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Federal Authority for Nuclear Regulation

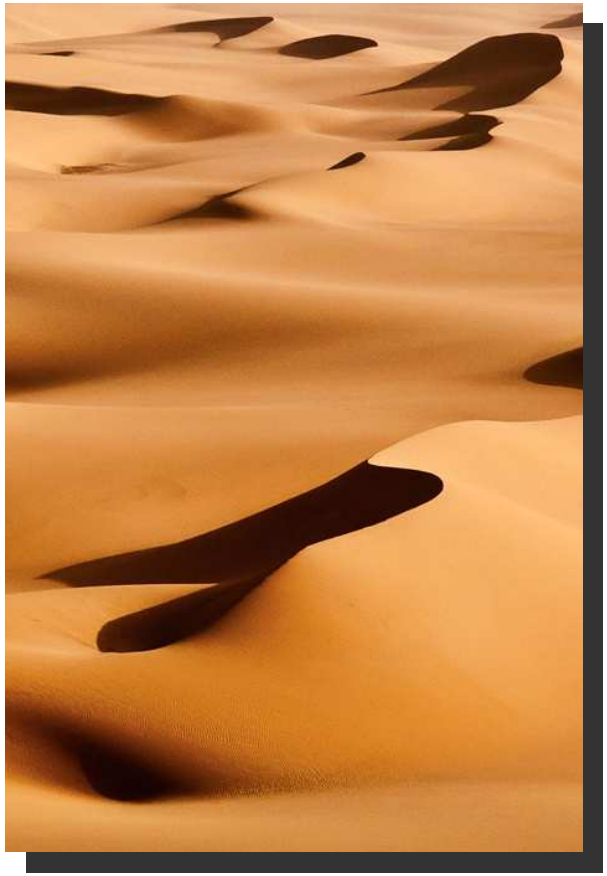
RADIATION "LOW DOSES" AND THE "EXEMPTION" CRITERIA

Daniele GIUFFRIDA

FANR EXPERT IN
RADIATION PROTECTION

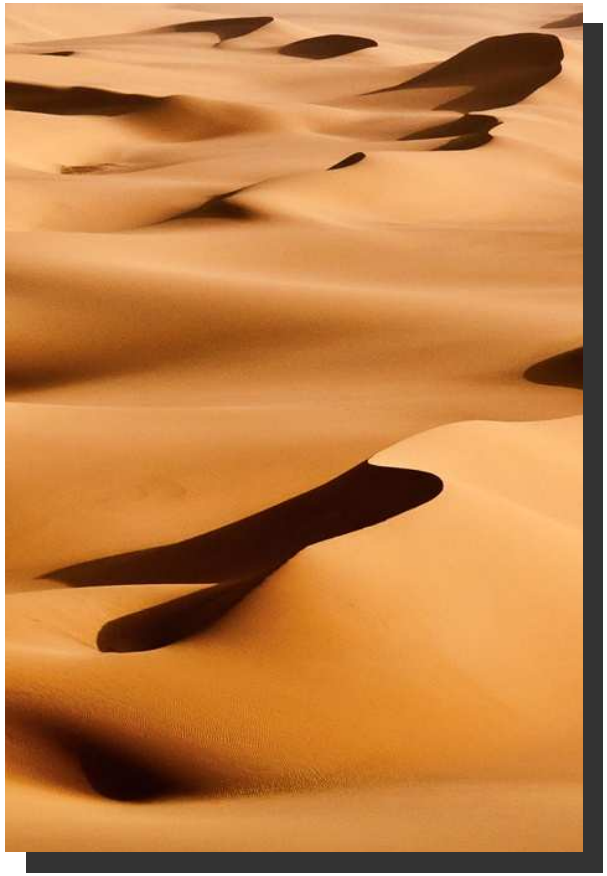
USE OF RADIATION - ADRET

- See inside the human body without opening it
- Cure diseases
- Sterilise against parasites, germs, bacteria
- Improve qualities of materials
- Improve the characteristics of crops
- Glow in the dark
- Provide a source for long-term batteries
- Generate electricity in remote locations
- Fight mosquitoes and other pests
- Generate electricity for an entire country
- Check welding qualities
- …..
- Examine water, oil and gas wells deep in the ground



USE OF RADIATION - UBAC

- Skin redness, erythema
- Skin swelling, edema
- Ischaemic dermal necrosis
- Cataract
- Loss of hair, and loss of hairs
- Sterility
- Modifications in the blood composition
- Nausea, vomit, diarrhoea
- Cardiovascular diseases
- Cancerogenesis
- …..
- Death



LECTURE OUTLINE

- RADIATION RISKS AT HIGH RADIATION DOSES
- RADIATION RISKS AT LOW RADIATION DOSES
- THE (ICRP!) RADIATION PROTECTION SYSTEM
- THE SCOPE AND PURPOSE OF A REGULATORY SYSTEM
- THE RATIONALE FOR EXCLUSION AND EXEMPTION
- SOME REFLECTIONS AND CONCLUSIONS

THE NEED FOR A PROTECTION SYSTEM

More than 1000 articles on X-rays in the year following Roentgen's X-ray discovery

Many injuries were reported, and quickly the need for a protection system emerged

Mostly based on experimental evidence (redness, swelling, radiodermatitis), not on full understanding of phenomena

First skin cancer as a direct result of radiation exposure was described within 6 years of Roentgen's discovery

[17]

1928: IXRPC

INTERNATIONAL RECOMMENDATIONS FOR X-RAY AND RADIUM PROTECTION

INTERNATIONALE
RICHTLINIEN FÜR RÖNTGENSTRAHLEN- UND RADIUMSCHUTZ

RECOMMANDATIONS INTERNATIONALES POUR LA PROTECTION VIS A VIS DES RA YONS X ET DU RADIUM

STOCKHOLM 1929
KUNGL. BOKTRYCKERIET. P. A. NORSTEDT & SÖNER

283376

INTERNATIONAL RECOMMENDATIONS FOR X-RAY AND RADIUM PROTECTION

on the proposal of the Radio-Physics Section adopted by the Second International Congress of Radiology in Stockholm, July 27th, 1928

1. The dangers of over-exposure to X-rays and radium can be avoided by the provision of adequate protection and suitable working conditions. It is the duty of those in charge of X-ray and radium departments to ensure such conditions for their personnel. The known effects to be guarded against are:
(a) Injuries to the superficial tissues;
(b) Derangements of internal organs and changes in the blood.

I. *Working Hours etc.*

2. The following working hours etc. are recommended for whole-time X-ray and radium workers:
(a) Not more than seven working hours a day.
(b) Not more than five working days a week. The off-days to be spent as much as possible out of doors.
(c) Not less than one month's holiday a year.
(d) Whole-time workers in hospital X-ray and radium departments should not be called upon for other hospital service.

