IAEA
International Atomic Energy Agency

2. Why Optimization of Protection and Safety?

Plan of this presentation

- Short historical background on the pathological effects associated with ionising radiations discovery.
- Elaboration of the so called radiation protection system: the ICRP concepts.
- International and national regulations with brief introduction on the optimization of protection and safety

Historical Background (1/7)

From biological basis to the regulatory principle of optimization to deal with low doses exposure

End of 1895 : X Rays discovery by Röntgen.

Immediate development of diagnostic radiology. Without any precaution.

1902: first X ray dosimeter by Holznecht

First world war 14-18 : the “petites Curie”.

Since beginning of 20’s century, the first pathological effects are recognised: they are deterministic). Just after the end of the world war, the radiographers training includes prevention measures.

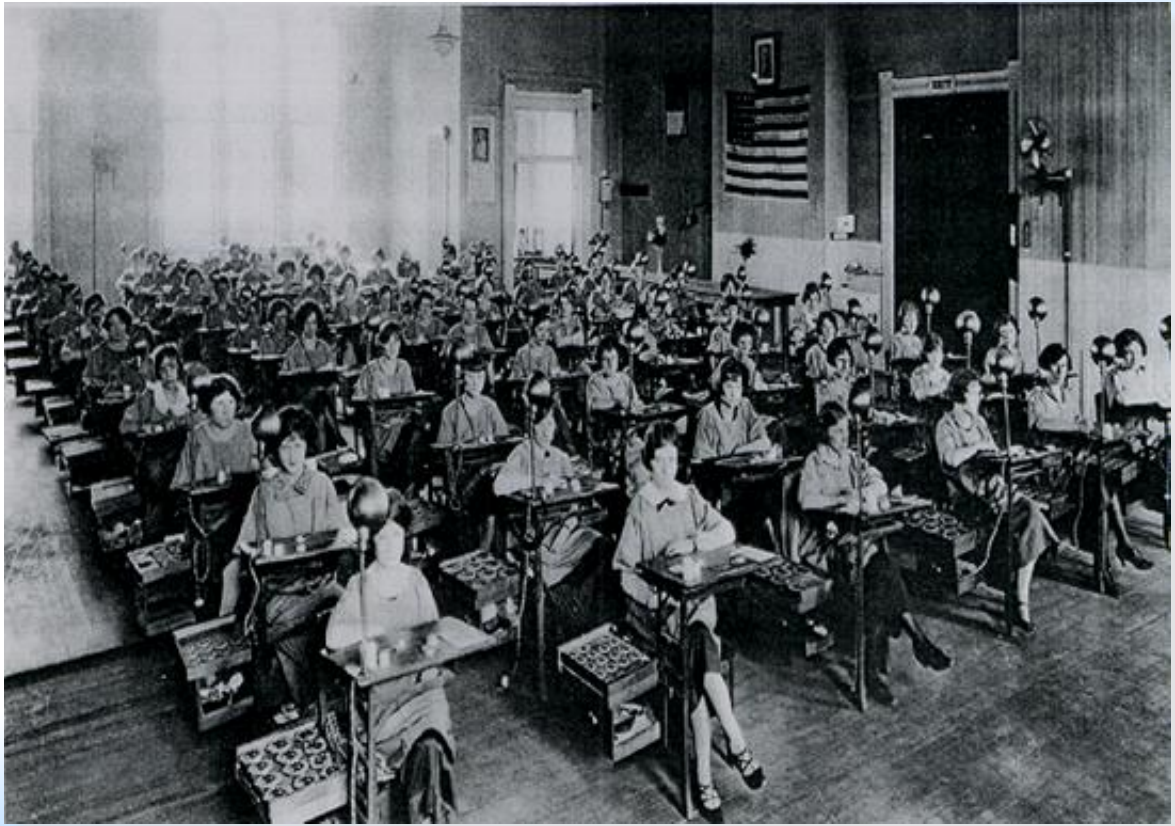
During the 20’s : first recognised deaths within the radiology professionals.

Historical Background (2/7)

During the same period, increase of industrial use of radium, discovered at the beginning of the century by Mrs Curie, in the watch making industry for example.

1924 – USA: Abnormal number of diseases and deaths (jaws' cancers, anaemia's,…) within the female workers of radium painting population in the United States Radium. (They will receive compensations in 1928).

Historical Background (3/7)



Historical Background (4/7)

1928

Setting Up of the International Committee for Protection against X Rays and Radium, which will become International Commission on Radiological Protection in 1950.

- 3 protection principles

1945

Hiroshima et Nagasaki bombing.

1952

Acknowledgment, through the follow up of big statistical data of a link between exposure of the H and N populations and the development of leukaemia's (stochastic effects).

Historical Background (5/7)

Historical Background (7/7)

1946

Atomic Bomb Casualty Commission (ABCC)

1954

Lucky Dragon Affair. A Japanese tune fishing boat is exposed to the radioactive fall down from an H Bomb explosion. The sailors come back ill to Japan, with contaminated fishes.

