# What do BEIR VII and UNSCEAR Mean to You ?

Presented by:

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**NMA / NRC**

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## Why do we care about BEIR and UNSCEAR?

- International and National Authorities rely on the work of UNSCEAR, BEIR (NAS), NCRP and others for their evaluation of the scientific information on the health effects of exposure to ionizing radiation
- Over time, the findings of these Committees do affect international and national regulation
  - ICRP radiation protection guidance
  - IAEA Transport Regulations
  - NRC
  - EPA

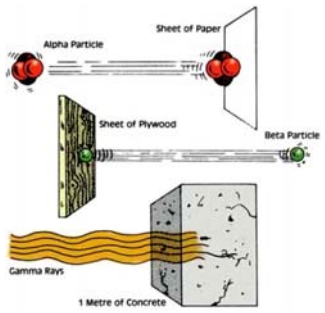




## Overview of Presentation

- Radiation and Radioactivity
- Basis for estimating risks from ionizing radiation
- BEIR VII and UNSCEAR
  - Risks of Cancer
  - Effects other than Cancer
  - Hereditary Effects of Radiation
- Summary Observations

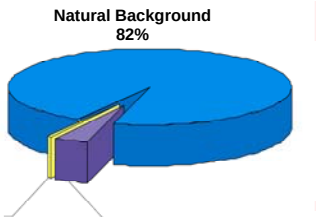
## Radioactivity








## Background Levels of Radiation

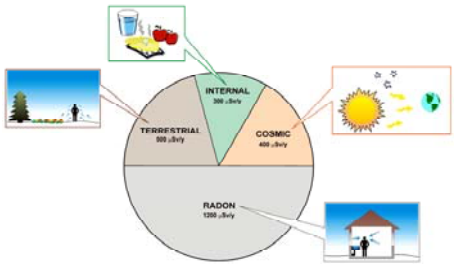



After BEIR VII





## Background Radiation is Everywhere




After UNSCEAR 2000

## Average Radiation Dose From Natural Sources

| Source | Worldwide Average Annual Effective Dose (mSv) | Typical Range (mSv) |
|---|---|---|
| **External Exposure** | | |
| Cosmic rays | 0.4 | 0.3 – 1.0 [a] |
| Terrestrial gamma rays | 0.5 | 0.3 – 0.6 [b] |
| **Internal Exposure** | | |
| Inhalation (mainly radon) | 1.2 | 0.2 – 10 [c] |
| Ingestion | 0.3 | 0.2 – 0.8 [d] |
| **Total** | 2.4 | 1-10 |

a Range from sea level to high ground elevation
b Depending on radionuclide composition of soil and building materials
c Depending on indoor accumulation of radon gas
d Depending on radionuclide composition of foods and drinking water





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## Sources of Health Effects Data

- Studies of humans (epidemiology)
- Studies of animals and plants
- Studies of cells and cell components
- Need to understand interactions among these sources of data and limitations (uncertainty) of data

## Epidemiology Data for Cancer Risks

- Life Span Study (Japanese Atomic Bomb Survivors)
- Patients exposed to radiation for therapeutic purposes (e.g., thorotrast, fluoroscopy)
- Workers exposed to radiation (e.g., miners, radium dial painters, nuclear workers)
- Individuals exposed to environmental radiation (e.g., residential radon)





## Uncertainties in Extrapolation

- the exposed population for which risk estimates are developed
  - the cause-specific mortality and incidence rates and the age-structure of the population to which the rates are applied;
  - the methods used to transport excess cancer risks based on models for one population to another population;
- models used to describe the excess risks in this population;
  - the models used to describe risk at low doses;
  - the method used to extend the excess risk models beyond the period of observation
- the method used to allow for fractionation or dose-rate effects.





## Effects at Low Doses - 1

- DNA is the major target for effects of ionizing radiation (more about this later)
- Ionizing radiation can damage DNA directly as the result of interactions with radiation or indirectly via the transfer of free radicals or chemical intermediates
- In general, a significant radiation effect is only detectable above (about) 100 mGy [BEIR VII, UNSCEAR 2007]

## Effects at Low Doses - 2

**ICRP Feb 2007**

***The LNT hypothesis is not universally accepted as biological truth, but rather, because we do not actually know what level of risk is associated with very low-dose exposure,it is considered to be a prudent judgement for public policy aimed at avoiding unnecessary risk from exposure.***