II. *General X-Ray Recommendations.*

3. X-ray departments should not be situated below ground-floor level.
4. All rooms, including dark-rooms, should be provided with windows affording good natural lighting and ready facilities for admitting sunshine and fresh air whenever possible.
5. All rooms should be provided with adequate exhaust ventilation capable of renewing the air of the room not less than 10 times an hour. Air inlets and outlets should be arranged to afford cross-wise ventilation of the room.
6. All rooms should preferably be decorated in light colours.
7. X-ray rooms should be large enough to permit a convenient lay-out of the equipment. A minimum floor area of 250 sq. feet (25 sq. metres) is recommended for X-ray rooms and 100 sq. feet (10 sq. metres) for dark-rooms. Ceilings should be not less than 11 feet (3.5 metres) high.
8. A working temperature of about 18° C. (65° F.) is desirable in X-ray rooms.
9. Wherever practicable, the X-ray generating apparatus should be placed in a separate room from the X-ray tube.

III. *X-Ray Protective Recommendations.*

10. An X-ray operator should on no account expose himself unnecessarily to a direct beam of X-rays.
11. An operator should place himself as remote as practicable from the X-ray tube. It should not be possible for a well rested eye of normal acuity to detect in the dark appreciable fluorescence of a screen placed in the permanent position of the operator.
12. The X-ray tube should be surrounded as completely as possible with protective material of adequate lead equivalent.
13. The following lead equivalents are recommended as adequate:

X-rays generated by peak voltages	Minimum equivalent thickness of lead
Not exceeding 75	1 mm.
» » 100	1½ »
» » 125	2 »
» » 150	2¼ »
» » 175	3 »
» » 200	4 »
» » 225	5 »

14. In the case of diagnostic work, the operator should be afforded protection from scattered rays by a screen of a minimum lead equivalent of 1 mm.
15. In the case of X-ray treatment the operator is best stationed completely outside the X-ray room behind a protective wall of a minimum lead equivalent of 2 mm. This figure should be correspondingly increased if the protective value of the X-ray tube enclosure falls short of the values given in paragraph 13. In such event, the remaining walls, floor and ceiling may also be required to provide supplementary protection for adjacent occupants to an extent depending on the circumstances.
16. Screening examinations should be conducted as rapidly as possible with minimum intensities and apertures.
17. The lead glass of fluorescent screens should have the protective values recommended in paragraph 13.
18. In the case of screening stands, the fluorescent screen should, if necessary, be provided with a protective »surround» so that adequate protection against direct radiation is afforded for all positions of the screen and diaphragm.
19. Screening stands and couches should provide adequate arrangements for protecting the operator against scattered radiation from the patient.
20. Inspection windows in screens and walls should have protective lead values equivalent to that of the surrounding screen or wall.
21. Efficient safeguards should be adopted to avoid the omission of a metal filter in X-ray treatment.
22. Protective gloves, which should be suitably lined with fabric or other material, should have a protective value not less than ½ mm. lead throughout both back and front (including fingers and wrist). Protective aprons should have a minimum lead value of ½ mm.

IV. *Electrical Precautions in X-ray Rooms.*

23. The floor-covering of the X-ray room should be of insulating material such as wood, rubber or linoleum.

24. Permanent overhead conductors should be not less than 9 ft. (3 metres) from the floor. They should consist of stout metal tubing or other coronaless type of conductor. The associated connecting leads should be of coronaless wire kept taut by suitable rheophores.
25. Wherever possible, earthed guards should be provided to shield the more adjacent parts of the high tension system. Unless there are reasons to the contrary, the metal parts of the apparatus and room should be efficiently earthed.
26. The use of quick acting double-pole circuit breakers is recommended. Over-powered fuses should not be used. If more than one apparatus is operated from a common generator, suitable overhead multi-way switches should be provided.
27. Some suitable form of kilo voltmeter should be provided to afford a measure of the voltage operating the X-ray tube.

