

THE SYSTEM OF RADIOLOGICAL PROTECTION & THE ROLE OF INTERNATIONAL ORGANISATIONS IN THE DEVELOPMENT OF THE NATIONAL LEGAL FRAMEWORKS

Scientific bases, philosophy and regulatory framework of Radiological Protection

TRASNUSAFE EuroCourse 1
Managerial Competences and Leadership for Safety Culture
27th - 28th November 2013 Manchester, UK

LECTURE PLAN

- **International organisations involved in the establishment of radiation protection standards**
- **Basic principles of radiation protection**
 - Deterministic & stochastic effects
 - Principles: justification, optimisation, application of dose limits
 - Practical implementation of optimisation
- **European regulatory framework**

PART. I

**INTERNATIONAL ORGANISATIONS
INVOLVED IN THE ELABORATION OF THE
PROTECTION SYSTEM
AND THE ESTABLISHMENT OF
RADIATION PROTECTION STANDARDS**

INTERNATIONAL ORGANISATIONS (1)

**UNSCEAR:
United Nations Scientific Committee on the Effects of
Atomic Radiations**

- assesses the **levels of radiation** to which the population of the world is or may be exposed due to **natural** or **artificial** sources
- analyses the **consequences** for human **health** of the doses received
- publishes reports reflecting the **latest scientific and findings and statistical data on exposures**

<http://www.unscear.org/>

INTERNATIONAL ORGANISATIONS (2)

ICRP: International Commission on Radiological Protection

- an **independent**, international **non-governmental not for profit** advisory body comprising experts in various fields from around the world
- **Publishes not legally binding recommendations and guidances** "aimed principally at regulatory authorities, organisations, and individuals that have responsibility for radiological protection"
- Last publication describing the global system of radiological protection: **Publication** no.103 issued in 2007
- Structure:
 - **A Main Commission issuing recommendations**
 - **5 standing committees:** *Radiation effects, Doses from radiation exposure, Protection in medicine, Application of the Commission's recommendations, Protection of the Environment*
 - **a set of Task Groups and Working Parties to address new topics**
 - **+ Liaison organisations**

<http://www.icrp.org/>

INTERNATIONAL ORGANISATIONS (3)

IAEA: International Atomic Energy Agency

- is the world's center of cooperation in the nuclear field, set up as the world's "Atoms for Peace" organization in **1957** within the **UN** and works with its Member States
- <http://www.iaea.org/>
- regularly issues recommendations containing the Basic Standards for protection against ionising radiation and the safety of radiation sources
 - ✓ In cooperation with **FAO** (Food and Agriculture Organisation), **ILO** (International Labour Organisation), **OECD/NEA** (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development), **PAHO** (Pan American Health Organisation), **WHO** (World Health Organisation) and **European Commission**
 - ✓ **Guidance for IAEA Member States**
 - **Basic Safety Standards (interim edition 2011)**
 - ✓ Based on ICRP recommendations (*Publication 103, 2009 Statement on Radon and 2011 Statement on Tissue Reactions*)

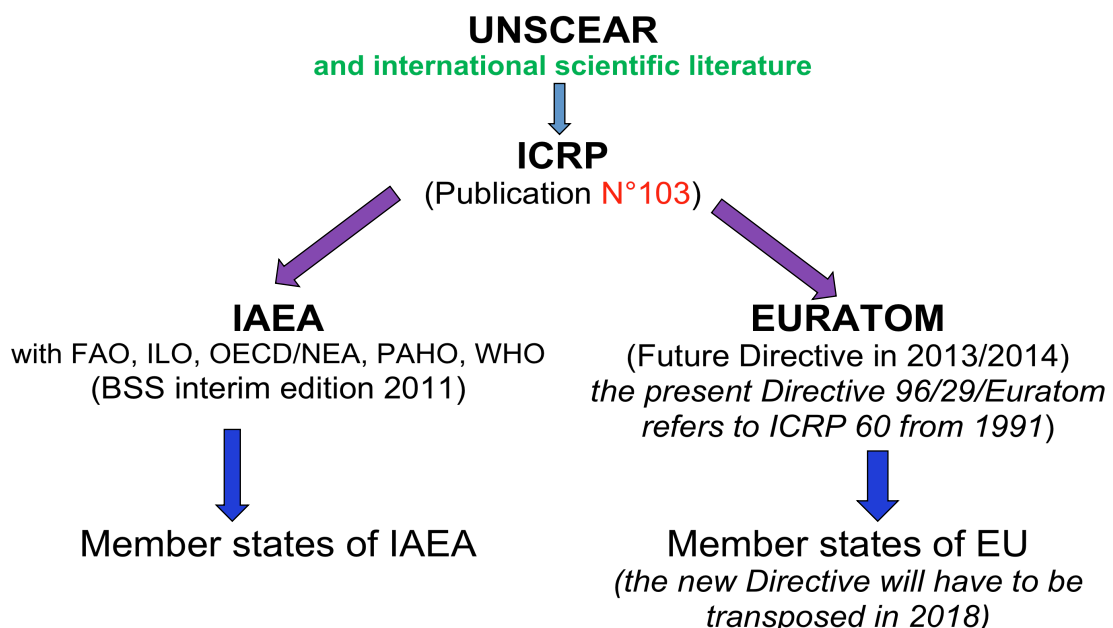
INTERNATIONAL ORGANISATIONS (4)

EURATOM: European Atomic Energy Community

- since 1957 has been issuing its own basic standards designed to protect workers and the public against the dangers resulting from ionising radiation
- these basic standards are published in Euratom Directives
(latest ones: *96-29/Euratom for radiation protection of workers and the public, 97-43/Euratom for radiation protection in the medical field*)
- a new Directive, merging all issues (protection and information of workers and the public, medical field, outside workers, high activity sealed sources) will be published soon (end 2013-2014)
- **Euratom standards are legally binding** since they must be transposed into the legislation of Member States; however they are minimum requirements of protection, and Member States can adopt more restrictive standards

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RADIATION PROTECTION STANDARDS ESTABLISHED AT THE INTERNATIONAL LEVEL

