IRSN
INSTITUT
DE RADIOPROTECTION
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History, Evolution and Rationale of the Radiological Protection System and in particular Dose Restrictions

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The System of Radiological Protection

- Recommended by the International Commission on Radiological Protection (**ICRP**), founded in 1928
- With the objective to contribute to an **appropriate level of protection** against the detrimental effects of ionizing radiation exposure **without unduly limiting** the benefits associated with the use of radiation
- The system aims primarily to protect human health with the objective to manage and control exposures so that deterministic effects (tissue reactions) are **prevented** and the risks of stochastics effects (cancer) are **reduced** to the extent reasonably achievable
- Several issues of General Recommendations: ICRP 26 (1977), ICRP 60 (1990), ICRP 103 (2007)

Historical perspective

- The system of RP was developed gradually during the 20th century integrating advances in **knowledge** about the effects of radiation, the evolution of the **ethical and social values** as well as the feedback **experience** from its practical implementation
- Until the Second World War the Commission was only dealing with the protection of **medical staffs**
- After the war the focus was on **nuclear energy** and radiological protection developed to protect workers inside nuclear installations and the public outside. This resulted in a coherent and effective regime of radiological protection based on solid concepts, principles and norms (ICRP 60)
- The reality of **nuclear accidents** together with the threat of malevolent events and the raising concerns on **natural exposures** and exposure **situations inherited from the past** in the nineties profoundly challenged the ICRP 60 system and resulted in the general principles presented in ICRP 103

Foundations of the RP System

Social and Ethical Principles/Values

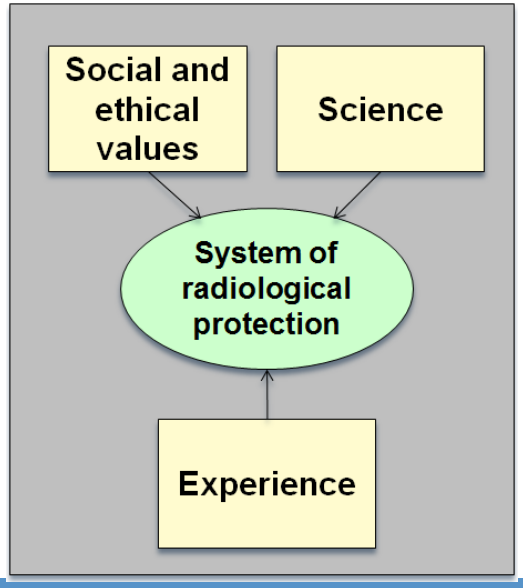
- Beneficence
- Non-maleficence
- Autonomy/Dignity
- Justice
- Prudence
  - Reasonableness
  - Tolerability
    - » Peaceful
    - » Vigilant
    - » Reaction
  - Accountability
  - Inclusiveness
  - Conservation/biodiversity/ sustainability