The world becomes conscious about military nuclear trials and their impacts.

1955

Setting up of UNSCEAR - United Nation Scientific Committee on the Effects of Atomic Radiations (for assessing levels and effects of exposures at the world level).

Historical Background (7/7)

IAEA

1956

Setting up of IAEA - International Agency for Energy Atomic (UN) – For promoting peaceful nuclear energy uses.

1957

Rome Treaty setting up the EURATOM community (European Community for Atomic Energy)

Setting up of the AEEN, which will become NEA (Nuclear Energy Agency) within OECD in 1965.

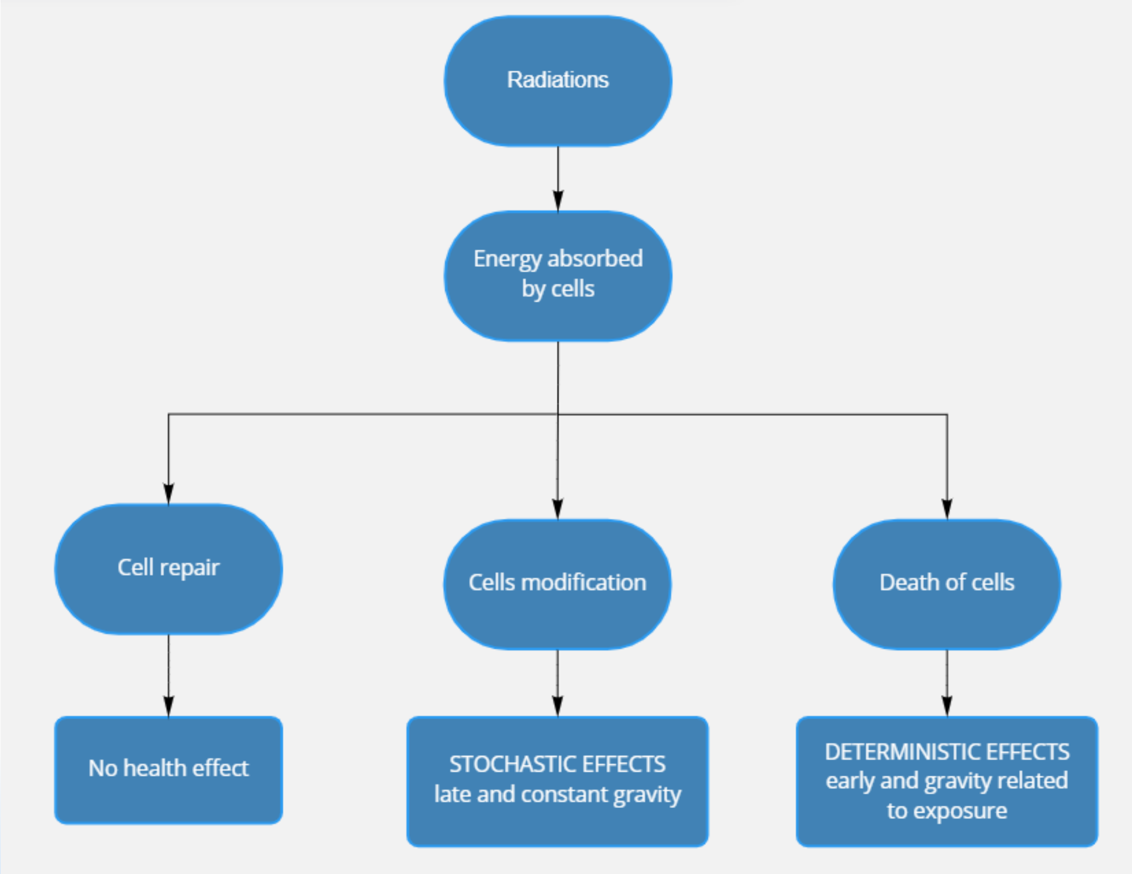
1963

Moscow treaty forbidding atmospheric nuclear tests, (USA, USSR and UK)

1975

ABCC becomes RERF (Radiation Effects Research Foundation).

The pathological effects of ionizing radiation



Some threshold examples for deterministic effects

	DOSE* (Sievert)	EFFECT	LATENCY PERIOD
Lens of the eye	5	cataract	6 months to several years
Skin	3	erythema	1 to 3 weeks
Gonads	3	sterility	a few weeks
Whole body	0.5	vomiting	1st day
	3-5	death (LD50)	1 to 2 months
	5-15	death (LD50)	10 to 20 days
	>15	death (LD50)	1 to 5 days

*incured over less than 2 days

Management of Deterministic effects: Prevention Principle (1/2)

- Dose effect relationships well quantified
- Easy to translate into regulation
- The limit is an individual guarantee that deterministic effects will not occur

150 mSv/year for the lens
500 mSv/year for skin, hands and feet

This was relying on scientific evidence up to 2011

Management Of Deterministic Effects: Prevention Principle (1/2)

Do still occur deterministic effects following normal occupational exposures now a day? Yes in few cases in medical interventional procedures

The dose limits for eye lens will evolve in the near future; new evidence is now that the threshold is reduced by a factor 10

ICRP recommends now a dose limit to the eyes of 20 mSv a year.