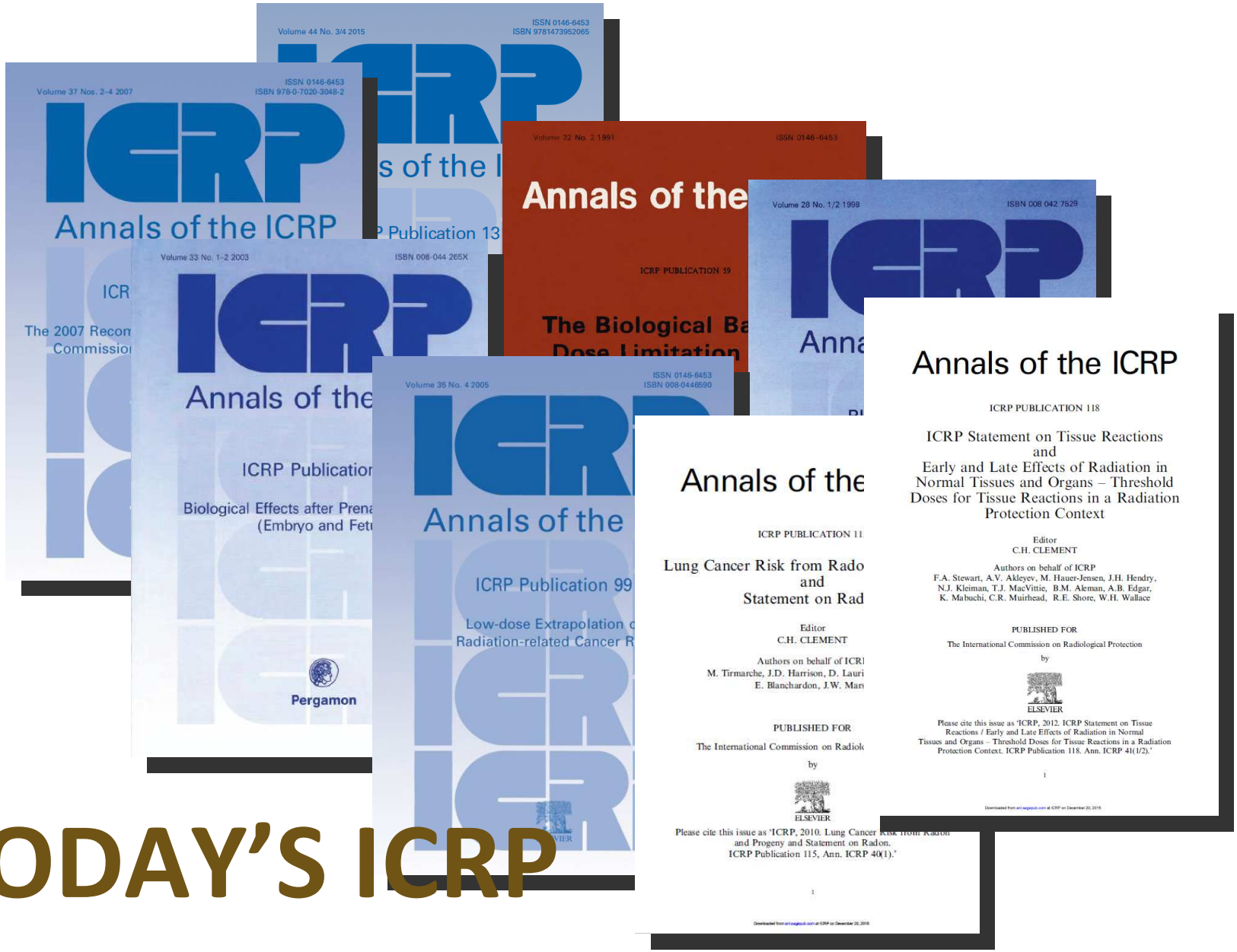
V. *Radium Protective Recommendations.*

(A) *Radium Salts.*
28. Protection for radium workers is required from the effects of:
(a) Beta rays upon the hands;
(b) Gamma rays upon the internal organs, vascular and reproductive systems.
29. In order to protect the hands from beta rays, reliance should be placed, in the first place, on distance. The radium should be manipulated with long-handled forceps, preferably made of wood, and should be carried from place to place in long-handled boxes, lined on all sides with about 1 cm. of lead. All manipulations should be carried out as rapidly as possible.
30. Radium, when not in use, should be stored in a safe as distant as possible from the personnel. It is recommended that radium tubes or applicators be inserted into separate lead blocks in the safe, giving a thickness of protective wall amounting to 5 cms. of lead per 100 milligrammes of radium element.
31. A separate room should be provided for the »make-up» of screened tubes and applicators, and this room should only be occupied during such work.
32. In order to protect the body from the penetrating gamma rays during handling of the radium, a screen of not less than one inch thickness of lead should be used, and proximity to the radium should only occur during actual work and for as short a time as possible.
33. The measurement room should be a separate room, and it should contain the radium only during its actual measurement.
34. Nurses and attendants should not remain in the same room as patients undergoing radium treatment.
35. All unskilled work or work which can be learnt in a short period of time should preferably be carried out by temporary workers, who should be engaged on such work for periods not exceeding six months. This applies especially to nurses and those engaged in »making-up» applicators.
36. Discretion should be exercised in transmitting radium salts by post. In the case of small quantities it is recommended that the container should be lined throughout with lead not less than 3 mms. thick. It is more satisfactory to transport large quantities by hand in a suitably designed carrying case.
(B) *Emanation.*
37. In the manipulation of emanation, protection against the beta and gamma rays has likewise to be provided.
38. The handling of emanation should be carried out, as far as possible, during its relatively inactive state.

39. The escape of emanation should be very carefully guarded against, and the room in which it is prepared should be provided with an exhaust fan.
40. Where emanation is likely to come in direct contact with the fingers, thin rubber gloves should be worn to avoid contamination of the hands with active deposit. Otherwise, the protective measure recommended for radium salts should be carried out.
41. A separate pumping room should be provided with a connecting tube from the special room in which the radium is stored in solution. The radium in solution should be heavily screened to protect people working in adjacent rooms. This is preferably done by placing the radium in solution in a lead-lined box, the thickness of lead recommended being according to the following table:

Quantity of radiumelement	Thickness of lead
0.1 gram	6 inches 15 cms
1.0 »	6.5 » 16½ »
1.5 »	6.8 » 17 »
2.0 »	7.2 » 18 »

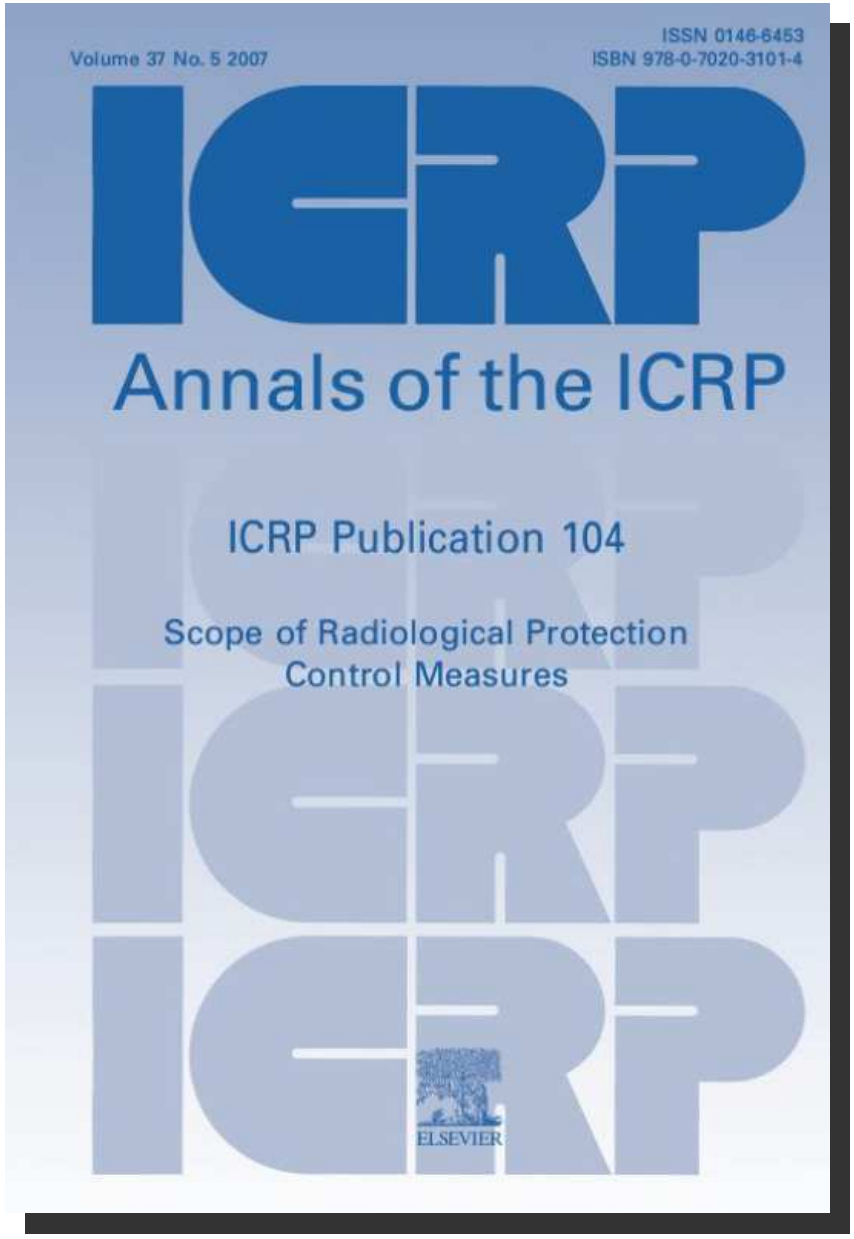
RADIATION PROTECTION SYSTEM



TODAY'S ICRP

RADIATION REGULATION

TWO DIFFERENT SYSTEMS…



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SOMMARIO

LEGGI ED ALTRI ATTI NORMATIVI

DECRETO LEGISLATIVO 29 luglio 2015, n. 129.

Disciplina sanzionatoria delle violazioni delle disposizioni del Regolamento (UE) n. 1177/2010, che modifica il Regolamento (CE) n. 2006/2004, relativo ai diritti dei passeggeri che viaggiano via mare e per vie navigabili interne. (15G00144) . . *Pag.* 1

DECRETO LEGISLATIVO 6 agosto 2015, n. 130.