Science

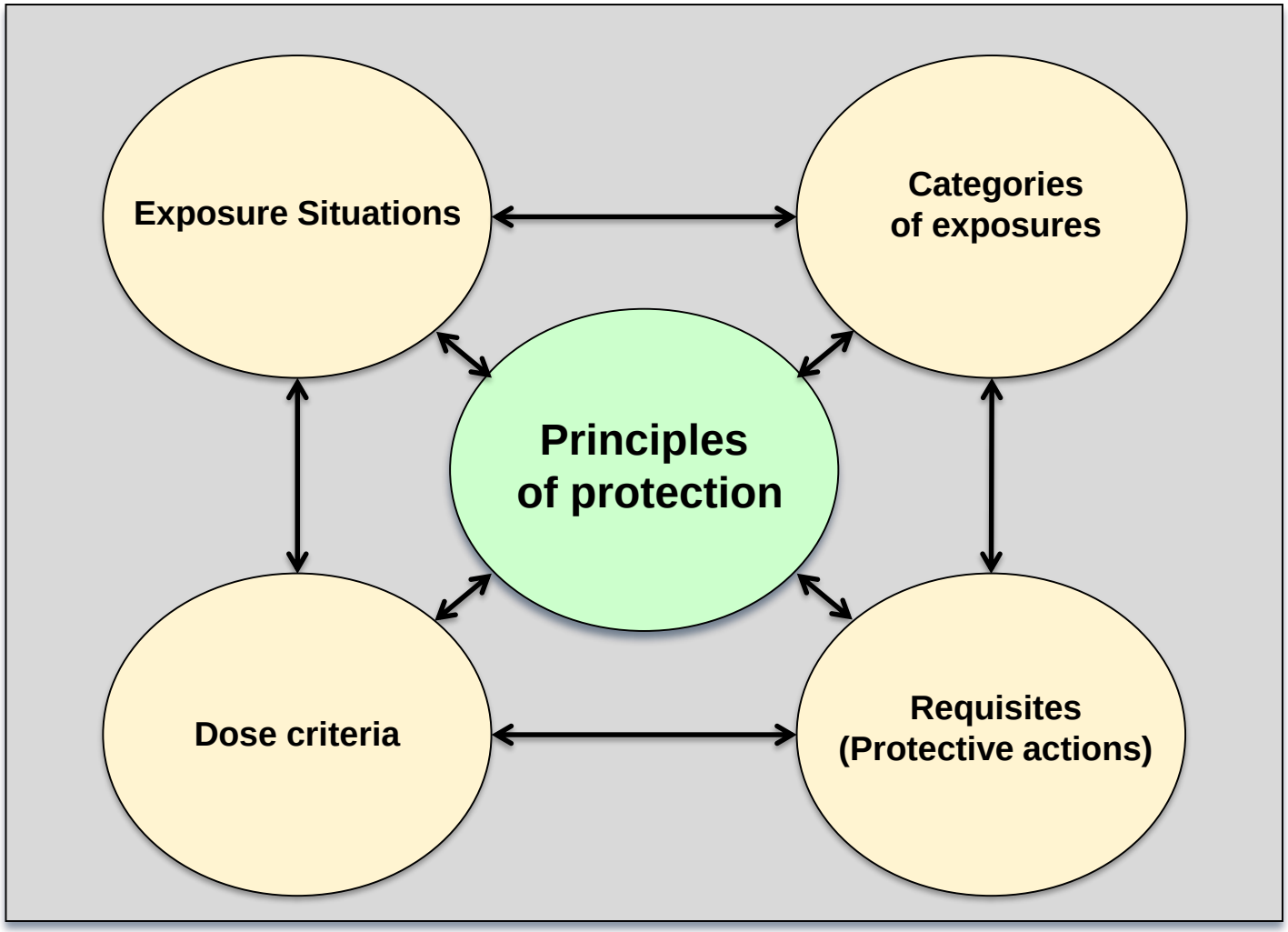
- Epidemiology
- Radiobiology
- Anatomy
- Physiology
- Metrology
- ……

Experience

- Hiroshima/Nagasaki
- Nuclear Installations
- Industrial/Medical
- Chernobyl
- Fukushima
- ……



Structuration of the System of Protection



3 issues of ICRP General Recommendations

- **ICRP 26 (1977):** an approach mainly based on the dose limit (called dose-equivalent limits)
- **ICRP 60 (1991):** highlighting of optimisation and introduction of the dose constraint (dose restriction within the optimisation)
- **ICRP 103 (2007):** the optimisation takes precedence over the limitation
- Nota: The principle of optimisation is the cornerstone of the ICRP System of RP but this presentation is mainly focused on the issue of dose restriction

ICRP 26: Global approach

- A "System of dose limitation" (§68)
  - No source of exposure is **unjustified** in relation to its benefits or those of any available alternative
  - Any necessary exposures are kept **as low as is reasonably achievable** (cost-benefit)
  - The dose equivalents received do not exceed certain **specified limits** (dose-equivalent limits)
- The broad process of balancing would be legitimate only if the detriment to each individual does not exceed an **acceptable level**; = compliance with the dose limit (§70)
- It may thus be necessary to make subjective **value judgements** (§71)
- The dose limits should not be regarded as a dividing line between safety and danger; when slightly exceeded, what is important is the failure of the control (§81)
- The limits for occupational exposure are regarded as upper limits (§84)
- The limit for public exposure is a more theoretical concept (§84)

ICRP 26: Occupational limits

- Judging the acceptability by **comparing with risk for other occupations** recognized as having high standards for safety (average annual mortality ≤ 10-4) (§96)