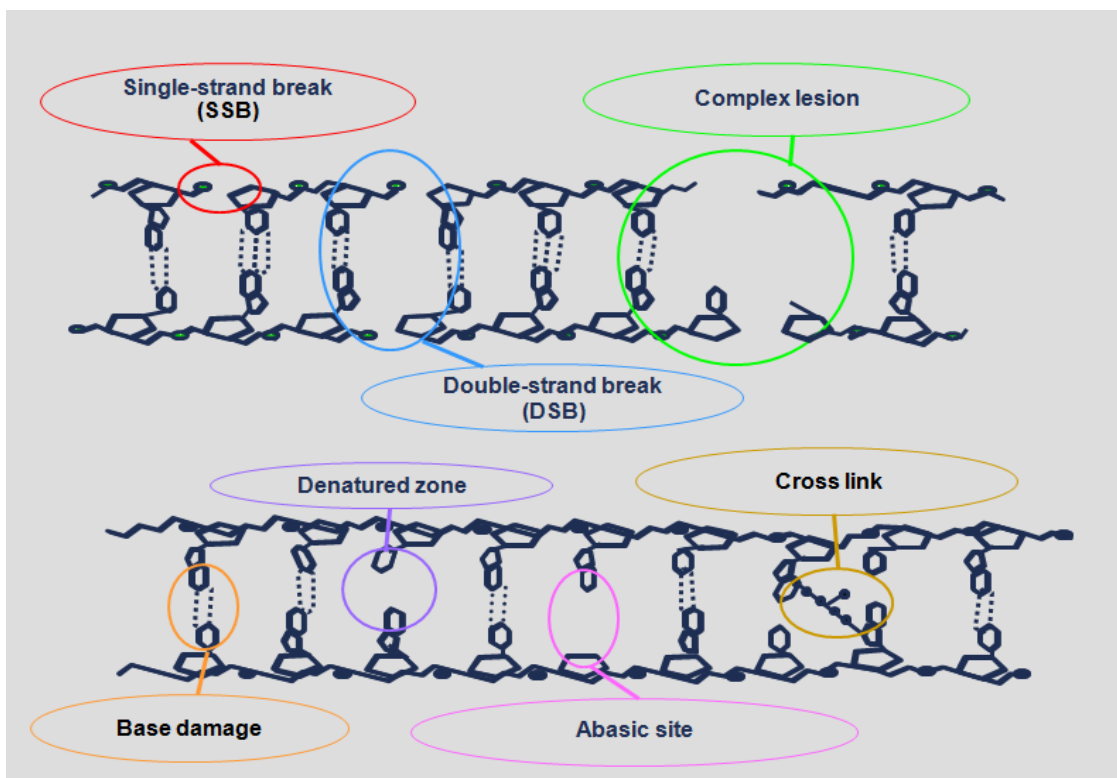


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Part. II

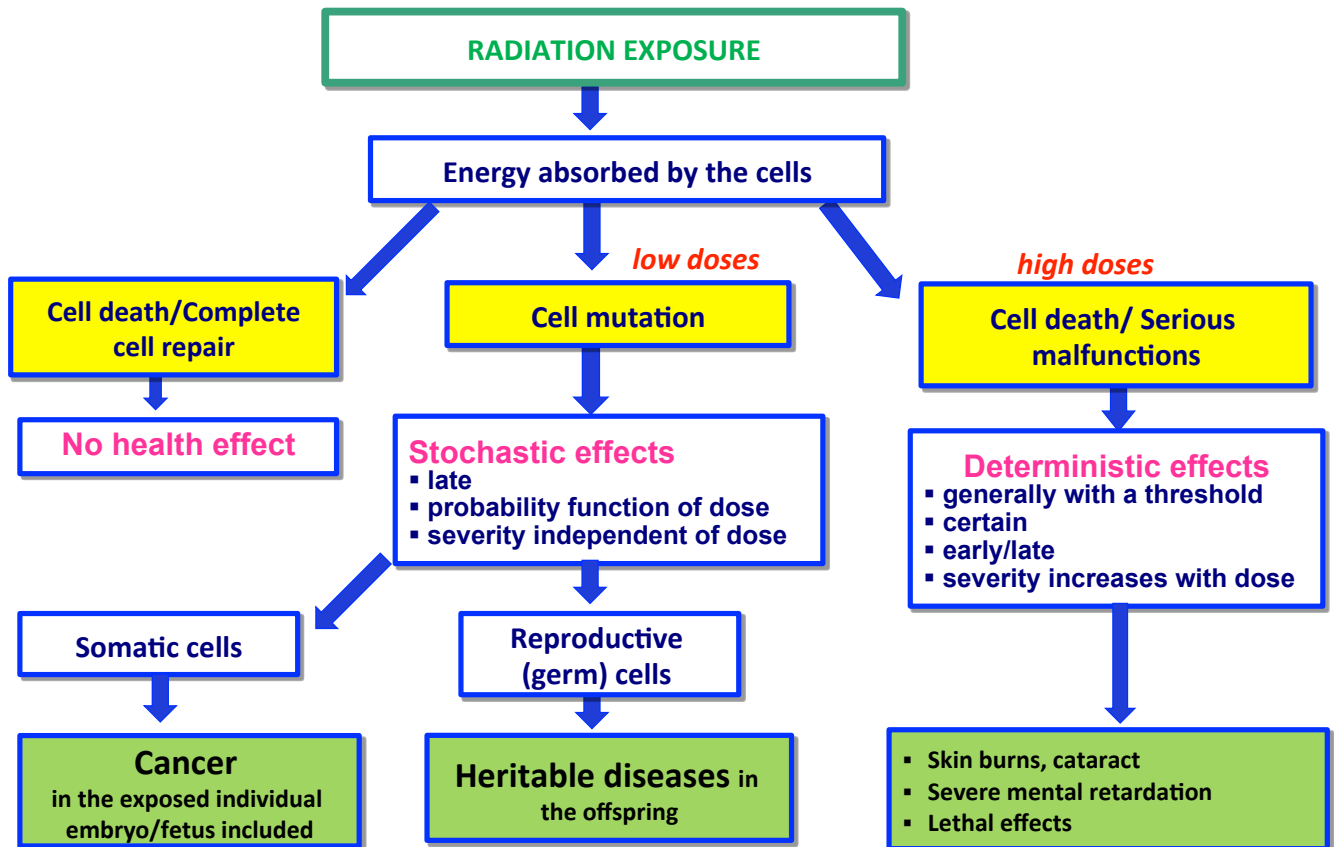
BASIC PRINCIPLES OF RADIATION PROTECTION

RADIATION IMPACT ON DNA

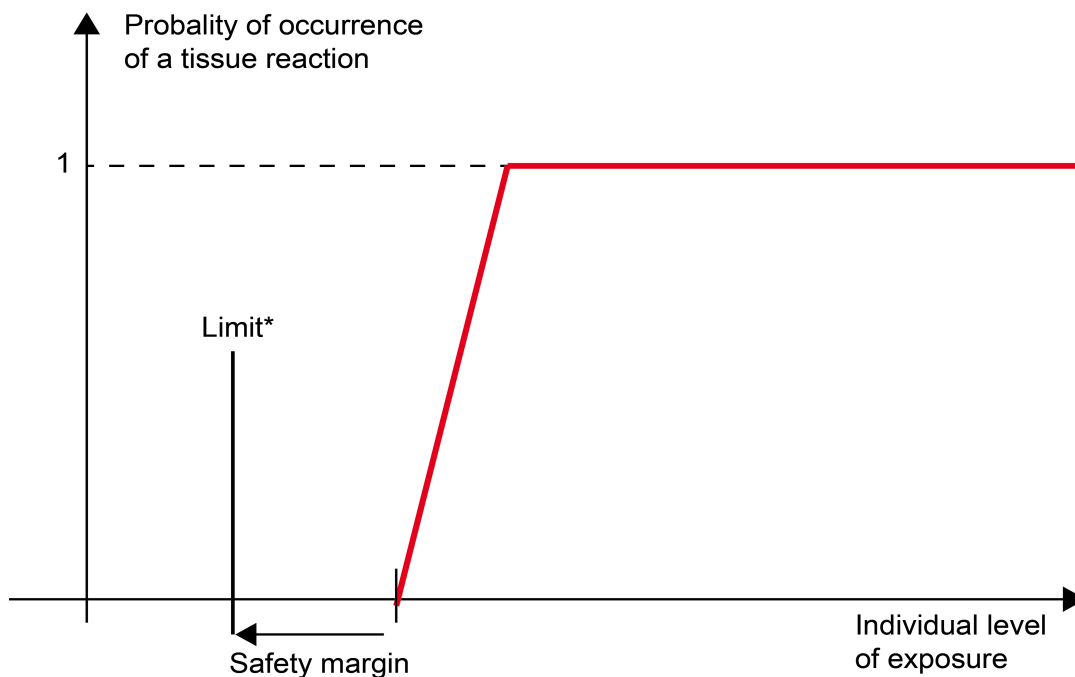


from: Quintiliani and Saporita, G. Ital. Med. Lav. 1981

THE PATHOLOGICAL EFFECTS OF IR



DETERMINISTIC EFFECTS: THE THRESHOLD MODEL



* in normal conditions

SOME EXAMPLES OF THRESHOLDS° FOR DETERMINISTIC EFFECTS (from ICRP 118)