Attuazione della direttiva 2013/11/UE sulla risoluzione alternativa delle controversie dei consumatori, che modifica il regolamento (CE) n. 2006/2004 e la direttiva 2009/22/CE (direttiva sull'ADR per i consumatori). (15G00147) . . . . . *Pag.* 10

DECRETI PRESIDENZIALI

DECRETO DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 3 agosto 2015.

Sospensione del sig. Massimiliano Scarabeo dalla carriera di assessore e consigliere regionale della regione Molise. (15A06408) . . . . . *Pag.* 25

DECRETI, DELIBERE E ORDINANZE MINISTERIALI

Ministero dell'economia e delle finanze

DECRETO 20 luglio 2015.

Riparto delle risorse di cui all'articolo 8, comma 2, del decreto-legge 19 giugno 2015, n. 78. (15A06240) . . . . . *Pag.* 26

…TWO DIFFERENT PURPOSES

A System of Radiological Protection aims to provide:

- Science, values, experience
- Epistemological framework for risk estimation
- Paradigm for protection
- Fundamental Principles
- Policies (concept, tools, requisites)

→ **RP Philosophy**
(based on RP Science!)

General indications on “doses”

A (legal) Regulatory System aims to provide:

- A legal and formal structure for controlling radiation exposures
- A clear field of (operational) application of the Law
- A sharp definition between acceptable/non acceptable
- A (complementary) system for fines and sanctions

→ **RP practice**
(based on juris-prudence)

Doses, (radio)activities, work activities, derived limits…

HOW DOES RADIATION CREATE HARM?

CLASSICAL PARADIGM (SINGLE HIT) FOR HIGH DOSE EXPOSURES

Radiation deposits energy in a cell (molecule).

Molecular bonds are affected:

1. Either nothing happens…
2. Or the cell dies or mutates…
3. And if the number of affected cells is high, a lesion is developed (health effect)

UBAC OF RADIATION EXPOSURE

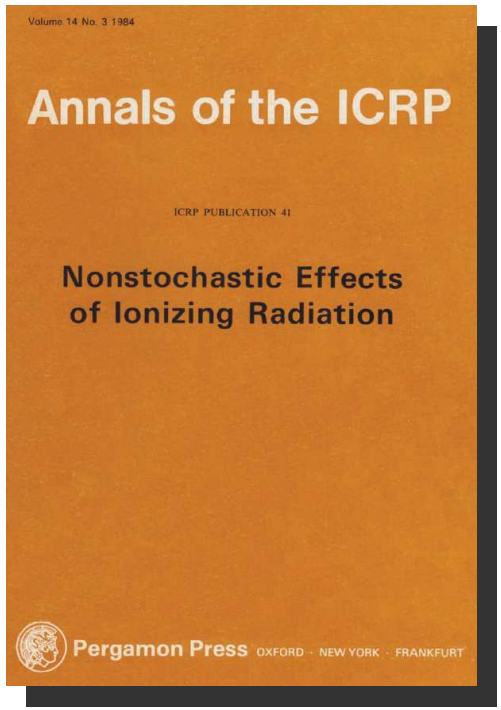
“HIGH DOSES”

1. Associated with “acute” exposures
2. Effects presenting themselves after hours, days, weeks (or later)
3. “Serious” effects on tissues and organs
4. Existence of a dose “threshold”
5. Gravity of the effect increasing with radiation exposure
6. Ability to describe effects using the concept “dose”

“LOW DOSES”

ICRP 41 – “NON STOCHASTIC EFFECTS”

“When the term ‘**stochastic**’ was introduced to describe single-cell effects, such as mutagenesis, effects caused by injury in populations of cells were called ‘**non-stochastic**’”

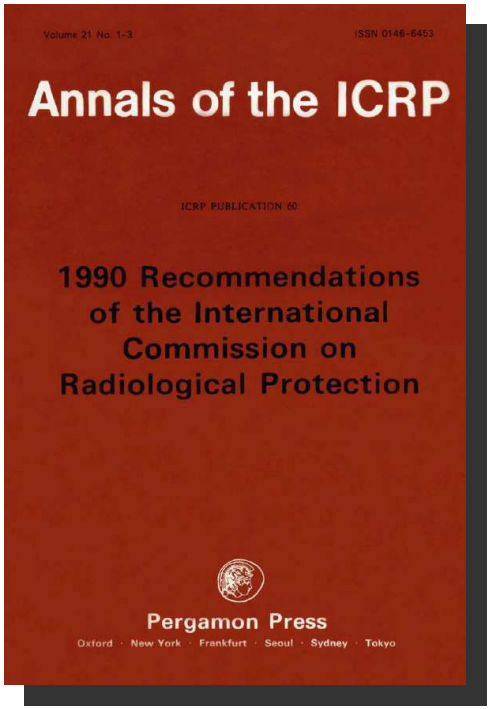


1984

[7]

ICRP 60 – “DETERMINISTIC EFFECTS”

“This was later considered to be an unsuitable term, and it was replaced with the term ‘**deterministic**’, meaning ‘**causally determined by preceding events**’”

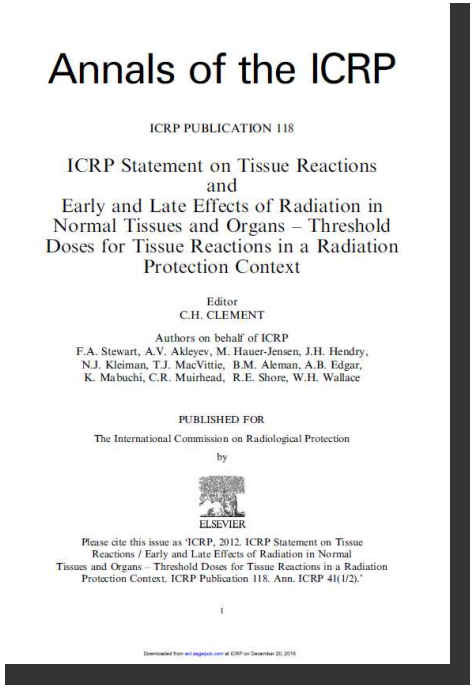


1990

[8]

ICRP 118 – “TISSUE REACTIONS”

“These effects, previously called ‘deterministic effects’, are now referred to as ‘**tissue reactions**’ because it is increasingly recognised that **these effects are not determined solely at the time of irradiation, but that many types of tissue reactions can be modified after radiation exposure**.”