- Ideally, account should be taken of all components of the harm (not only fatality). However, the summation and comparison are difficult to make. As a first approximation, an assessment **based on mortality** only can be regarded as conservative (§97)

- Comparison relates on the **average risk** for all concerned workers. In many cases of occupational radiation exposure, the annual average dose is **no greater than 1/10 of the dose limit** (§99, 100)

- **Prevent** non-stochastic effects and **limit** the occurrence of stochastic effects to an acceptable level (§103)

- **50 mS/y** for stochastic effects (§104)

ICRP 26: Public limits

- Radiation risks are a very minor fraction of the total risk. Reasonable to consider these risks in the light of the **public acceptance of other risks**. This acceptance is motivated by the expected **benefits**, an assessment of the **social cost** of a possible reduction of the risk or an implicit judgement that the risk is **negligible** (§117)

- The **acceptable level** of a risk (fatal) that an individual can modify to only a small degree (e.g. public transport) would be in the range from **10^{-6} to 10^{-5}/y** (§118)

- 10^{-2}/Sv $\Rightarrow$ 1 mSv/y. However, **ICRP recommends 5 mSv/y** (critical group) (§119) because the actual exposure of individuals is likely to be of the order of **10%** (§120). If average doses from combined optimised exposures > 1 mSv/y , the situation might still be justified (§121)

ICRP 26: Other dose restrictions

- Protection standards:
  - Limits
  - **Reference levels**: recording levels, investigation levels, intervention levels (§149-152) (concepts not related to optimisation)

- Operational optimisation
  - The application of the process of optimisation to the restriction of exposure and, in particular, to the selection of levels of protection, requires a **case-by-case** review of situations. In practice, a series of radiation protection strategies is defined (§153) (**no specific concept** for dose restriction within optimisation)

ICRP 60: Global approach

- The basic system of protection is set for **occupational, medical and public** exposures and distinguishes between a **practice**, which causes exposures to radiation, and **intervention**, which decreases exposures (§98)
- **Justification of a practice:** No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes (§112)
- **Optimisation of protection:** In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be **constrained by restrictions** on the doses to individuals (**dose constraints**), or the risks to individuals in the case of potential exposures (**risk constraints**), so as to limit the inequity likely to result from the inherent economic and social judgements (§112)
- **Individual dose and risk limit**: The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits. They are aimed to ensure that no individual is exposed to radiation risks that are judged to be unacceptable in any normal circumstances (§112)