Up to date dose limits are presented in slide 40

The stochastic or probabilistic effects

Increase of the number of observed cancers in an exposed population

Impossibility to predict who in the exposed population will develop a radio induced cancer

Impossibility to identify among occurred cancers those induced by radiations

Existence of an excess of radio induced cancer

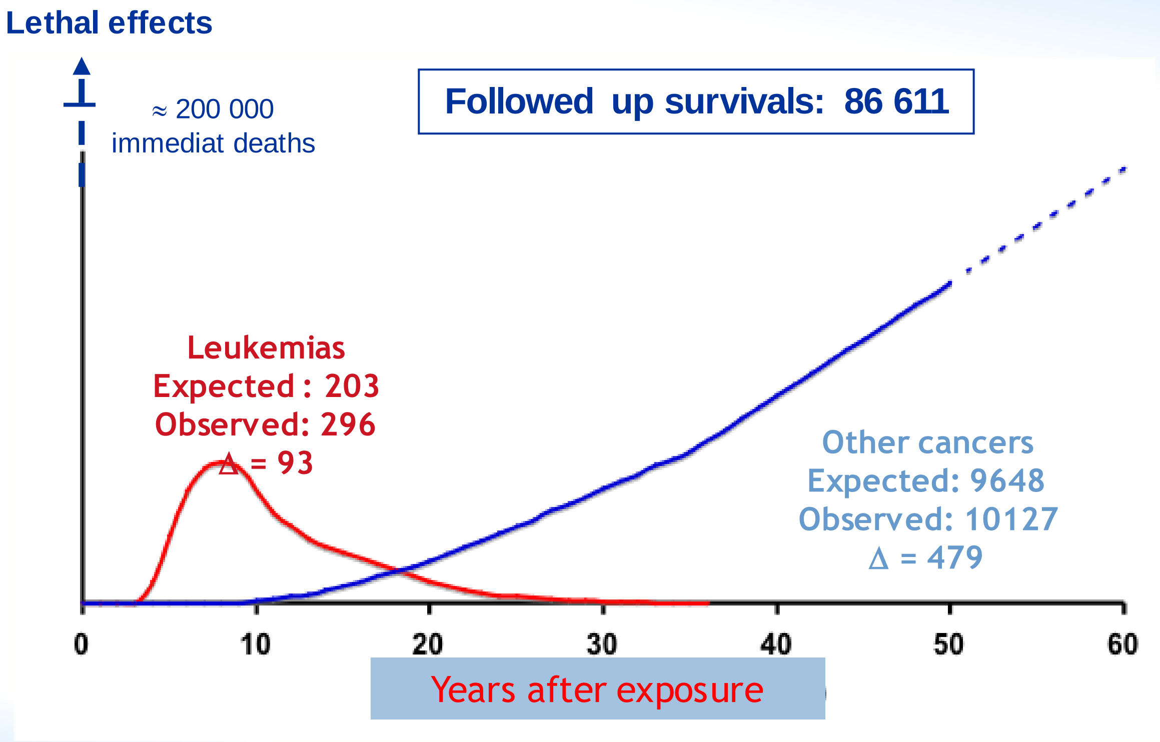
To significantly demonstrate the existence of an excess of radio induced cancer: it is necessary to follow up during 10 to 30 years