Annals of the ICRP

ICRP PUBLICATION 118

ICRP Statement on Tissue Reactions
and
Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context

Editor
C.H. CLEMENT

Authors on behalf of ICRP
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1

2012

[6]

SEVERAL VARIABLES INVOLVED

The “way” in which energy is deposited during an interaction with a tissue depends on several factors:

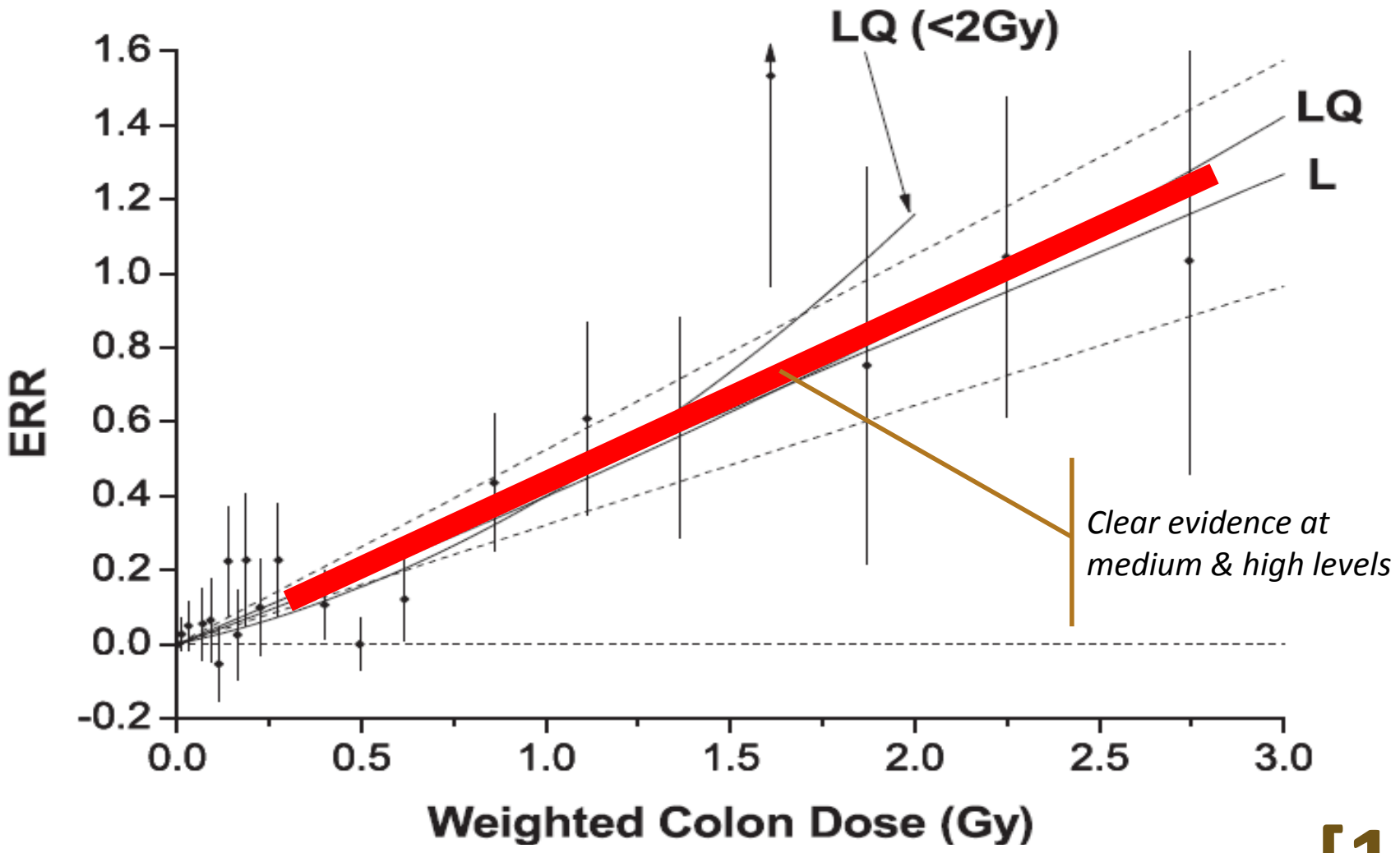
- Kind of radiation
- Energy of radiation
- LET of the particle,
- RBE (chosen for dose and dose rate!)
- Fractionation

SEVERAL “LEVELS” INVOLVED

Radiation interacts at different “levels” with the human body:

- Entire body
- Tissues and organs

SOLID CANCERS



[11]

DOSE THRESHOLD

Tissue reactions are characterized by a radiation dose "threshold" because a certain number of cells need to be impaired for the effect to become visible

"The reason for the presence of this threshold dose is that radiation damage (serious malfunction or death) of a critical population of cells in a given tissue needs to be sustained before injury is expressed in a clinically relevant form"

[9]

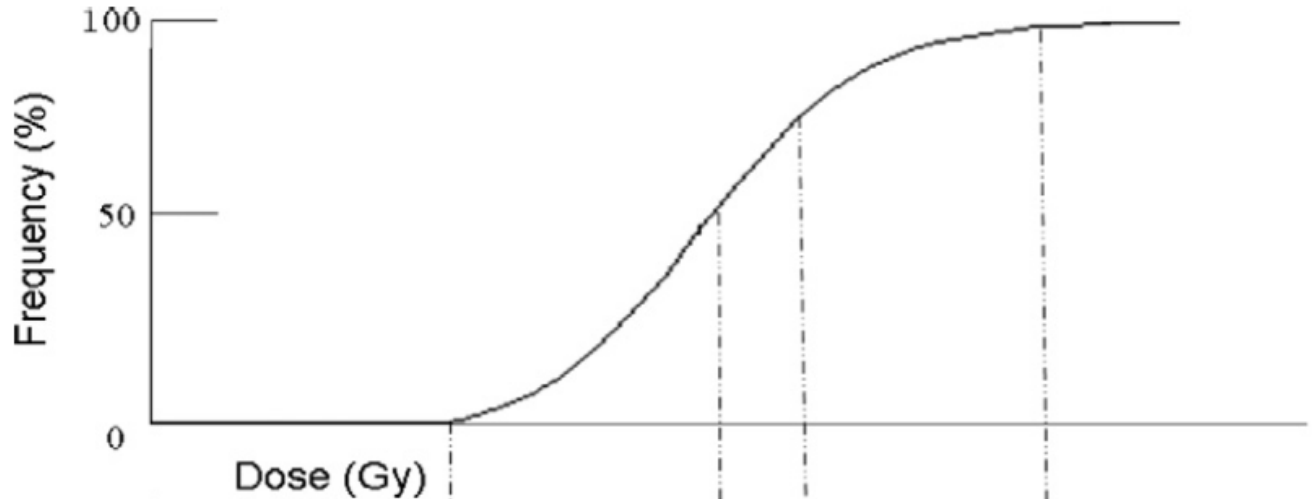
THRESHOLDS - TISSUE REACTIONS

Thresholds for Tissue Reactions

- Circulatory disease: 0.5 Gy (acute or protracted)
- Cataract induction: 0.5 Gy (acute or protracted)
- Skin effects:
  - Early transient erythema: 2 Gy
  - Permanent epilation: 7 Gy
  - Ischaemic dermal necrosis: 18 Gy
- Mortality:
  - 1 Gy (without care), 2-3 Gy (with good care), acute
  - 4-8 Gy per week, or 10-14 Gy over 1-3 months likely tolerated