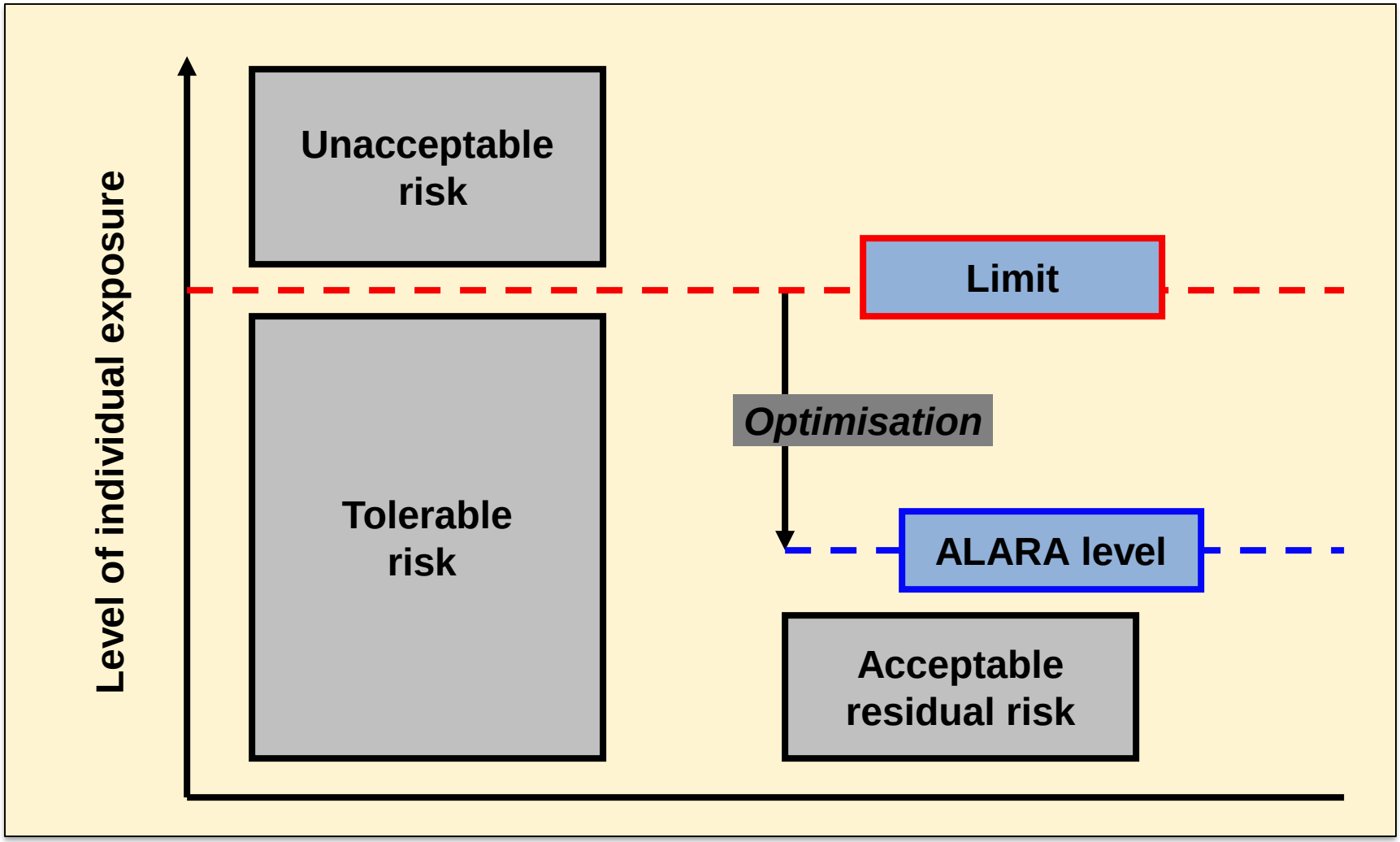
ICRP 60: Global approach

- The definition and choice of **dose limits** involve **social judgements**, it cannot be based on health considerations alone (§123)
- The dose limit should not be regarded as (§124):
  - Demarcation between safe and dangerous
  - The most simple and effective way of keeping exposures low and forcing improvements
  - The sole measure of the stringency of a system of RP
- An important feature of optimisation is the choice of **dose constraints**, the source related values of individual dose used to limit the range of options considered **in the procedure of optimisation** (§144). Fixed at national or local level for a specified source (§145), taking account of actual and potential exposures (§146)
- For **public exposure**, the dose constraint should be applied to the mean dose in the **critical group** (§186). The main aim of constrained optimisation in public exposure should be to develop practical restrictions on the sources, e.g. on the release of radioactive waste to the environment (§187)

ICRP 60: Occupational dose limits

- To impose a **limit on the choice of dose constraints** and to provide a protection against **errors of judgement** in the application of optimisation (§147)
- Comparison with other industries is **not altogether satisfactory** (§148)
  - Standards of industrial safety neither constant nor uniform worldwide
  - Mortality data relate to averages over whole industries whereas DL apply to individuals
  - Inclusion of non-fatal conditions would have led to less restrictive DL
  - Few grounds for believing that society expects the same standards
- More comprehensive approach: attributable **probability of death** is a major but not sufficient factor, **length of life lost** and the incidence of **non-fatal conditions** have been considered in the detriment (§149)
- 3 words to indicate the degree of **tolerability of risk**: unacceptable (in normal conditions), tolerable (not welcome but can reasonably be tolerated) and acceptable (without further improvement). DL = boundary between unacceptable and tolerable (§150)