1000 individuals when exposure is around 1 Sievert per person

Several tenth of thousand of individuals for 1/10 Sievert

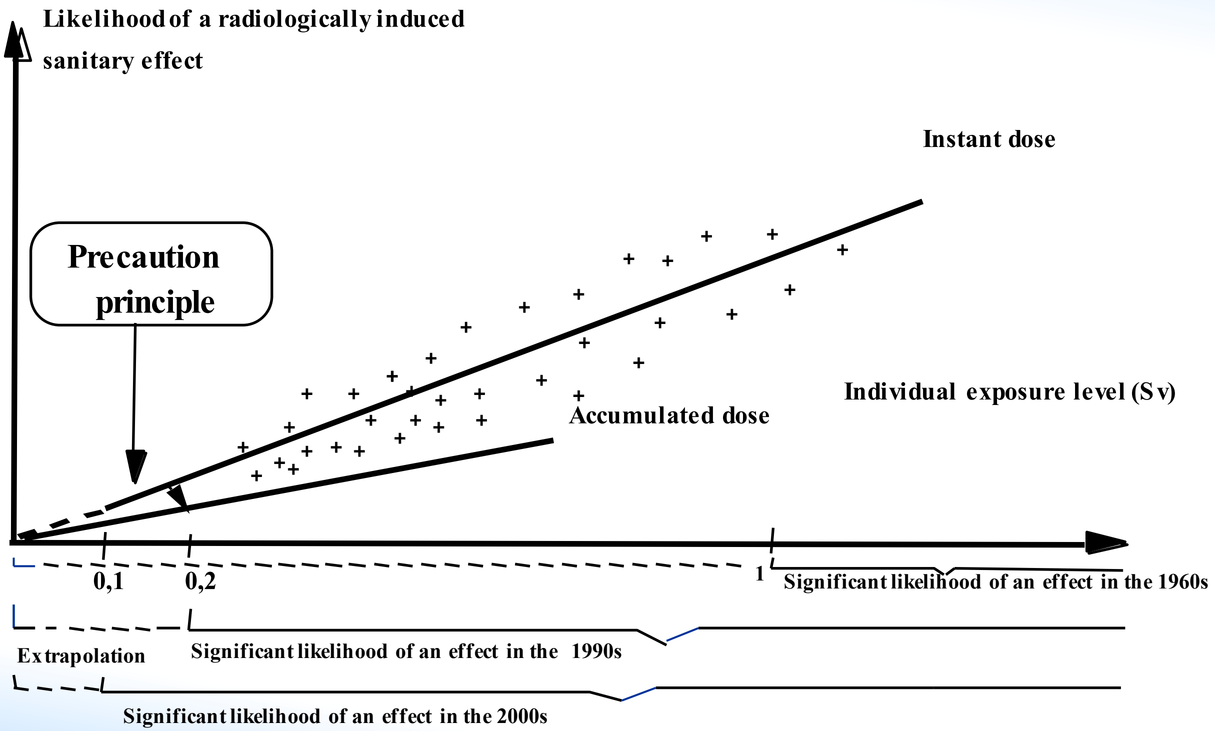
10 000 000 individuals for 1/100 Sievert

Health effects from HIROSHIMA- NAGASAKI



Source: Preston *et al.*, Rad Res 2004

The dose effect relationship for stochastic effects to low doses



To manage uncertain situation, precaution is a behaviour…

Which is ethical

That answers to a willingness to be socially responsible

That induces a pragmatic way of acting to:

- Be responsible to build and, to maintain the risk at a reasonable level, not misallocating resources and ensuring an equitable distribution of the risk
- Be vigilant and let the door open to knowledge progress

The risk for stochastic effects (ICRP 103 - Whole lifetime)

- Risks of death from cancer : 27,5 %
- Risk increase for 1 Sievert (Sv)
  - for workers : 4,1 %
  - for the public : 5,5 %

- Loss of life expectancy associated with a cancer : 16 years

The exposure risk relationship for radiation induced stochastic effects (ICRP 103 –Whole life)

Nominal probability coefficients (10^{-2} per Sv)

Population exposée	Cancer	Heavy hereditary effects	Total
Workers	4.1	0.1	4.2
Public	5.5	0.2	5.7

The exposure - risk relationship is assumed to be linear without any threshold

The risk for stochastic effects

A worker who, during his working life (35 years), would have received 20 mSv each year, would have cumulated 700 mSv, which corresponds to a risk of death from radiological induced cancer of 2.8 % .

(i.e a total risk of dying from a cancer of 30,4% in western Europe, of 32,5 % in the USA and Canada,…)

To put into perspective individual risks of death

Death causes	Annual individual Risk
All causes	**$8{,}92.10^{-3}$**
All cancers	**$2{,}50.10^{-3}$**
Lung cancer	$4{,}00.10^{-4}$
Leukemia	$1{,}36.10^{-4}$
Work accident	**$2{,}00.10^{-4}$**
Metallurgy	$4{,}24.10^{-5}$
Building	$1{,}66.10^{-4}$
Wood	$7{,}51.10^{-5}$
Chemistry	$2{,}81.10^{-5}$
Mine	$1{,}53.10^{-4}$
Home life	**$6{,}42.10^{-5}$**
Road accident	**$1{,}45.10^{-4}$**
Radio-induced cancer (worker: 20 mSv)	**$8{,}00.10^{-4}$** (estimate)

Making use of the exposure risk relationship
“What happens if?”

IAEA

100 workers are exposed 1Sv each?

1000 workers are exposed to 0,1 Sv each?

How many radio induced cancer are expected in each case?

What is the sum of the individual doses in each case?

The Collective dose concept (1/2)

Number of exposed individuals	Individual Dose	Individual risk excess*	Population Risk	Population dose
100	1 Sv	4/100	4 cancers	100 Men-Sv
1 000	0,1 Sv	4/1000	4 cancers	100 Men-Sv
10 000	0,01 Sv	4/10000	4 cancers	100 Men-Sv

(*) Assuming a linear no threshold dose risk relationship for the workers (4% for 1 Sievert)

This is only possible because of the LNT shape of the relationship

The Collective dose concept (2/2)

- Sum of individual doses for exposed individuals
- Expressed in Man.Sievert (Man.Sv)
- Corresponds to the potential health detriment to a population as a whole
- A risk indicator for that population
- A Performance indicator for protective actions
- Must "never" be taken without reference to individual risk levels and others factor

The Collective dose concept (3)

The loss of life expectancy for one man Sievert is around…

- 16 years for one cancer
- Multiplied by the probability of a cancer occurrence
- i.e. 0,055
- 0,88 year

… one man year

ICRP concepts for managing radiation risks

3 Principles to be responsible in managing radiological risk

Justification of practices

- Expected benefits must over weight detriment

Optimization of protection and safety

- To maintain the risk of exposures, the number of exposed people, the individual doses and the likelihood of exposure as low as reasonably achievable (ALARA) with the economical and social factors being taken into account
- Making use of risks and doses constraints for :
  (a) reducing inequity (b) taking care of multiple sources.