## Effects at Low Doses - 3

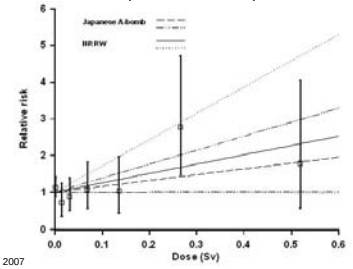
- **In extrapolating risks from high dose rates of LET to low dose rates use a DDREF**
  - **< 3 UNSCEAR 2000**
  - **2 ICRP Feb 2007**
  - **1.5 (95% CI: 1.1, 2.30) BEIR VII**
- **There is a continued need for judgment based on understanding of molecular and cellular mechanisms**





**Trends With Dose in Relative Risk (and 90% CI) for Leukaemia Excluding Chronic Lymphocytic Leukaemia in NRRW** [M12] **and Among Japanese Atomic Bomb Survivors** [P10]

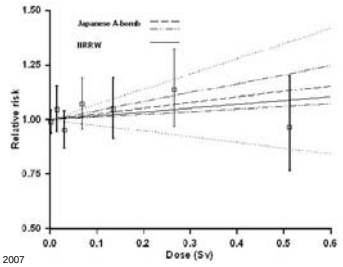
(based on the linear component of a linear-quadratic dose-response)




After UNSCEAR 2007

**Trends With Dose in Relative Risk (and 90% CI) for Malignant Neoplasms Other Than Leukaemia and Lung Cancer in NRRW** [M12] **and Among Japanese Atomic Bomb Survivors** [P10]

(based on a linear dose-response)




After UNSCEAR 2007





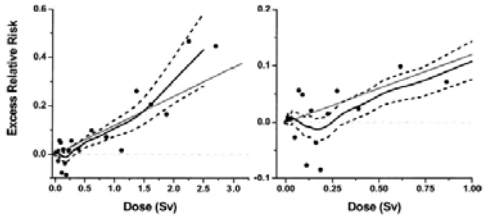
## Life Span Study

- **Major source of data**
- **Linear dose response for solid cancers**
- **Linear quadratic dose response for leukemia**
- **Lifetime Cancer risk 4-6 % per Sv**





**Mortality From *Non-Cancer* Diseases in the LSS Cohort Versus Dose for the Period 1968 - 1997** [P4]




Individual points are dose category-specific ERR estimates. The thin straight solid line is the fitted linear ERR model without any effect of age at exposure, sex or attained age. The thick solid curve provides a smoothed estimate derived from individual points, with the two dashed lines indicating ± 1 SE. The right panel represents the same data as in the left panel, but show the low-dose portion of the fitted curve in greater detail

After UNSCEAR 2007

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## BEIR VII - 1

- BEIR VII Phase 2
  - 7th in series of reports from National Research Council prepared for U.S. government on the relationship between ionizing radiation and health
  - Intended to update BEIR V
  - Intended to develop best possible risk estimate for low-dose, low linear energy transfer (LET) radiation
  - Review recent evidence on genetic effects
  - Identify data gaps in knowledge e.t.c.





## BEIR VII - 2

- ***The Committee concludes that the current scientific evidence is consistent with the hypothesis that there is a linear no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans.***

## BEIR VII - 3

- Cancer risk estimates not changed much since 1990
- Cancer risk model based primarily on LSS study
- At doses below 100 mSv ***"statistical limitations make it difficult to evaluate risk in humans"***





## BEIR VII - 4

- LNT model "a computationally convenient starting point"
- Use DDREF of 1.5 to estimate risks of solid cancers (cancers other than leukemia)
- Use a linear –quadratic model to estimate risk of leukemia





## Comparison of BEIR VII and UNSCEAR 2000 Risk Estimates*

| Cancer Category | Males | | Females | |
|---|---|---|---|---|
| | UNSCEAR 2000* | BEIR VII | UNSCEAR 2000 | BEIR VII |
| **Incidence** | | | | |
| Leukemia | 50 | 100 | 50 | 72 |
| All solid cancers | 740 | 800 | 910 | 1,310 |
| | | | | |
| **Mortality** | | | | |
| Leukemia | 50 | 69 | 60 | 52 |
| All solid cancers | 380 | 410 | 660 | 610 |

* per 100,000 of all ages exposed to 0.1 Gy and DDREF of 1.5.