The tolerability of risk model adopted in ICRP Publication 60



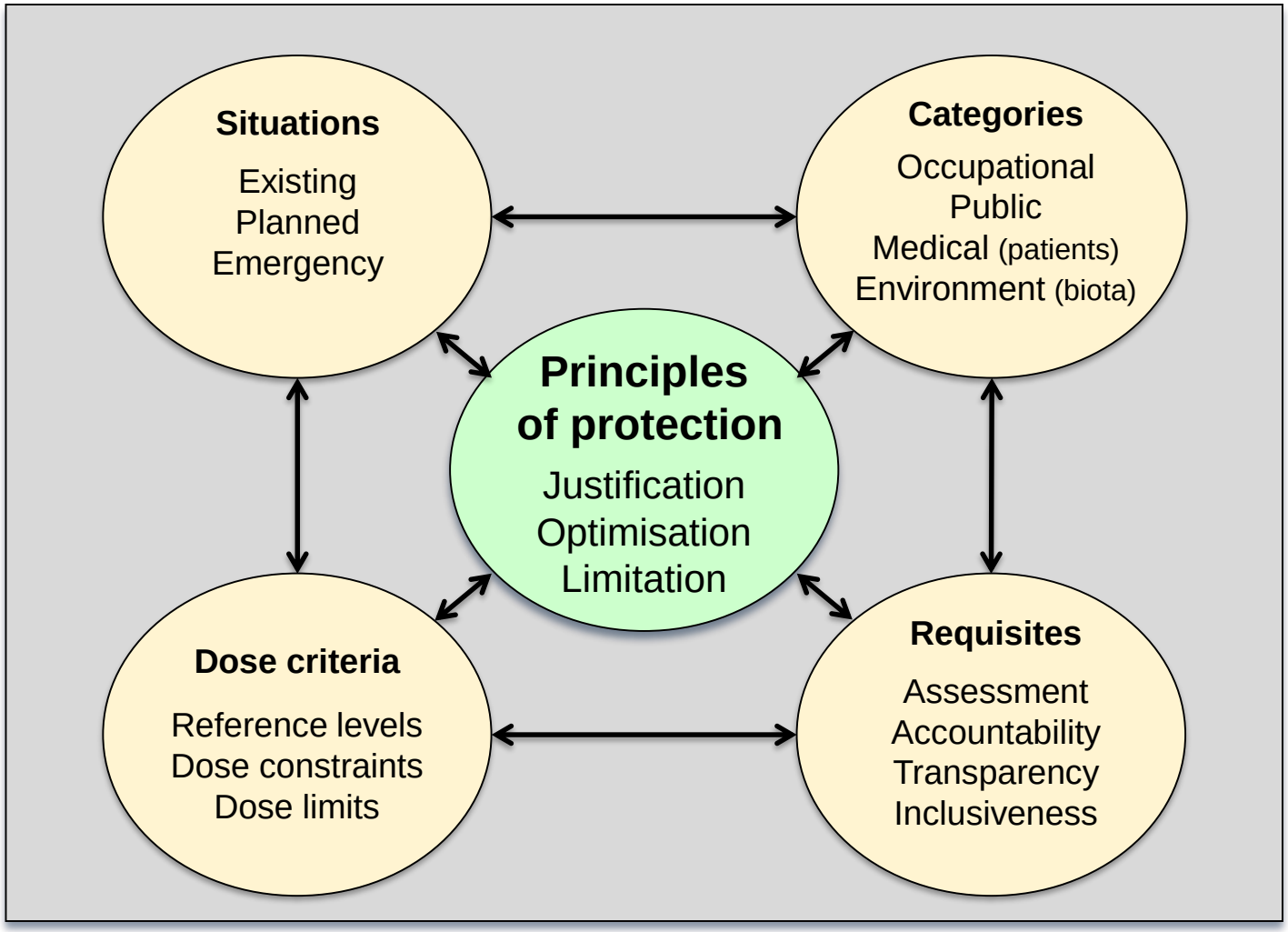
ICRP 60: Choice of occupational dose limit