Limitation of individual exposures

Justification of activities

IAEA

- What is called an activity?
- Who decides what activities are justified?
- Is a justified activity justified for ever?
- Is there a difference for justification between old and new activities?
- What happens in the medical sector?

When is an activity considered as justified

It may be implemented and therefore creating situations with new doses

The radiological risk has then to be managed in a reasonable way:

- Doses have firstly to be optimized
- Secondly checking they do not exceed dose limits

ALARA : a predictive approach (1/2)

To try to maintain exposures as low as reasonably achievable (i.e) possible, implies adopting a predictive attitude in order to:

- Evaluate and predict individual and collective exposures
- Envisage actions likely to reduce exposures
- Select those actions considered reasonable

ALARA : a predictive approach (2/2)

To what questions should the evaluation try to answer?

Who performs the evaluation? The health physicists? The RPO?

What can be considered as reasonable?

Why optimizing protection and safety and not minimizing radiological risk?

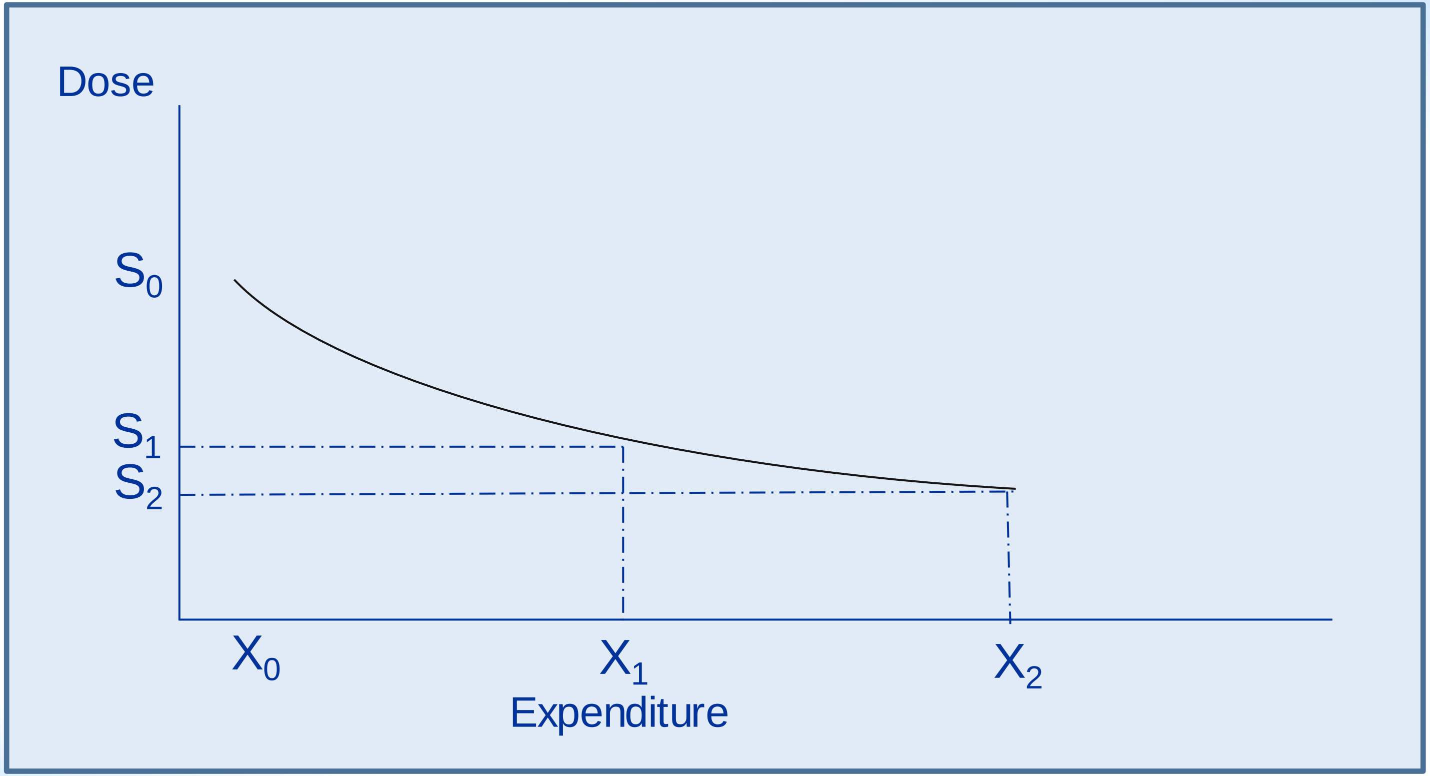
It is difficult to achieve zero risk

- natural radioactivity
- law of decreasing returns; the more we try to reduce the highest becomes the cost.