Effect	Organ/tissue	Acute exposure*(Gy)	Time to develop effect
Cataract (visual impairment)	eye	~ 0.5	> 20 years
Skin burns	skin (large areas)	5 - 10	2 - 3 weeks
Main phase of skin reddening		< 3 - 6	1 - 4 weeks
Permanent sterility	testes	~ 6	3 weeks
	ovaries	~ 3	< 1 week
Depression of haematopoiesis	bone marrow	~ 0.5	3 - 7 days
Cognitive defects	brain	1 - 2	Several years
Cognitive defects (Infants < 18 months)		0.1 - 0.2	

° Threshold dose is defined for practical purposes as the dose resulting in only 1% incidence of specified tissue or organ reactions (from ICRP 103)

* Acute exposure = dose incurred in a very short time (from ICRP 103)

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THE MANAGEMENT OF DETERMINISTIC EFFECTS

- Dose-effect relationship well quantified
- Existence of threshold dose under which no deterministic effects are observed (widely discussed now)
- Easy to translate into regulation
- The limit is an individual guarantee that deterministic effects will not occur

Present limits for workers :
150 mSv/year for the lens*
500 mSv/year for skin, hands and feet

*New BSS :
20 mSv/year for the lens

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THE STOCHASTIC EFFECTS (from ICRP 103)

- radiological protection in the low dose range is primarily concerned with protection against **radiation-induced cancer** and **heritable diseases**
- these diseases are termed **stochastic effects**, as they are **probabilistic** in nature
- it is **assumed** that any exposure is capable of causing an effect, with **no threshold (LNT)**
- as a consequence it is not possible to prevent stochastic risks and dose limits are set to limit their occurrence and thus **to prevent unacceptable levels of risk**
- radiological protection is concerned with controlling exposures to ionising radiation so that **the risk of stochastic effects is limited to an acceptable level**

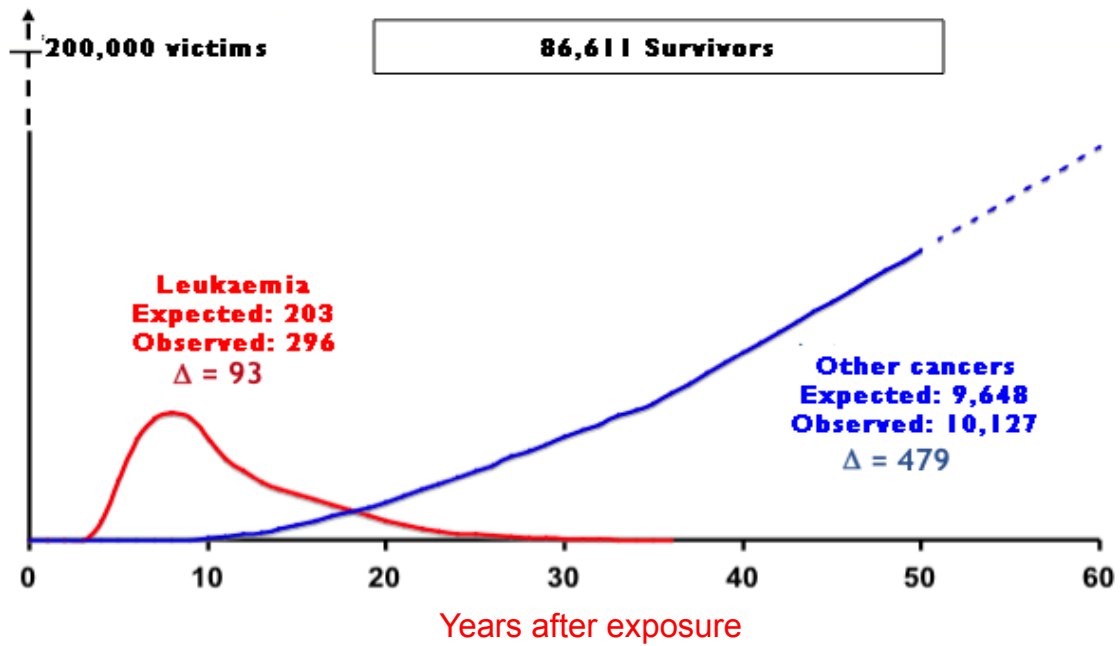
EPIDEMIOLOGY and STOCHASTIC EFFECTS

In epidemiology, to significantly demonstrate the existence of an excess of radio-induced cancer : It is necessary to Follow up populations during 10 to 30 Years

Moreover, the size of the exposed population required is:

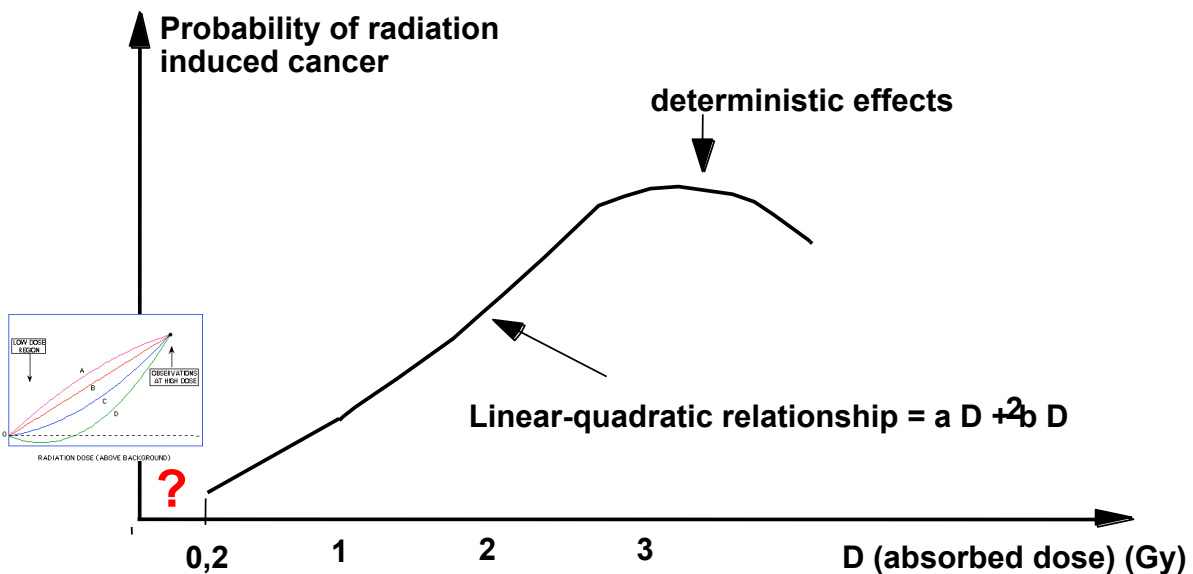
- **1000s individuals when exposure is around 1 Sievert per person**
- **10s x 1000 individuals for 1/10 Sievert**
- **Several millions of individuals for 1/100 Sievert**