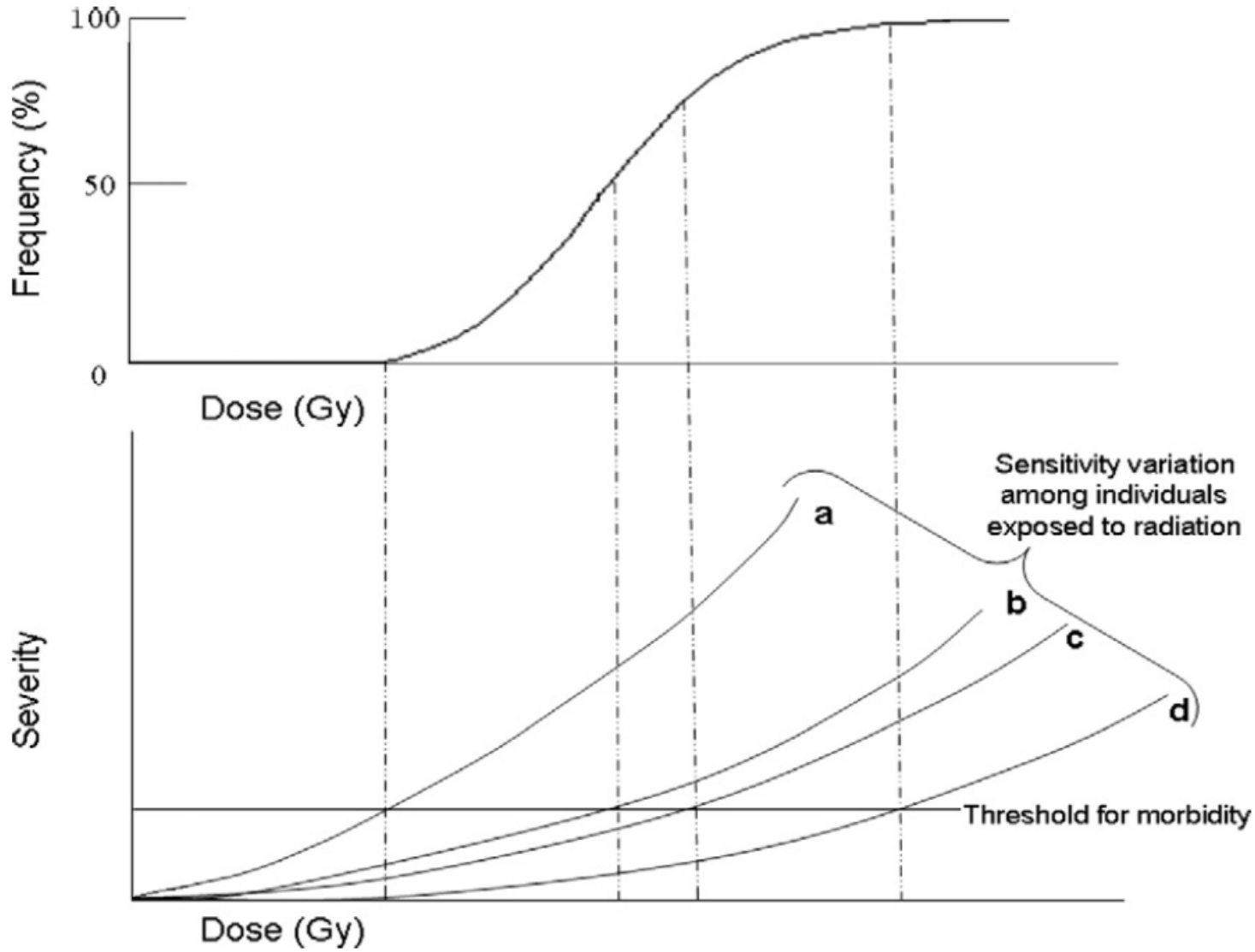
[15]

FREQUENCY, SEVERITY, SENSITIVITY



[9]

FREQUENCY, SEVERITY, SENSITIVITY



[9]

DOSE RANGE

Tissue reactions appear at “high doses”, i.e., at , and their severity increases with the radiation dose, as the affected cell population increases

“in the absorbed dose range up to around 100 mGy (low LET or high LET) no tissues are judged to express clinically relevant functional impairment”

[9]

SEVERAL “LEVELS” INVOLVED

Radiation interacts at different “levels” with the human body:

- Entire body
- Tissues and organs
- Group of cells in organs
- Single cell
- Cell nucleus
- The DNA in the cell nucleus

WHY DOES RADIATION CREATE HARM?

CLASSICAL PARADIGM (SINGLE HIT) FOR LOW DOSE EXPOSURES

Radiation deposits energy in a cell molecule

Molecular bonds are affected:

1. Nothing happens
2. The cell dies
3. The cell develops a mutation, that can be transmitted

UBAC OF RADIATION EXPOSURE

"HIGH DOSES"

1. Associated with "acute" exposures
2. Effects presenting themselves after hours, days, weeks (or later)
3. "Serious" effects on tissues and organs
4. Existence of a dose "threshold"
5. Gravity of the effect increasing with radiation exposure
6. Ability to describe effects using the concept "dose"

"LOW DOSES"

A. Associated with "chronic" exposures

B. Effects presenting themselves after years

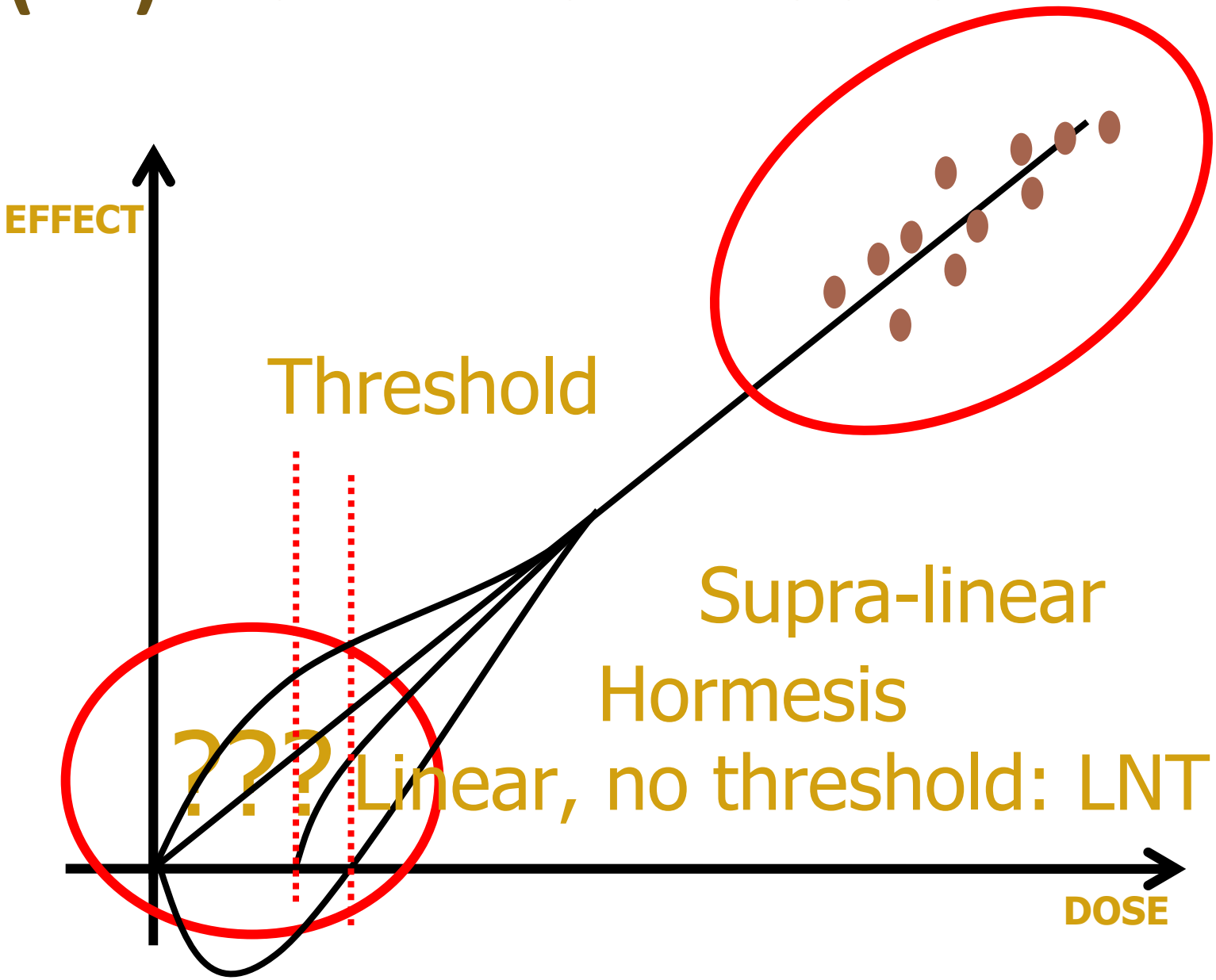
C. Effects not directly leading to death