Inappropriate allocation of social resources, leading for example to an increase of other types of risks (conventional,…)

Transfer of the risk, for example between two categories of exposed populations (workers vs public, or workers specialty 1 vs workers specialty 2)

Law of diminishing returns



Example of risk transfer between public and workers

Floor drains effluent treatment (20 years of operation)

	public dose index	workers dose index	total dose index
No treatment	100	0	100
Storage	75	15	90
Storage and filtering	e	50	50

Having optimized, how to deal with the limit?

What is then the role of the limit ?

What happens when the optimized solution is higher than the limit ?

i.e. if all what is considered as reasonable does not lead to doses under the limit?

The two roles of the limit

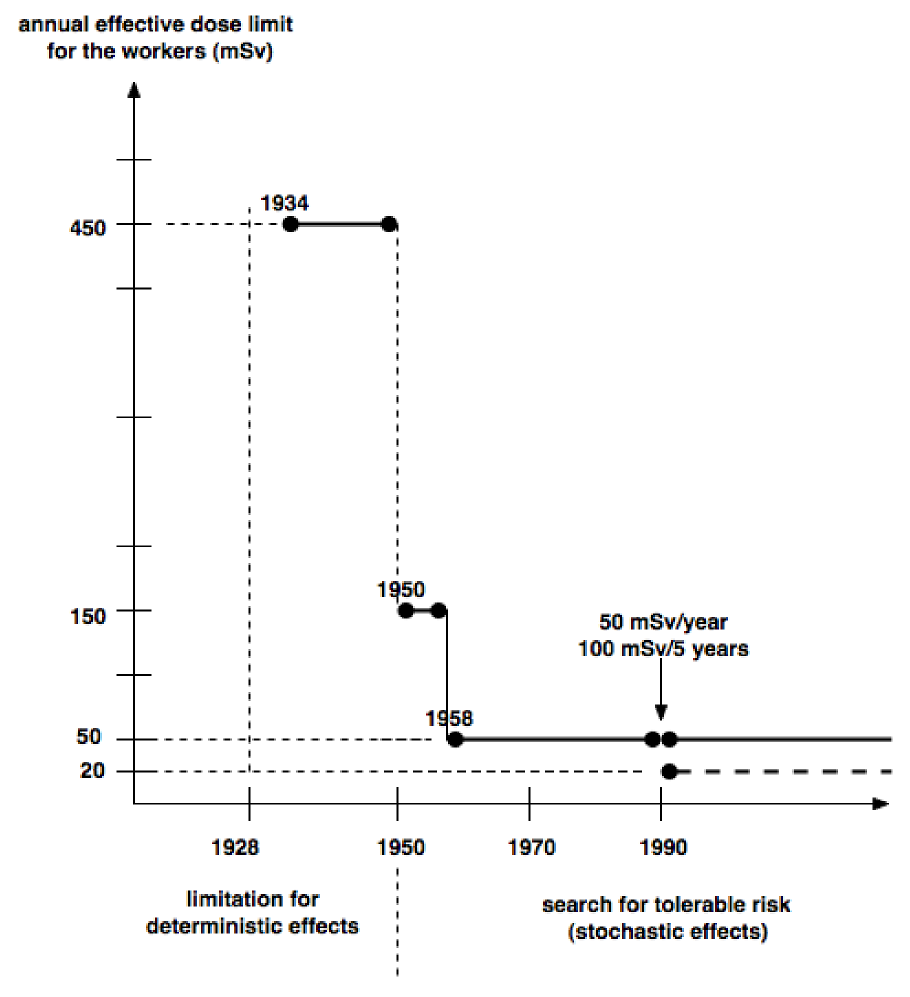
Individual guarantee that deterministic effects

- will not occur

Individual guarantee that the residual risk for

- stochastic effects is socially tolerable
- Above the limit is unacceptable
- *For such reasons the limit shall not be exceeded whatever the cost*

Evolution of the annual effective dose limit



Up to date Dose Limits :
equivalent dose or effective dose (mSv)

	Workers (Ext +Int mSv/an)	**Public** (Ext +Int mSv/an)
Whole body	20 (100 for 5 years)	1
Lens *	20 (100 for 5 years)	15
Skin*	500	50
Extremities* **(hands, feet)**	500	-

**** Equivalent dose***

Misinterpretations of the dose limit concept

It is not a border between safe and unsafe [harmlessness threshold]

It does not applied to the source but to the individual.