HIROSHIMA AND NAGASAKI COHORTS FOLLOW UP

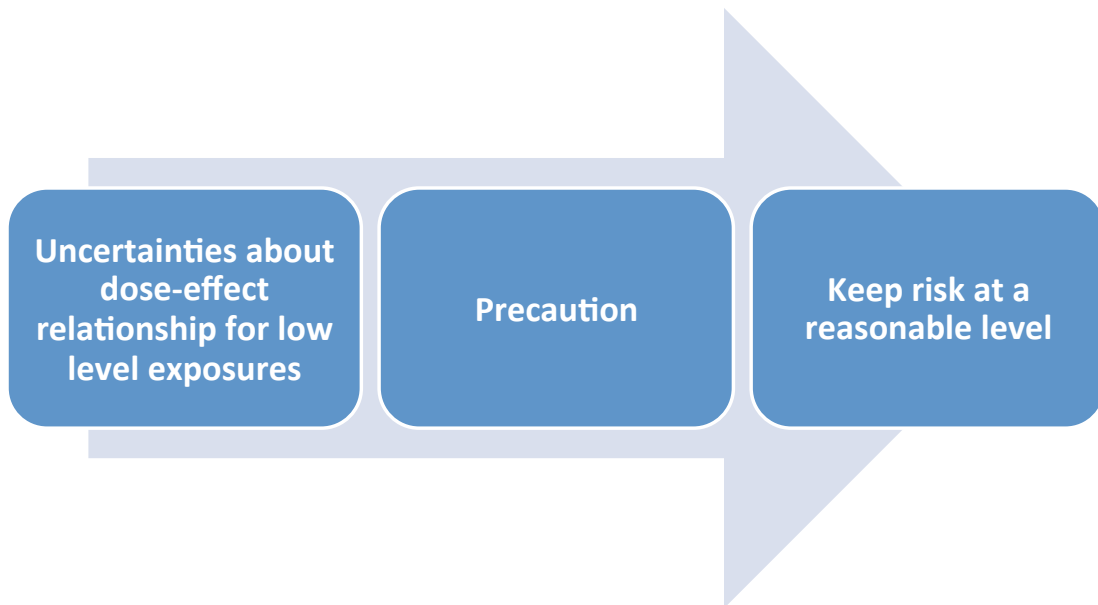


Preston *et al.*, Rad Res 2004

THE DOSE-EFFECT RELATIONSHIP FOR STOCHASTIC EFFECTS



THE MANAGEMENT OF STOCHASTIC EFFECTS : THE PRECAUTIONARY PRINCIPLE FOR LOW DOSES



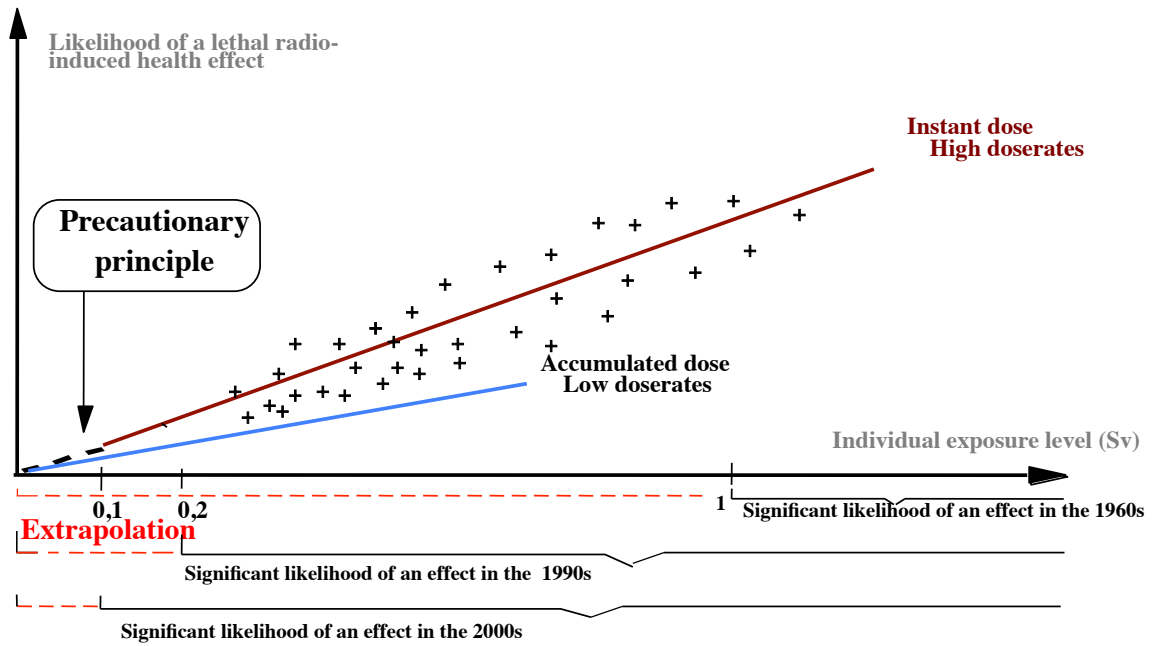
TO MANAGE UNCERTAIN SITUATIONS, PRECAUTION IS A BEHAVIOUR

which is ethical

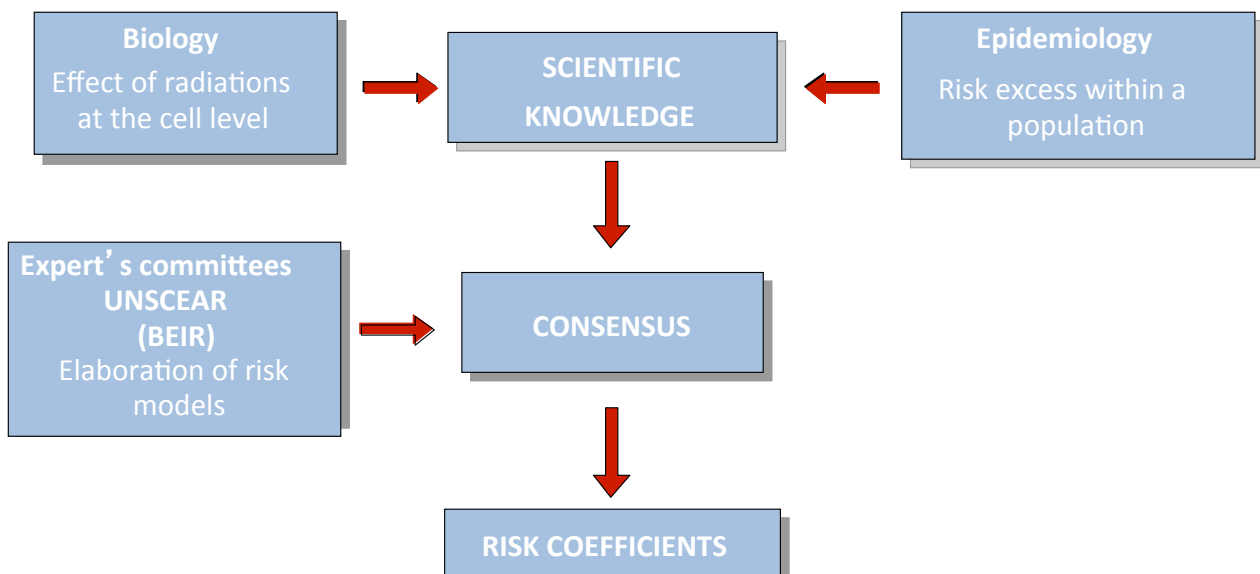
that answers to a willingness to be socially responsible in:

- Building the exposure - risk relationship, favouring the acquisition of new knowledge
- Maintaining the risk at a reasonable level
- Ensuring an equitable distribution of risk
- Taking into account the available protection resources