D. Doubts regarding a dose "threshold"

E. Risk not directly related to radiation exposure

F. Some inexplicable effects; use of "dose"

(ER) RISK AT LOW DOSES



[12]

LOW DOSES AND LNT

"The system of radiological protection recommended by the Commission continues to be based upon the *assumption that at doses below approximately 100 mSv, a given increment in dose will produce a directly proportionate increment in the probability of incurring cancer or heritable effects attributable to radiation*"

[9]

WHY DOES RADIATION CREATE HARM?

"NEW" PARADIGM (NON TARGETED EFFECTS)

New experimental evidence for non-targeted radiation effects, e.g.:

1. Bystander effect
2. Genomic instability
3. Abscopal effects
4. Release of clastogenic factors
5. Adaptive response

THE ICRP SYSTEM OF RP

The system of Radiation Protection has been developed mostly for “low doses”, at levels at which most individuals (workers and populations) are exposed

The current RP System (ICRP103) is composed (among others) of a definition of (EFFECTIVE) DOSE, and various TYPES and CATEGORIES of exposure situations, with limits, constraints and reference values

EQUIVALENT AND EFFECTIVE DOSES

$$H_{\mathrm{T}} = \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}}$$

[9]

RADIATION WEIGHTING FACTORS - wR

Table 2. Recommended radiation weighting factors.

Radiation type	**Radiation weighting factor, w_R**
Photons	1
Electrons[a] and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	A continuous function of neutron energy (see Fig. 1 and Eq. 4.3)

All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

[a] Note the special issue of Auger electrons discussed in paragraph 116 and in Section B.3.3 of Annex B.

[9]

NEUTRON WEIGHTING FACTOR - wR

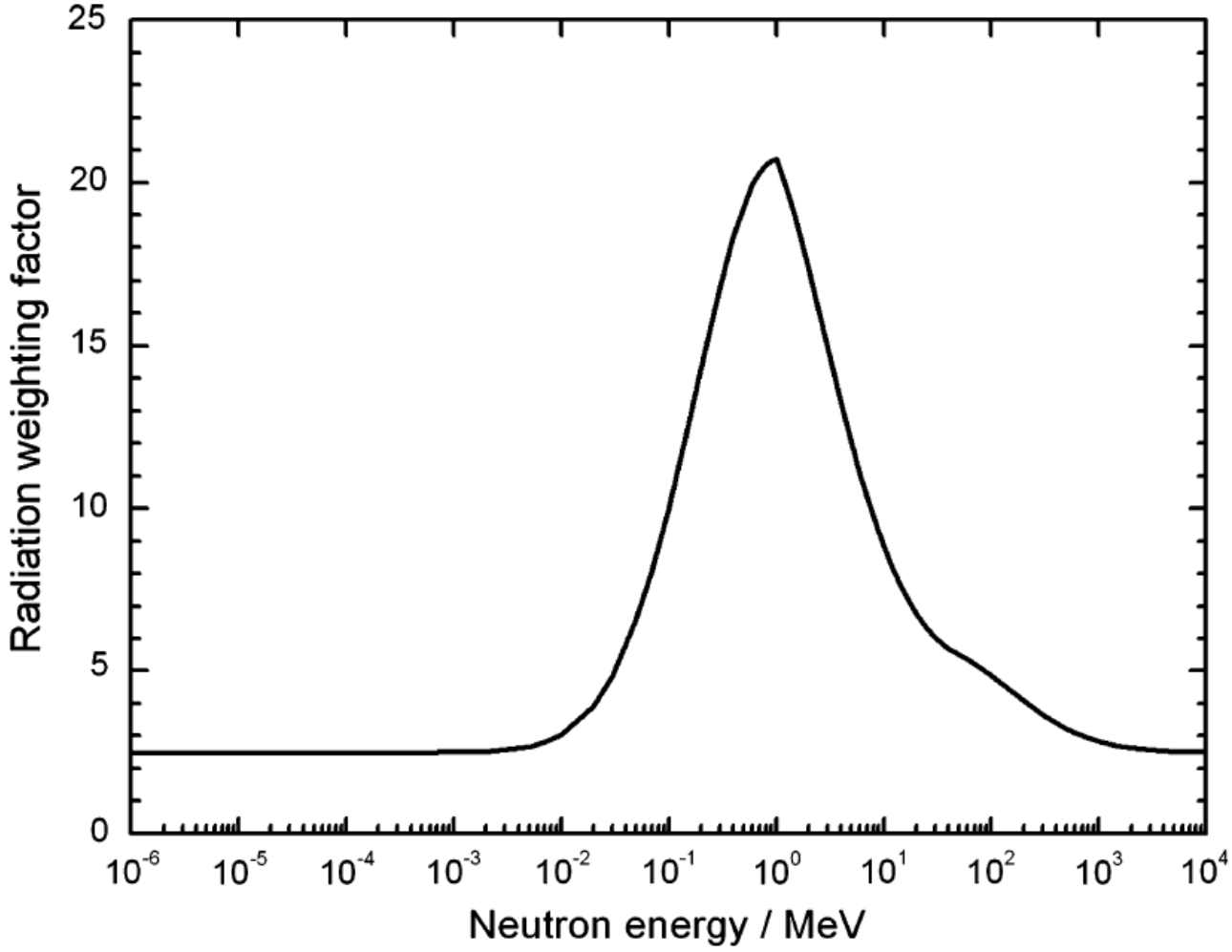


Fig. 1. Radiation weighting factor, w_R, for neutrons versus neutron energy.