- Taking account of a range of quantifiable factors in its approach to detriment (§151) + annual dose over working life (§152)
- **Multi-attributes** approach, inevitably subjective (§153)
  - Lifetime attributable probability of death
  - Time lost if the attributable effect occurs
  - Reduction of life expectancy
  - Annual distribution of the attributable probability of death
  - Increase in the age specific mortality rate (probability of dying in a year at any age)
- Weighting of mortality, morbidity and hereditary disorders (§154)
- Several possible values of DL tested: 10, 20, 30 et 50 mSv/y (= 0.5, 1, 1.4 and 2.4 Sv lifetime dose) (§155). 50 mSv/y probably too high (§161)
- Working life dose prevented from exceeding 1 Sv + protection against deterministic effects (§162)
- Some **flexibility** is needed with time reference (control period) (§164)
- DL = 20 mSv/y averaged over 5 years (100 mSv/5y) without exceeding 50 mSv in any single year (§166) + optimisation (§167) + derived limits (§171) + pregnant women protection (§178)

ICRP 60: Public dose limit

- Rarely limiting in practice. Useful to frame the choice of DC (§188)
- At least 2 approaches possible for setting public DL (§190)
  - 1. The same as for occupational DL (judging unacceptability is more complex)
  - 2. Base the judgement on the variation in the existing level of dose from **natural sources**
- After assessment of the consequences of additional doses from 1 to 5 mSv/y, the ICRP recommends DL = **1 mSv/y with flexibility** (§191)
- In special circumstances, a higher value could be allowed in a single year, provided that the average over 5 years does not exceed 1 mSv in a year (retrospective application) (§192)
- This does not imply that higher doses from other sources than deliberate practices (e.g. radon) should be regarded as unacceptable (§193)
- Derived limits (lens, skin, hands and feet): reduction by a 10 compared to occupational limits because the total period of exposure may be twice as long as for occupational exposure and because public may show a wider range of sensitivity than workers (§194)

ICRP 103: System of protection



ICRP 103: Global approach

- Human exposures come from a **network of events and situations** (source + pathways + doses to individuals) (§169)
- 3 types of exposure situations: **planned, emergency, existing** (§176)
- 3 categories of exposure: **occupational, medical, public** (§177)
- 3 principles of RP: **justification, optimisation** of protection, application of **dose limits** (§203)
- Source-related and individual-related considerations (§172, 197)
- Concept of **representative person** instead of critical group (§193)
- Levels of protection (section 5.5): **dose constraint**, **reference level** (optimisation, source-related concepts) + **dose limit** (individual-related concept)

Source-related versus individual-related

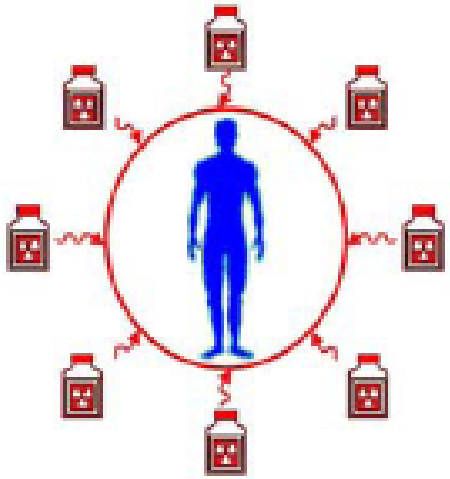
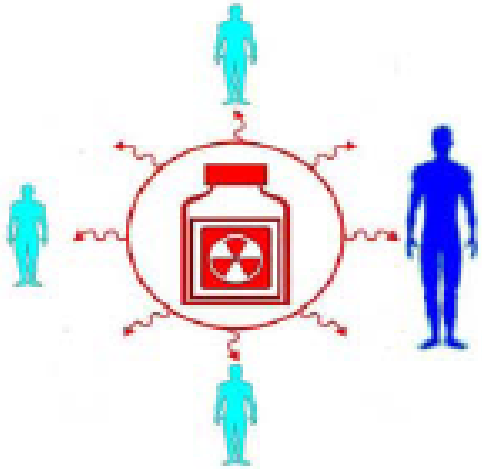
Dose Limits	Constraints and Reference Levels
Protect individual workers from occupational exposure and the Representative Person from public exposure	
	
From all regulated sources in planned exposure situations	From a source in all exposure situations

Fig. 3. Dose limits contrasted with dose constraints and reference levels to protect workers and members of the public.