DOSE-EFFECT RELATIONSHIP FOR STOCHASTIC EFFECTS AT LOW DOSES



THE CONSTRUCTION OF RISK FOR STOCHASTIC EFFECTS

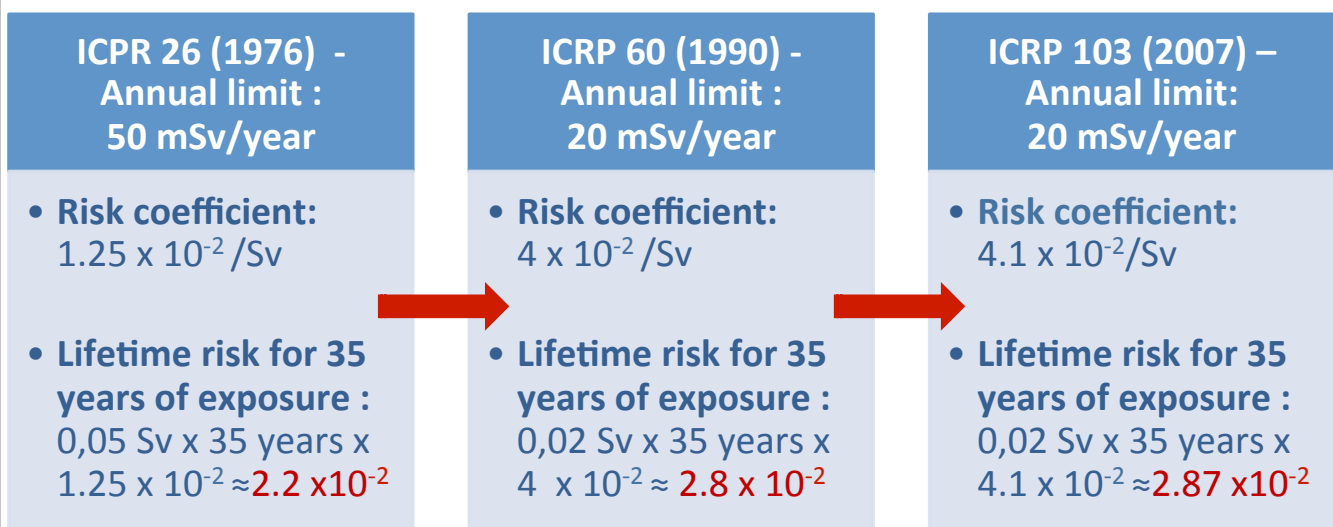


RISK COEFFICIENTS USED IN RADIATION PROTECTION

Nominal probabilities for stochastic effects (% per Sv)

Exposed population	Death by radio induced Cancer	Heritable effects	Total
	ICRP103	ICRP103	ICRP 103
Whole population	5.5	0.2	5.7
Adult Worker	4.1	0.1	4.2

LEVELS OF RISK ASSOCIATED WITH INDIVIDUAL DOSE LIMITS RECOMMENDED BY ICRP IN 1976, 1990 AND 2007



STOCHASTIC RISK (ICRP 103)

Risk of fatal cancer in the worldwide population

≈ 25%

Increase of the risk of fatal cancer corresponding to a lifetime exposure of 1 Sv

≈ 5%

Loss of life expectancy associated with a fatal cancer

≈ 16 years

Loss of life expectancy associated with a lifetime exposure of 1 Sv ≈ 1 year

STOCHASTIC RISK

A worker who receives 20mSv/y during his/her working life (35 y) reaches a dose of 0.7Sv

This corresponds to an increase of his/her lifetime risk due to radiation induced cancer of 2.87% (ICRP 103)

COLLECTIVE DOSE

Number of exposed individuals	Individual dose	Excess of individual risk (ICRP 103)	Collective risk on the population	Collective dose for the population
100	1Sv	4.1/100	4.1 cancers	100 man - Sv
1000	0.1Sv	4.1/1000	4.1 cancers	100 man - Sv
10000	0.01Sv	4.1/10000	4.1 cancers	100 man - Sv

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

COLLECTIVE DOSE

- Sum of individual doses of exposed individuals
- Collective dose unit : person.sievert (p.Sv)
- **Indicator of potential health detriment in an exposed population**
- Performance indicator of protective actions
- Should never be used without reference to individual dose distribution and time distribution

THE 3 RADIATION PROTECTION PRINCIPLES

JUSTIFICATION OF PRACTICES

- Expected benefits > Health detriment.

OPTIMISATION OF RADIATION PROTECTION

- Maintain individual exposures and the number of exposed individuals **As Low As Reasonable Achievable**, taking in to account economical and societal factors (**ALARA**).

LIMITATION OF INDIVIDUAL DOSES

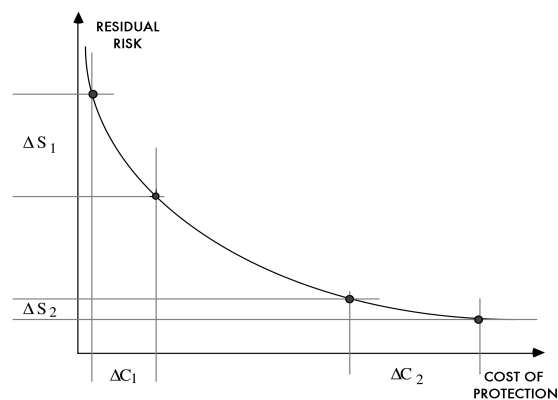
THE ZERO RISK OBJECTIVE

Misallocation of protection resources

Risk transfers between groups at risk

Individualistic attitude

**THE LAW OF MARGINAL
DIMINISHING RETURNS**

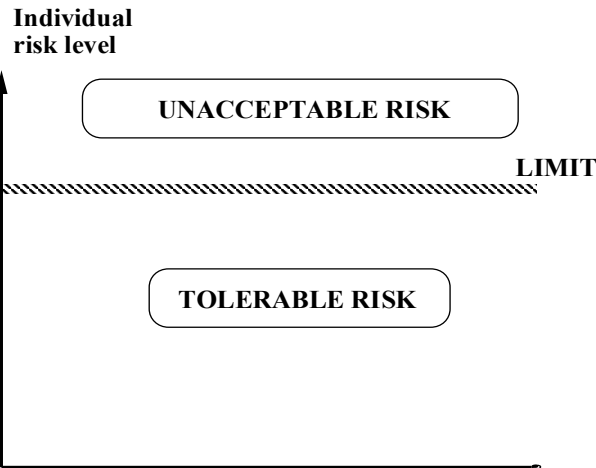


LIMITATION OF EXPOSURE

Two meanings of the individual dose limit

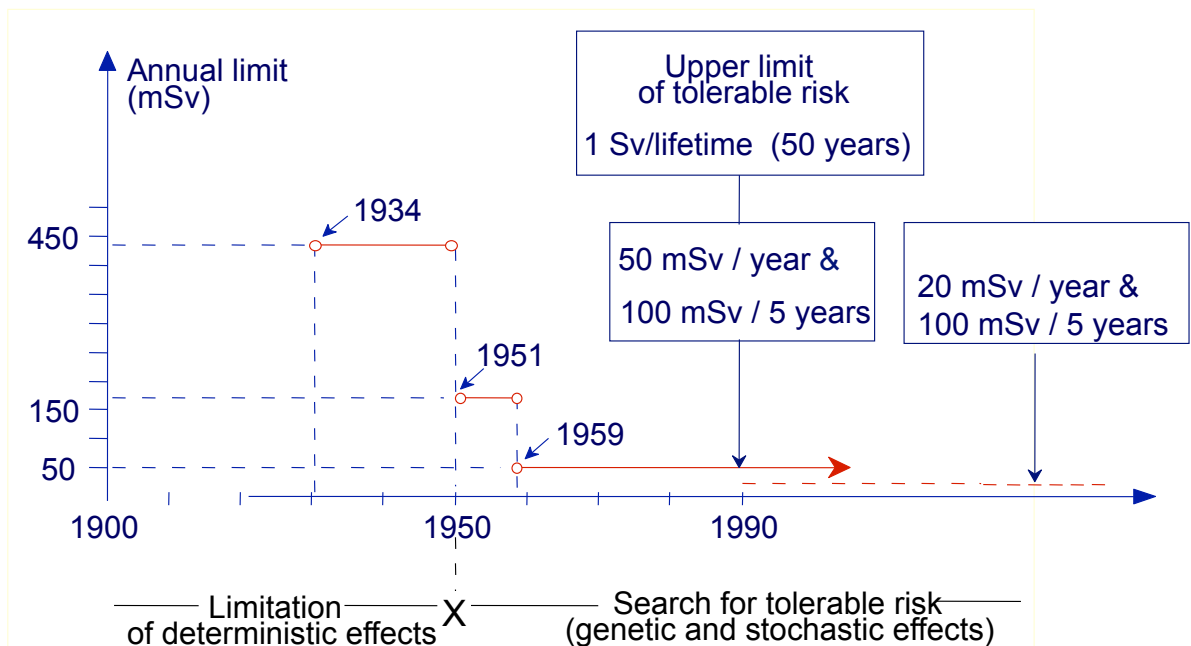
Individual guarantee that deterministic effects will not occur