It does not applied to intervention situations [Situations de facto]

It does not applied to medical exposure as they are provided for the benefit of patients

ICRP and the dose constraint concept

Annual dose constraints between 1–20 mSv should be used for occupational exposures. Dose constraints for a specific practice should be decided on a case-by-case basis.

They are management tools for optimization of protection and safety

In large industries, dose constraints may be set up by the management and appear as a managerial tool; while in other industries or in the medical and research sectors, they may be proposed by the regulatory bodies in relationship with the concerned stakeholders.

Misinterpretations of the dose constraint concept

It is not a dose limit

It is not a border between safe and unsafe [harmlessness threshold]

It does not applied to the source but to the individual.

What is the situation in your country?

- What are the dose limits in your country?
- Have they evolved recently
- Have you dose constraints in your facility? In your profession?
- What are they?
- What are they used for? .

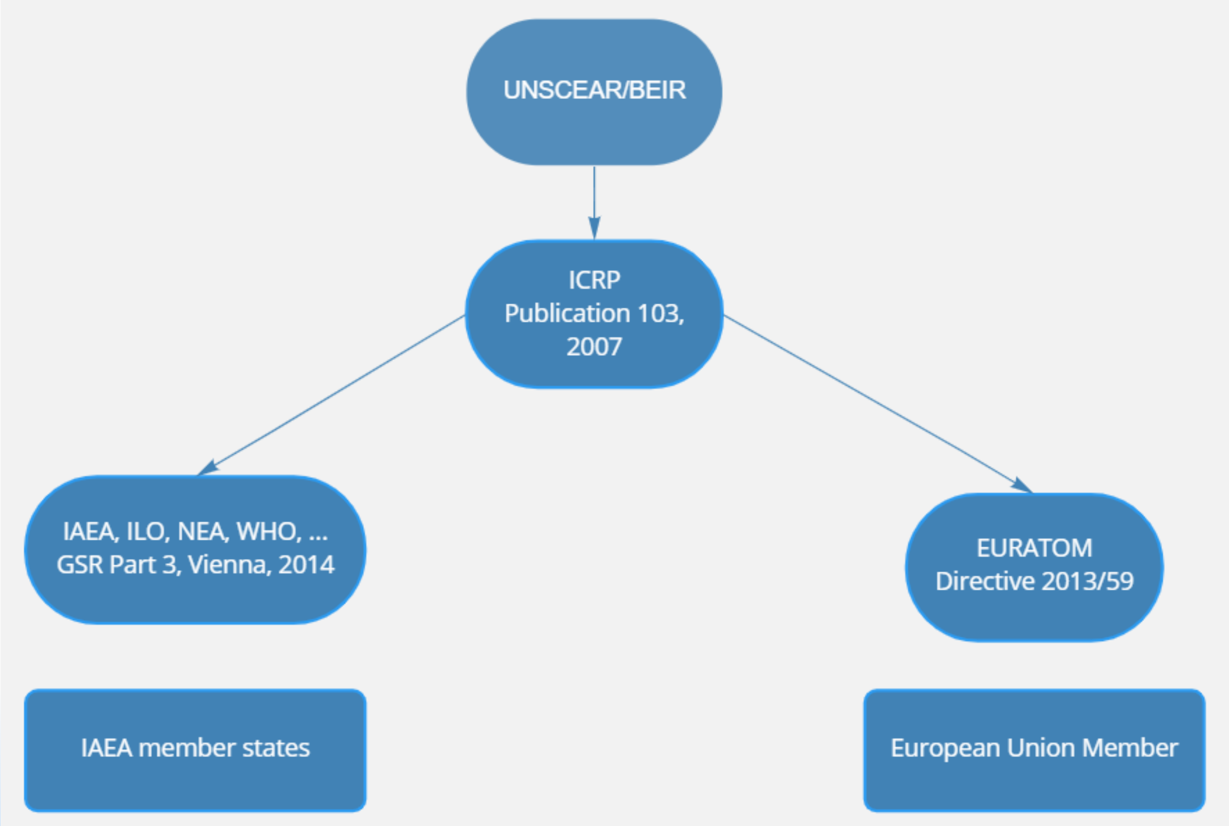
International and National Regulations Focus on the IAEA BSS*

Use of ICRP concepts is not mandatory per se

ICRP being a NGO

But all international organisations and national regulatory bodies rely on ICRP recommendations to elaborate BSS and regulations

Radiation Protection Standards set up at international level



Other references on *Optimization of Radiation Protection*

- Optimization of Radiation Protection, Safety Reports Series no. 21, IAEA, Vienna 2002 (under revision)
- Occupational Radiation Protection, General Safety Guide, No. GSG-7, IAEA, Vienna, 2018
- Optimization of Radiation Protection - ALARA: A Practical Guidebook, European ALARA Network, First publication, 2019
- A less recent reference, but still useful is the European commission book: "ALARA from theory towards practice" EC Report EUR 13796 EN DG Science, Research and Development, 1991

Safety Principles in the International Basic Safety Standards (GSR Part 3, IAEA 2014) *

IAEA

The safety principles are presented in the introduction / background / 1.7

Principle 4: Justification of facilities and activities

- *Facilities and activities that give rise to radiation risks must yield an overall benefit*.