ICRP 103: Dose restrictions

- **Dose limits** apply only in **planned ES** but not to medical exposures of patients (§243)

- Numerical values **unchanged** (nominal coefficient almost the same) (§243) => no further explanation about their selection

- The multi-attribute approach necessarily includes **societal judgements**, which would not necessarily be the same in all contexts and societies. Need for **flexibility** to allow for national and regional variations. Such variations in protection are best introduced by the use of **source-related** dose constraints applied in the process of **optimisation** (§241)

- **Constrained optimisation** whatever the exposure situation

- **Factors influencing** the choice of source-related dose constraints and reference levels (section 5.9.3 + Table 5)

Summary for dose limits

	ICRP 26	ICRP 60	ICRP 103
Science	Fatal cancer W: 1%/Sv P: 1%/Sv	Mortality + morbidity + hereditary effects W: 5,6%/Sv P: 7,3%/Sv	Cancer incidence (mortality + morbidity) + hereditary effects W: 4,2%/Sv P: 5,7%/Sv
Ethical values Experience	Comparison with other industries (W: $\leq 10^{-4}$/y; P: 10^{-6} to 10^{-5}/y) Expo = ±10% DL	Multi-attributes approach Tolerability of risk model Choice ± empirical (tests)	Societal judgements
Limits	W: 50 mSv/y P: 5 mSv/y	W: 20 mSv/a (100/5y) P: 1 mSv/y	W: 20 mSv/y (100/5y) P: 1 mSv/y
Corresponding level of risk	W: 5 10^{-4}/y P: 0,5 10^{-4}/y	W: 11,2 10^{-4}/y P: 0,7 10^{-4}/y	W: 8,4 10^{-4}/y P: 0,6 10^{-4}/y
Comments	Comparison with average dose (10% DL)	Lowering of DL not in accordance with risk increasing Other industries: risk ÷ 3 to 5	Cf. optimisation: selection of DC and RL / characteristics of the situation (Table 5)

Focus on the dose restrictions within optimisation Dose constraint (DC) and Reference level (RL): a same concept

- **Source-related, prospective** (§216, 230 of ICRP 103)
- Used in conjunction with the **optimisation** to **restrict** individual doses (§42, 198, 225)
- Needs to be defined (§225), i.e. set on a **case by case** basis
- Initial intention would be to not exceed, or remain at, these levels (§225), i.e. **not to go or stay above**
- Ambition to reduce all doses **ALARA below** (§225)
- Chosen values will depend on **circumstances** (§228, 234)
- DC should be lower than the pertinent DL (§230, 259)
- Treating a DC as a target value is not sufficient (§231)
- DC and RL are **not demarcation** between safe and dangerous (§228)

Why a different terminology?

- In specific circumstances, particularly in **Emergency ES and Existing ES**, it could be the case that **no viable protective option can immediately satisfy the level of protection selected** from generic considerations. For this reason, in Emergency ES and Existing ES, the Commission proposes to use the term RL (§43)

- **Dose constraint** for Planned ES (except medical) and **Reference level** for Existing ES and Emergency ES because in Planned ES the restriction on dose can be applied at the planning stage and the dose can be forecast so as to ensure that the **DC will not be exceeded** (§226)

- The difference in name does not imply any fundamental difference in the application of the system of RP (§43)

Selection of values

- The Commission presumes that there will generally be a **dominant source** (§199)
- **3 defined bands** of doses with **attributes** (Table 5)
- **Projected dose** over an appropriate time period (§238)
- Annual **effective** dose in Planned ES and Existing ES (§238)
- Total **residual** dose as a result of the emergency (acute or annual basis) (§238)
- **100 mSv = maximum** value for a RL (acute or in a year), because of an increased likelihood of deterministic effects and a significant risk of cancer (§236)
- Exposures >100 mSv justified only under **extreme circumstances** (§236)

Selection of values

- First step = **characterise** the exposure situation (§242)
- Selected taking account the **characteristics** of the ES
  - **Nature** of exposure
  - **Benefit** from the ES to individuals and society
  - Other **societal criteria**
  - Practicability of reducing or preventing exposures (i.e. **controllability**)
  - National or regional attributes and preferences (**prevailing circumstances**)
  - Past **experience**
- Process of **generic optimisation** or on the basis of **best practice** for the selection of a specific value (§43, 242)

Selection of DCs: who?