Individual guarantee that residual risk for stochastic effects is socially tolerable



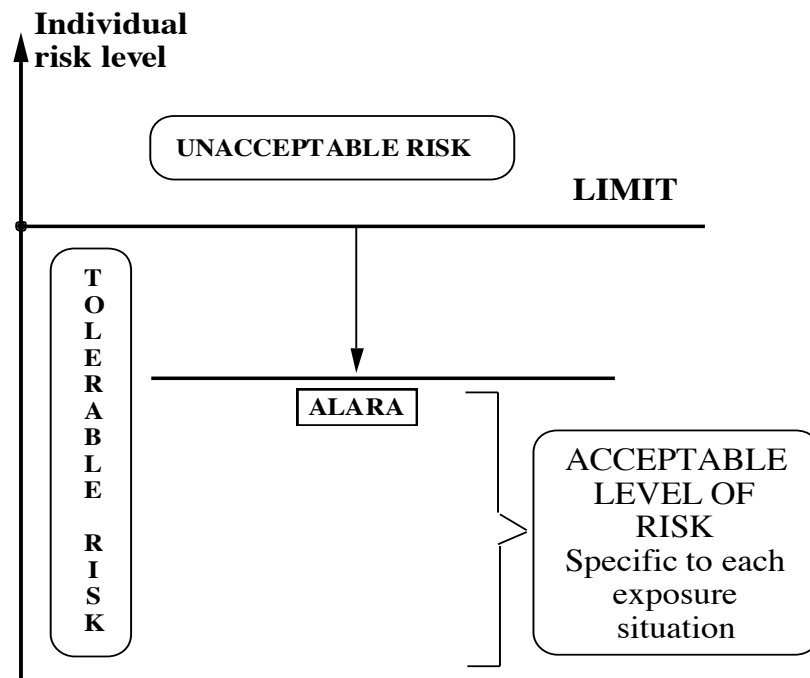
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THE EVOLUTION OF INDIVIDUAL DOSE LIMITS



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THE ALARA PRINCIPLE AND THE ACCEPTABILITY OF RISK



LEGAL STATUS

...of Dose Limits

- Exceeding = Infraction (obligation of result)
- Responsibility shared among employers/licenseses
- Employer is the main responsible

...of ALARA (I)

- “Mandatory” as the respect of limits, but... obligation of means and not of result
- All “responsible” to adopt an attitude, a behaviour to implement ALARA
- From dosimetric evaluation to dosimetric objective...
- ... not legally opposable

LEGAL STATUS

...of Limit

- Exceeding = Infraction
- Responsibility shared among employers/licenseses
- Employers main responsible

...of ALARA (II)

- Responsibility shared among licensees/employers
- Licensees: responsible to provide workers with "optimised sources and working conditions"
- Employers: co-responsibility for the prior evaluation of exposures for their workers
- Licensees: main responsible a posteriori of the non implementation of ALARA

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THE PRACTICAL IMPLEMENTATION OF ALARA

- The ALARA principle is a pragmatic response to the uncertainty characterizing the risk associated with low level of radiation.
- Applying the ALARA approach is a way to eliminate unnecessary exposures and all exposures which can be avoided at a reasonable cost for the society.

Requires:

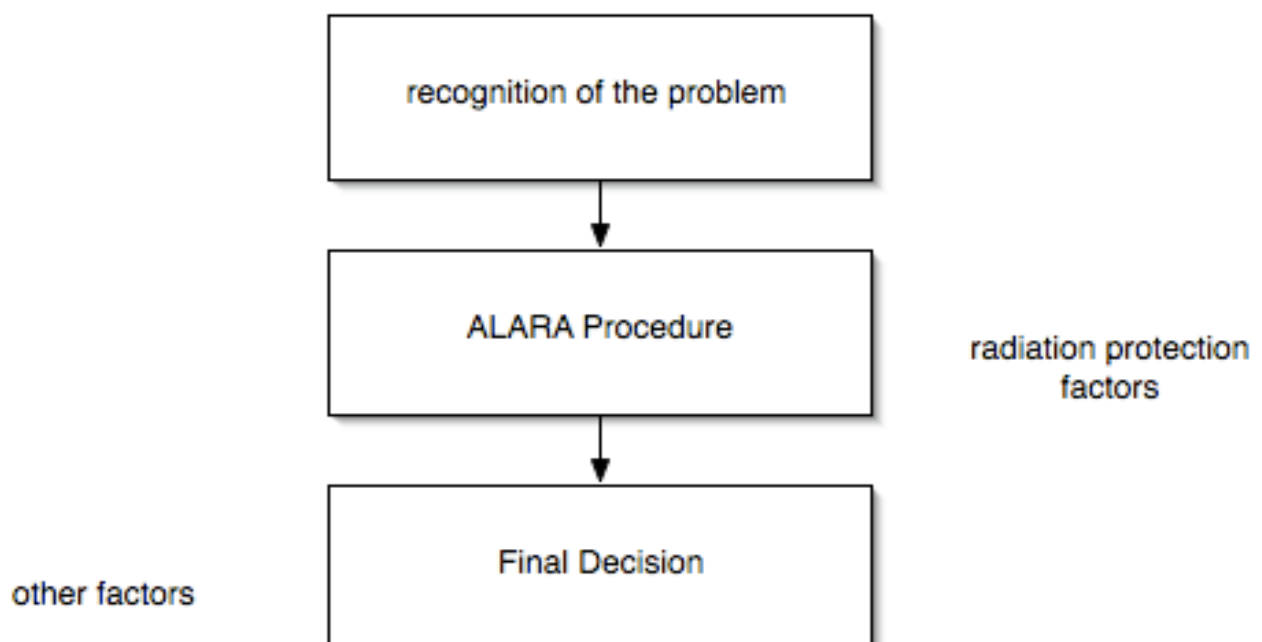
- Predictive and analytical approach
- Commitment of involved parties
- Work management
- Structures and tools adapted to the specificity of the exposure situations

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ALARA : a predictive approach

