
- Some parts of RP system, especially in emergency situations, it doesn’t work well if it is not well implemented in governmental policy and regulations and well understood, previous to the emergency, with ethical justifications, at least by politicians and key-stakeholders.
- It may be effective to reconstruct already existing ideas of RP from view of (bio)ethics.
- Fundamental distrustfulness have been caused from Conflict of Interest issue, which RP community should face directly and struggle.

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

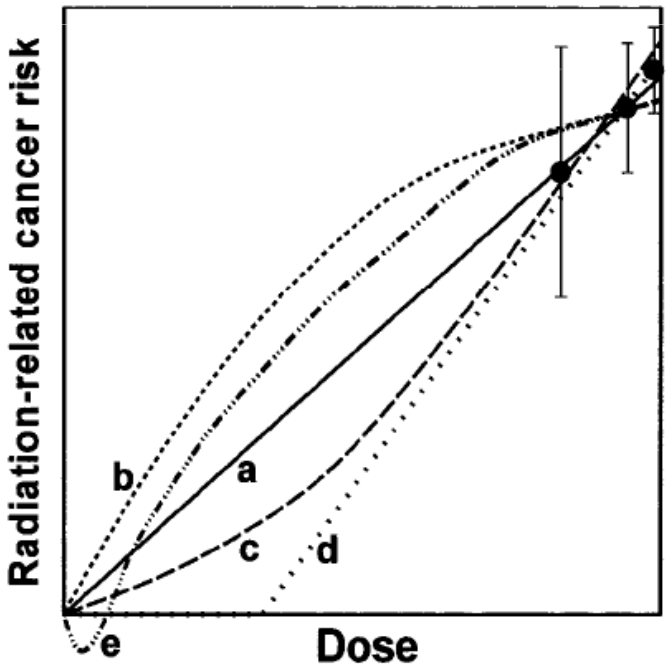
  ICRP, NCRP, ICRP, NCRP, UNSCEAR,

  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。