Principle 5: Optimization of protection

- *Protection must be optimized to provide the* ***highest*** *level of safety that can* ***reasonably*** *be achieved.*

The safety principles are based on the "Fundamental Safety Principles",

Safety Standards Series No SF-1, IAEA, Vienna 2006

Safety Principles in the International Basic Safety Standards (GSR Part 3 IAEA 2014)

The BSS then remind the core of radiological protection system:

Principle 6: Limitation of risks to individuals

- *Measures for controlling radiation risks must ensure that no individual bears an **unacceptable** risk of harm*

Principle 10: Protective actions to reduce existing or unregulated radiation risks **must be justified and optimized**.

More on optimization (GSR Part 3, Para 1.15)

IAEA

The optimization of protection and safety, when applied to the exposure of workers …, is a process for ensuring that the magnitude and likelihood of exposures and the number of individuals exposed are **as low as reasonably achievable**, with economic, societal and environmental factors taken into account.

…Optimization is a **prospective** and **iterative** process that requires both **qualitative** and **quantitative** judgements to be made.

More on dose constraint (GSR Part 3, Para 1.22)

Dose constraints are applied to occupational exposure and to public exposure in planned exposure situations*.

Dose constraints are used as boundary conditions in defining the range of options for optimization of protection and safety

Dose constraints are not dose limits; exceeding a dose constraint does not represent non-compliance with regulatory requirements, but it could result in follow-up actions.

** For emergency exposure situations and existing exposure situations, see chapter 3.0*

More on dose constraint (GSR Part 3, Para 1.23)

For occupational exposure, the dose constraint is a tool to be established and used by the person or organization responsible for a facility or activity *.

After exposures have occurred, the dose constraint may be used as a benchmark for assessing the suitability of the optimized strategy for protection and safety (referred to as the protection strategy) that has been implemented and for making adjustments as necessary.

** In some countries, the dose constraint has to be agreed on by the Regulatory Authority.*

GSR Part 3, General Requirement 11

Req.11 The government or regulatory body shall establish and enforce requirements for the optimization of protection and safety, and registrants and licensees shall ensure that protection and safety is optimized

- **In particular:**

3.24. For occupational exposure and public exposure, registrants and licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection to contribute to achieving the following objectives:

- To determine measures for protection and safety that are optimized for the prevailing circumstances, with account taken of the available options for protection and safety as well as the nature, likelihood and magnitude of exposures;

(b) To establish criteria, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that do occur.

GSR Part 3, General Requirements

Req. 11 : 3.25. For occupational exposure and public exposure, registrants and licensees shall ensure, as appropriate, that relevant constraints are used in the optimization of protection and safety for any particular source within a practice

Req.14 : Registrants and licensees and employers shall conduct monitoring to verify compliance with the requirements for protection and safety

GSR Part 3, General Requirements

Req.21 : Employers, registrants, and licensees shall be responsible for the protection of workers against occupational exposure,…shall ensure that protection and safety is optimized,…

Req.23 : Employers and registrants and licensees shall cooperate to the extent necessary for compliance by all responsible parties with the requirements for protection and safety

International BSS and other national BSS to regulations

As countries are members of the international organisation such as IAEA, EC, they are committed with the elaboration of their BSS, and that the national regulations are in adequacy with them.

Implementing optimization of radiation protection is mandatory, as well as coping with dose limits, however it is not as simple…

Legal statute of the dose limit

Going beyond = infringement

Obligation of results; quite easy to check

Sharing responsibility between the employer and the operator for workers;

Main responsible: the employer for workers

the source owner for public

Legal statute of optimization of protection and safety (1)

“Mandatory” as dose limits

But... obligation of means not of results

What does it mean?

Legal statute of optimization of protection and safety (2)

What does it mean?

To compare with "keep control of his vehicle in all circumstances" versus "respect speed limit"

All are "responsible" a priori to have an attitude, a behaviour aiming at implementing optimization of protection and safety

From the analysis will emerge optimized objectives...

... Non opposable juridico

Legal statute of optimization of radiological protection (3)

IAEA

Sharing responsibility between the employer and the operator for workers

The **operator** is responsible for providing all workers with *optimized sources and working conditions*

The **employer** is co-responsible for predicting and co optimizing the exposures of his workers

The **operator** is responsible for *non-implementation of optimization of radiation protection* both for workers and public

Optimization: a compromise between stakeholders

On what may and what shall be done reasonably to maintening exposures as low as possible

On the objectives in terms of both collective risks and individual risk distribution.

On risks transfers that are compatible with an equitable risks distribution

On resources to be made available

Optimization of protection and safety : a few keywords

Mandatory for managing stochastic risks to low doses exposure.

Reasonable

Predictive and iterative

Obligation of means