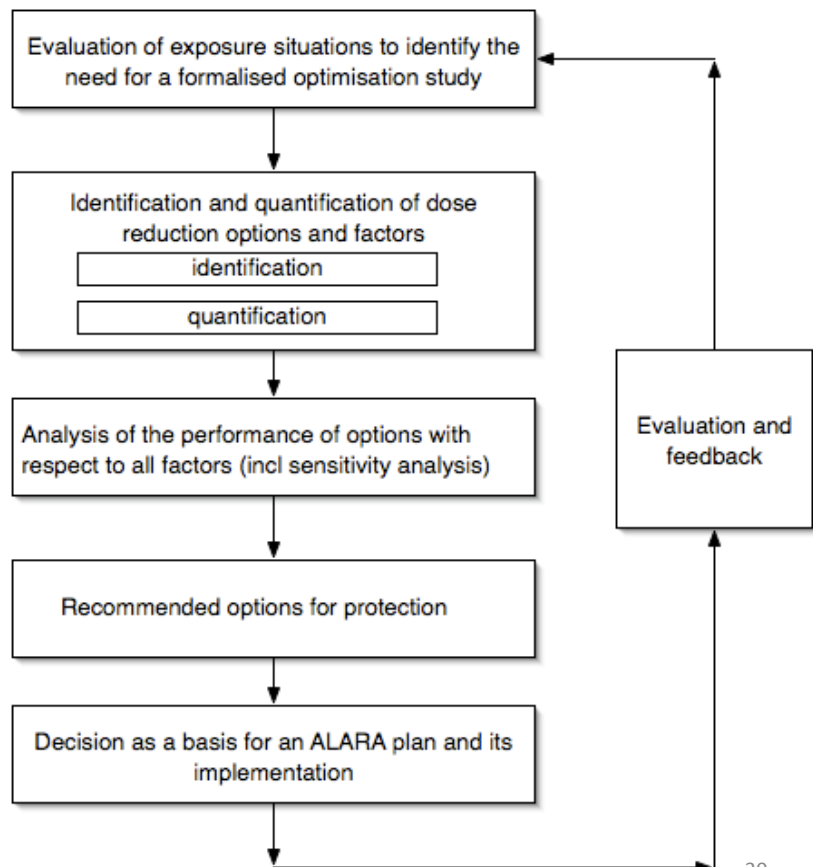
- To try to maintain exposures as low as reasonably achievable (i.e) possible, implies adopting a predictive attitude in order to:
 - Evaluate and predict individual and collective exposures
 - Who? Where? When? How? How long? What if...?
 - Envisage actions likely to reduce exposures
 - Select those actions considered reasonable

THE RADIOLOGICAL PROTECTION OPTIMISATION APPROACH



THE RADIOLOGICAL PROTECTION OPTIMISATION PROCEDURE

The procedure is a simple checklist of 5 steps and sub-steps that structure the approach to any problem or decision in radiation protection.



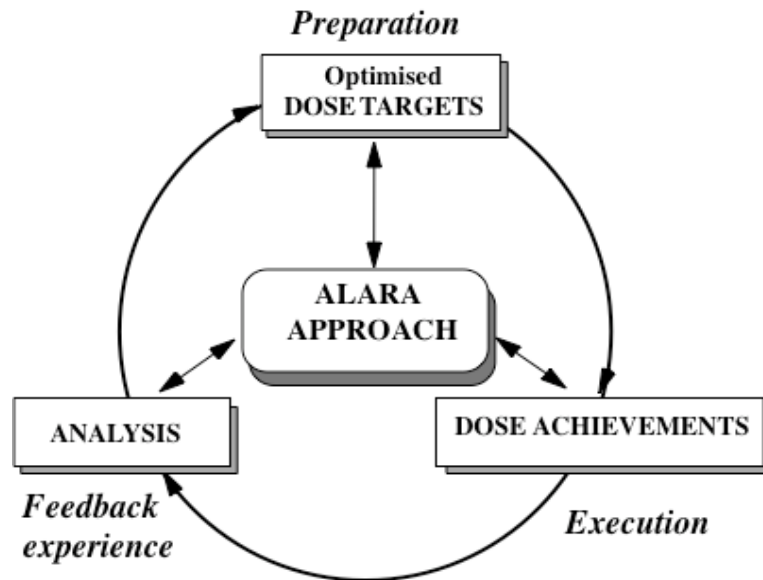
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Implementing the radiological protection optimisation procedure...

- Will lead to optimised dose objectives in terms of collective dose, and individual doses
- They have to be checked against reality
 - to point out gaps
 - to keep track of new data (e.g. real source term), for improving situation “on the spot”, repeatedly
- ... making feedback analysis to prepare the next operations, making use again of the radiological protection optimisation procedure

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... Within a global ALARA approach following the operational phases of any activity



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... Within a global ALARA approach being a kind of quality or safety approach ... devoted to radiological protection

- Relying on an ALARA culture spread over all involved parties
- Relying on the Commitment of all of them
 - From the managers setting the firm's objectives to the outside workers taking care of their own (and colleagues') protection
- Integrated into a global work management policy, which is often first "win win"
- Benefiting from adequate management and decision making Structures and from tools adapted to the specificity of the exposure situations to predict, follow up and analyze these situations

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Comparison with other exposure risks

Substance	Type of effect	Risk Coefficient	Annual limit	Risk for occupational lifetime exposure (35 years)
Nickel & compounds	Lung cancer	$4 \cdot 10^{-4} (\mu\text{g}\cdot\text{m}^{-3})^{-1}$	1000 $\mu\text{g}\cdot\text{m}^{-3}$	$4.4 \cdot 10^{-2}$
Arsenic	Lung cancer	$1.5 \cdot 10^{-3} (\mu\text{g}\cdot\text{m}^{-3})^{-1}$	200 $\mu\text{g}\cdot\text{m}^{-3}$	$3.3 \cdot 10^{-2}$
Ionizing Radiation	Cancer	$4.1 \cdot 10^{-2} (\text{Sv})^{-1}$	0.02 Sv	$\sim 2.9 \cdot 10^{-2}$
Benzene	Leukaemia	$6 \cdot 10^{-6} (\mu\text{g}\cdot\text{m}^{-3})^{-1}$	16 000 $\mu\text{g}\cdot\text{m}^{-3}$	$1.0 \cdot 10^{-2}$
Asbestos	Lung cancer & Mesothelioma	$2 \cdot 10^{-1} (\text{fiber}\cdot\text{cm}^{-3})^{-1}$	0.1 $(\text{fiber}\cdot\text{cm}^{-3})^{-1}$	$0.2 \cdot 10^{-2}$

Sources : NEA, CEPN, ICRP 103

Conclusion

- ALARA (optimisation of radiological protection) is considered as the core of the system of radiological protection
- Implementing ALARA means finding and implementing the reasonable actions of protection
- Implementing ALARA means reducing collective doses, while focussing in priority on the most exposed individuals
- Implementing ALARA means integrating the radiological risk management into a global risk approach

PART III

EUROPEAN REGULATORY FRAMEWORK

EURATOM TREATY: 10 Chapters

Chapter III: Health and Safety

- **Basic standards within the Community (maximum permissible doses, fundamental principles) (articles 30, 31, 32)**
- **National legislation (article 33)**
- **Continuous monitoring of radioactivity in the environment (articles 35 et 36)**
- **Opinion of Commission on any plan for radioactive releases (article 37)**

Directive 2013 /2014 Euratom laying down Safety Standards

SCOPE

This Directive applies to any planned, existing or emergency exposure situation which involves a risk from exposure to ionising radiation

Planned exposure situation: means an exposure situation that arises from the planned operation of a radiation source or from a human activity

Existing exposure situation: means an exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken

Emergency exposure situation means a situation of exposure due to an emergency;

Directive 2013 or 2014 Euratom laying down Safety Standards

ENTRANCE/EXIT OF SYSTEM FOR PRACTICES

Practices = human activities that can increase the exposure of individuals to radiation from a radiation source and is managed as a planned exposure situation

- Notification
- Registration or Licensing, Authorization
- Exemption (no entry into the RP system, no need for notification)
- Release from regulatory control

Directive 2013 or 2014 Euratom laying down Safety Standards

ENTRANCE/EXIT OF SYSTEM FOR PRACTICES

- Decisions introducing a practice shall be justified in the sense ...to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment, that it may cause. (art 5.a)
- review of existing ...practices ... whenever there is new and important evidence about their efficacy or potential consequences or new and important information about other techniques and technologies. (art 20)
- Prohibition (deliberate addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics...) (art 22)

Directive 2013/2014 Euratom laying down Safety Standards

OPTIMISATION/GENERAL PRINCIPLES

- Radiation protection of individuals subject to public or occupational exposure shall be optimised ... keeping the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors. (art 5b)
- The optimisation of the protection of individuals subject to medical exposure shall apply to the magnitude of individual doses... (art 5b)
- This principle shall be applied ...in terms of effective dose (and) where appropriate, in terms of equivalent doses,

Directive 2013/2014 Euratom laying down Safety Standards

OPTIMISATION/GENERAL PRINCIPLES

Art 6-1 dose constraints are established for the purpose of **prospective** optimisation of protection:

- for occupational exposure, the dose constraint shall be established as an operational tool for optimisation by the undertaking under the general supervision of the competent authority....
- for public exposure, the dose constraint shall be set for the individual dose that members of the public receive from the planned operation of a specified radiation source....