# UNSCEAR

- United Nations Scientific Committee on the Effects of Atomic Radiation
- Lead Agency for UN on health effects of ionizing radiation
- Reviews all scientific literature and synthesizes state of knowledge on a regular basis (~ every five years since 1955)
- The work of the Scientific Committee receives considerable leverage from contributions in kind provided by 58 National Organizations comprising the 21 national delegations to the Scientific Committee and by the 4 International Organizations that participate in its deliberations





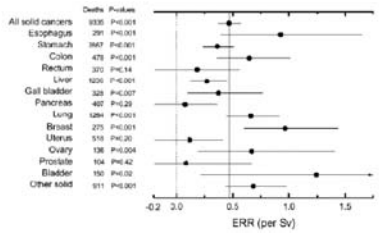
# UNSCEAR 2007

- UNSCEAR 2000 (Cancer, low dose, combined effects…) and 2001 (Hereditary)
- UNSCEAR 2007 Annexes
  - Epidemiology
  - Non-cancer
  - Non-targeted
  - Immune system
  - radon





**Estimates of the Site Specific Solid Cancer ERR with 90% Confidence Intervals and One-Sided P-Values for Testing the Hypothesis of No Dose Response**




All estimates and P-values are based on a model in which the effects of age at exposure and of attained age were fixed at the estimates for all solid cancers as a group. The light dotted vertical line at 0 corresponds to no excess risk, while the dark solid vertical line indicates the sex-averaged risk for all solid cancers.

After UNSCEAR 2007

## UNSCEAR 2007

- Risk estimates comparable to UNSCEAR 2000
  - Leukaemia - 0.5% $Sv^{-1}$
  - Solid cancer - 4-7.4% $Sv^{-1}$
- Lifetime risks of solid cancer to those exposed as children may be a factor of 2-3 higher than estimates for population exposed at all ages
- No clear evidence of non-cancer effects at low doses
- *Bystander effects appear limited to the irradiated organ, and since risk estimates are to an organ and not a cell, bystander effects are essentially encompassed in current radiation risk estimates for carcinogenesis*





## Hereditary Effects - 1

- Appreciable background of spontaneous mutations in humans
- To date, there is no evidence of hereditary effects in radiation-exposed human populations
- Experimental studies in plant and animals show that radiation can induce hereditary effects
- UNSCEAR 2001 report a hereditary risk based on radiation risk in mice and spontaneous risk in people





## Hereditary Effects - 2

- BEIR VII developed a doubling dose based on spontaneous mutations in humans and induced mutations in mice and recommended retaining 1 Gy for estimate of DD
- UNSCEAR 2001
  - Human/mouse model
  - DD OF 1 Gy
  - Risk of hereditary disorder of 3,000-4,700 cases per Gy for 1 million exposed
  - Represents 0.4 – 0.6 % of baseline frequency of hereditary disorders

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## ICRP 2007 - 1

- The most recent recommendations of the ICRP (Feb 2007) are based on its evaluation of the scientific literature developed since its previous recommendations of 1990 (ICRP 60, 1991). The main features of the most recent ICRP recommendations relevant to the current discussion are the following:
- The risk of cancer and of hereditary effects arising from exposure to low doses (up to about 100 mSv as single or annual doses) increase in simple proportion to increases in dose;





## ICRP 2007 - 2

- Based on cancer incidence data, the revised nominal risk coefficients for cancer (previous values from ICRP 60 in brackets) are:
  - $4.1 \times 10^{-5}$ per mSv ($4.8 \times 10^{-5}$ per mSv) for adult workers,
  - $5.5 \times 10^{-5}$ per mSv ($6.0 \times 10^{-5}$ per mSv) for the whole population

## ICRP 2007 - 3

- *Although no human studies provide direct evidence of radiation risk of hereditary disease, hereditary disease is seen in experimental animals; hence, it is reasonable to assume that radiation-related hereditary diseases can occur in people.*
- The ICRP suggests the following risks of hereditary disease ( previous values from ICRP 60 in brackets):
  - 0.1 x $10^{-5}$ per mSv (0.8 x $10^{-5}$ per Sv) for adult workers,
  - 0.2 x $10^{-5}$ per mSv (1.3 x $10^{-5}$ per mSv) for the whole population.





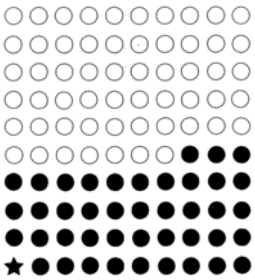
## Conclusions

- Current scientific evidence consistent with LNT
- Non Cancer effects occur at high doses
- Radiation exposure has never been demonstrated to cause hereditary effects in people but have been demonstrated in plants and animals, but prudent to assume occurs in people
- New biology (e.g. bystander effect) not affect risk estimates based on organs
- Threshold unlikely but risk of radiation induced cancers is small at small doses





## Approximate Lifetime Risk After Exposure to 0.1 Sv



After BEIR VII