- DC for **occupational exposure** (§257):
  - Usually appropriate to be set at the operational level
  - Further guidance may be required from experts bodies or regulatory authorities
  - The overall responsibility lies with those who are responsible for worker exposure

- DC for **public exposure** (§259):
  - Would typically be set by national regulatory authorities

Attributes to select source-related DCs and RLs

Band of projected dose (mSv/an)	Characteristics of the exposure situation	RP Requirements
20 à 100	- Sources not **controllable**, - Actions disproportionately disruptive, - **Action** 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

Prospective use

- Doses to be compared with DC and RL are usually **prospective doses** (§116)
- In principle, protective options [or protection strategies] that imply doses above such restrictions **should be rejected** (§42, §278)
- DC = **upper bound** for predicted dose in optimisation of protection, **basic level of protection**, level above which **protection is unlikely optimised** and action must almost always be taken (§230)
- DC introduced in ICRP 60 to ensure that optimisation does **not create inequity** in the dose distribution (§232)
- **Occupational** exposure: only options expected to cause doses below DC are considered in the process of optimisation (§233)
- **Public** exposure: upper bound on doses that members of the public could receive from the planned operation of a specified controlled source (§233)
- RL = level above which it is judged to be inappropriate to **plan to allow** exposures to occur and for which therefore protective actions should be planned and optimised (§234)

Retrospective use

- If DC or RL is exceeded, the **reasons should be investigated** but this fact alone should not necessarily prompt regulatory reaction (§q)
- If DC is exceeded, action includes determining whether protection has been optimised, whether appropriate DC has been selected, whether further steps to reduce doses would be appropriate (§231), i.e. **accountability**
- DC and RL are **not intended** as a form of retrospective DL (§216). DCs are **not to be used or understood** as prescriptive regulatory limits (§ 233)
- RL is a **benchmark** against which protection options can be judged retrospectively. The resulting distribution of dose may or may not include exposures > RL. Reduce exposures > RL, if possible (§235)
- RLs may be used as benchmark for **assessing effectiveness** of protection strategies (§286)

Summary for Dose constraints and Reference levels

- **Source-related, prospective** individual dose **restrictions**
- Used in conjunction with the **optimisation**
- Set on a **case by case** basis on the basis of generic considerations and past experience (see Table 5)
- With the intention of not going or stay above (**ceiling levels**)
- With the ambition to reduce doses **ALARA below** (DC and RL are not endpoints)
- Used for the selection of protective options at the **planning stage**
- To shift exposures **towards lower values**
- Also used **retrospectively**, with nuances between DC and RL: **accountability** but not regulatory limits

Dose criteria in ICRP 60: a two-speed system

Practices

Dose limit
(multi-sources ceiling level)

Dose constraint
(single-source ceiling level)

Optimisation

Intervention

Action/Intervention levels (floor levels)

Optimisation

What happens below AL/IL?

No further optimisation?

Dose criteria in ICRP 103: a unified approach

Planned exposure situations

Dose limit

Dose constraint

Optimisation

Emergency and existing exposure situations

Reference level (ceiling level)

Optimisation

ICRP 103: Scale of risks (continuum)

Dose (mSv/year)	Attitude toward exposed individuals (according to circumstances and individuals)	Control of the source (dominant parameter)
20 à 100	Reaction	Loss of control of the source
1 à 20	Vigilance	Source already existing or higher risk tolerated (with a better protection)
< 1	Quietude	Control of sources from design to disposal (from cradle to grave)

ICRP 103: Questions as conclusions

- Why a **discontinued series** of dose criteria: 1, 20, 100 mSv?
- Is the **rationale of 100 mSv** convincing (§236)?
  - Increased likelihood of deterministic effects: some thresholds are decreasing
  - Significant risk of cancer: what if the level of significance decreases?
- What is the **time-reference of 100 mSv**?
  - Incurred either acutely or in a year ((§236)
  - Implicitly during the response in case of emergency exposure situation?
- What about **cumulative exposures**?

Category/Situation	Planned	Emergency	Existing
Occupational			
Medical			
Public			

- What about **societal values**?
  - Who decides about the acceptable level? Need for an opening to the society
- What is the **tolerability of risk model** for Existing and Emergency ES?
- What about retrospective assessment of the **individual risk**?

Thank you for your attention