Art 6-2. Dose constraints shall be established in terms of individual effective or equivalent doses over a defined appropriate time period.

Directive 2013/2014 Euratom laying down Safety Standards

LIMITATION/GENERAL PRINCIPLES

- Dose limits for **occupational exposure** shall apply to the sum of annual occupational exposures of a worker from all authorised practices... (art 10)
- Dose limits for **public exposure** shall apply to the sum of annual exposures of a member of the public resulting from all authorised practices; the protection of the unborn child is comparable with that provided for members of the public (Art 11 et 13)
- Do not apply to :
 - medical exposures (\neq diagnostic reference levels)
 - interventions

Directive 2013/2014 Euratom laying down Safety Standards

LIMITATION/GENERAL PRINCIPLES

- **Workers:** 20mSv/year
- **Public:** 1 mSv/year
- **Apprentices and students (16-18 years):** 6 mSv/year
- **Pregnant women:** 1 mSv during pregnancy
- **Other limits**
- **Lens of eye:** 20 mSv /year or 100 mSv/5 years -
50mSv/year (workers)
15 mSv/year (apprentices-students)
15 mSv/year (public)
- **Skin, extremities:** 500 mSv/year (workers)
150 mSv/ year (apprentices-students)
50 mSv/ year (public only skin)

Directive 2013/2014 Euratom laying down Safety Standards

OPERATIONAL PROTECTION OF EXPOSED WORKERS (art 31)

- **Prior evaluation to identify the nature and magnitude of radiological risk**
- **Optimisation of radiation protection in all working conditions, including occupational exposures as a consequence of practices involving medical exposures**
- **Classification of exposed workers**
- **Control measures and monitoring relating to the different areas and working conditions, including, where necessary, individual monitoring**
- **Medical surveillance**
- **Education and training.**

Directive 2013/2014 Euratom laying down Safety Standards

OPERATIONAL PROTECTION OF EXPOSED WORKERS (2)

- A distinction shall be made between controlled areas and supervised areas on the basis of an assessment of the expected annual doses art 34
- **Controlled areas art 35:**
 - Delineated ; access restricted to individuals having received appropriate instructions ; written procedures for their control; signs indicating nature of sources and type of area
- **Supervised areas art 36:**
 - At a minimum, radiological surveillance of the working environment
 - If appropriate : signs indicating type of area, nature of sources and inherent risks; working instructions

Directive 2013/2014 Euratom laying down Safety Standards

OPERATIONAL PROTECTION OF EXPOSED WORKERS (3)

- **Classification of workers (art 38) :**
 - Category A : workers liable to receive an effective dose greater than 6 mSv/year or equivalent dose greater than 15 mSv/year for the lens of the eye, or 150 mSv/year for skin and extremities
 - Category B : exposed workers not classified in category A.
- **Information**
 - Health risks involved in their work - RP procedures and precautions
 - Women : need to early declare pregnancy
- **Training**

Directive 2013/2014 Euratom laying down Safety Standards

OPERATIONAL PROTECTION OF EXPOSED WORKERS (4)

- Individual monitoring (art 39)
 - Systematic for category A
 - For category B : sufficient to demonstrate that they are well classified
 - Records for category A
 - Always external exposure and when workers are liable to receive significant internal and lens or extremities exposure, an adequate system for monitoring shall be set up.

Directive 2013/2014 Euratom laying down Safety Standards

NORM (NATURALLY OCCURRING RADIOACTIVE MATERIALS)

Work Activities of concern (annex 5) :

- Extraction of rare earths from monazite,
- Production of thorium compounds and manufacture of thorium-containing products,
- Processing of niobium/tantalum ore,
- Oil and gas production,
- Coal-fired power plants, maintenance of boilers,
- Phosphoric acid production,
- Primary iron production,
- Geothermal energy production,
- TiO₂ pigment production,
- Thermal phosphorus production,
- Zircon and zirconium industry,
- Production of phosphate fertilisers
- Cement production, maintenance of clinker ovens,
- Tin/lead/copper smelting,
- Groundwater filtration facilities,
- Mining of ores other than uranium ore.

Directive 2013/2014 Euratom laying down Safety Standards

PROTECTION OF THE POPULATION IN NORMAL CIRCUMSTANCES

- **Representative person:**
 - identified, taking into account the effective pathways for transmission of the radioactive substances
- **Dose estimates as realistic as possible and includes external and internal components**
- **Records to be kept and be made available on request to all stakeholders**

Directive 2013/2014 Euratom laying down Safety Standards

RADIATION PROTECTION EXPERT

- **art. 4 Definition :**
- **Radiation protection expert** means an individual or, if provided for in the national legislation, a group of individuals having the knowledge, training and experience needed to give radiation protection advice in order to ensure the effective protection of individuals, and whose competence in this respect is recognised by the competent authority
- **Art 84 (1)**

He will give competent advice ...on matters relating to compliance with applicable legal requirements, in respect of occupational and public exposure.

Directive 2013/2014 Euratom laying down Safety Standards RADIATION PROTECTION EXPERT (2)

- **Advices art 84 2:**
 - (a) optimisation and establishment of appropriate dose constraints;
 - (b) plans for new installations ...
 - (c) categorisation of controlled and supervised areas;
 - (d) classification of workers;
 - (e) workplace and individual monitoring programmes and related personal dosimetry;
 - (f) appropriate radiation monitoring instrumentation;
 - (g) quality assurance;
 - (h) environmental monitoring programme;
 - (i) arrangements for radioactive waste management;
 - (j) arrangements for prevention of accidents and incidents;
 - (k) preparedness and response in emergency exposure situations;
 - (l) training and retraining programmes for exposed workers;

Directive 2013/2014 Euratom laying down Safety Standards RADIATION PROTECTION OFFICER

Definitions (Art 4)

- **Radiation protection officer** means an individual who is technically competent in radiation protection matters relevant for a given type of practice to supervise or perform the implementation of the radiation protection arrangements;

Directive 2013/2014 Euratom laying down Safety Standards

RADIATION PROTECTION OFFICER

His tasks may include (Art 86)

- (a) ensuring that work with radiation is carried out in accordance with the requirements of any specified procedures or local rules;
- (b) supervise implementation of the programme for workplace monitoring;
- (c) maintaining adequate records of all radiation sources;
- (d) carrying out periodic assessments of the condition of the relevant safety and warning systems;
- (e) supervise implementation of the personal monitoring programme;
- (f) supervise implementation of the health surveillance programme;
- (g) providing new workers with an appropriate introduction to local rules and procedures;
- (h) giving advice and comments on work plans;
- (i) establishing work plans;

INTERNET LINKS

European Union

RP ec.europa.eu/energy/nuclear/radiation_protection_radiation_protection_en.htm
Law eur-lex.europa.eu/en/index.htm

IAEA

ORPNET www-ns.iaea.org/tech-areas/communication-networks/norp/
RPOP <https://rpop.iaea.org/RPoP/RPoP/Content/index.htm>

European ALARA Networks

EAN www.eu-alara.net
EMAN www.eman-network.eu
OTHEA www.othea.net