[9
1

EQUIVALENT AND EFFECTIVE DOSES

$$H_{\mathrm{T}} = \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}}$$

$$E = \sum_{\mathrm{T}} w_{\mathrm{T}} H_{\mathrm{T}} = \sum_{\mathrm{T}} w_{\mathrm{T}} \sum_{\mathrm{R}} w_{\mathrm{R}} D_{\mathrm{T,R}}$$

[9]

TISSUE WEIGHTING FACTORS - wT

Table 3. Recommended tissue weighting factors.

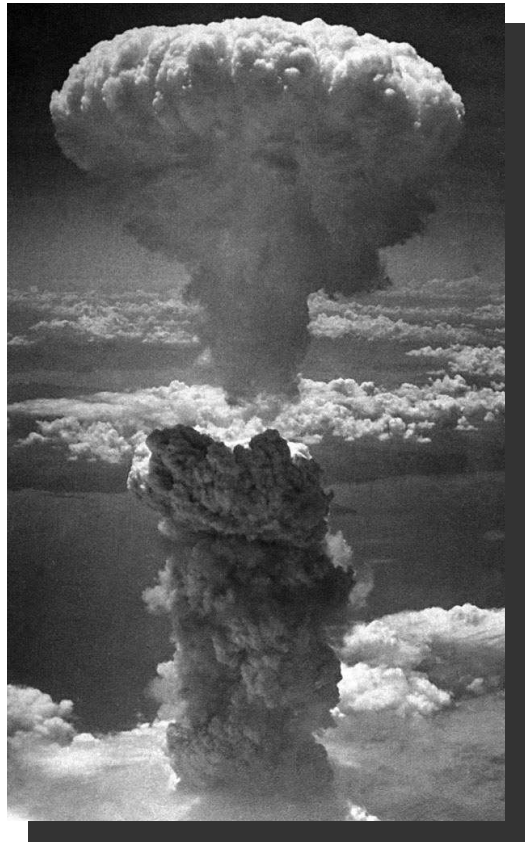
Tissue	w_T	$\sum w_T$
Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues*	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (♂), Small intestine, Spleen, Thymus, Uterus/cervix (♀).

[9]

ATOMIC BOMB LSS

- Continuing studies on Atomic Bomb Survivors keep providing additional evidence on radiation effects (Life Span Study)
- Data concern “cancer mortality” and “cancer incidence” (follow-up of 50+ years)
- More recent data were used in the 2007 Recommendations, which were not available in 1990



[9]

RISK COEFFICIENTS (ICRP 103)

Table 1. Detriment-adjusted nominal risk coefficients (10^{-2} Sv^{-1}) for stochastic effects after exposure to radiation at low dose rate.

Exposed population	Cancer		Heritable effects		Total	
	Present[1]	*Publ. 60*	Present[1]	*Publ. 60*	Present[1]	*Publ. 60*
Whole	5.5	6.0	0.2	1.3	5.7	7.3
Adult	4.1	4.8	0.1	0.8	4.2	5.6

[1] Values from Annex A.

[9]

RP FUNDAMENTAL PRINCIPLES

JUSTIFICATION

Do more good than harm

OPTIMISATION

Keep likelihood of exposures, number of people exposed, and magnitude of individual doses As Low As Reasonably Achievable (ALARA), taking into account economic and societal factors

DOSE LIMITATION

Doses to individuals should not exceed limits (for regulated sources in planned exposure situations)

RADIATION PROTECTION SYSTEM - ICRP

Three **types of exposure situations**:

- Planned Exposure Situations
- Emergency Exposure Situations
- Existing Exposure Situations

Three **categories of exposure**:

- Occupational Exposure
- Public Exposure
- Medical Exposure

[9]

EXPOSURE SITUATIONS

Planned Exposure Situation

Involves the planned operation of sources including decommissioning, disposal of radioactive waste and rehabilitation

Existing Exposure Situation

Already exists when a decision on control has to be taken, including natural background and residues from past practices operated outside the system

Emergency Exposure Situation

Is unexpected and requires urgent action

EXPOSURE CATEGORIES

Occupational Exposure

Incurred by workers in the course of their work and reasonably regarded as the responsibility of the operating management

Public Exposure

Incurred by members of the public

Medical Exposure

Incurred by patients as part of their own medical or dental diagnosis or treatment, volunteers helping in the support and comfort of patients, and biomedical research volunteers

[9]

RADIATION PROTECTION (ICRP103)

Limits, Constraints, Reference levels

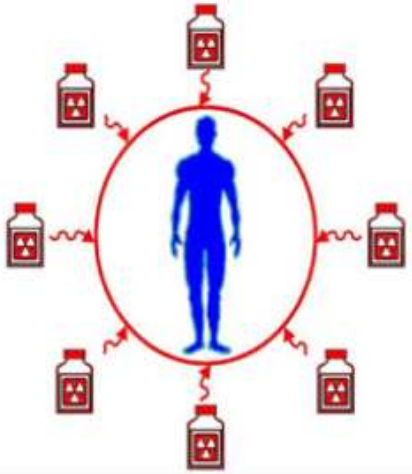
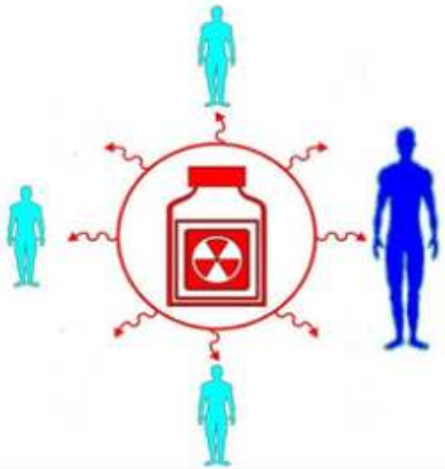
Dose Limits	Constraints and Reference Levels
Protect individual workers from occupational exposure and the Representative Person from public exposure	
	
From all regulated sources in planned exposure situations	From a source in all exposure situations

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

[9]

OCCUPATIONAL EXPOSURES
PLANNED EXPOSURE SITUATION

Exposure Situations	Exposure Types: Occupational	Exposure Types: Public	Exposure Types: Medical
Planned	Dose Limits Constraints	Dose Limits Constraints	Diagnostic Reference Levels *(Dose Constraints)*
Existing	Reference Levels	Reference Levels	
Emergency	Reference Levels	Reference Levels	

[15]

OCCUPATIONAL EXPOSURES
PLANNED EXPOSURE SITUATION

Exposure Situations	Exposure Types: Occupational	Public	Medical
Planned	Dose Limits Constraints		
Existing			
Emergency			

[15]

OCCUPATIONAL EXPOSURES
PLANNED EXPOSURE SITUATION

"Normal" radiological protection

Occupational Dose Limits	
Effective Dose (Whole Body)	20 mSv/a averaged over 5 years and 50 mSv/y
Equivalent Dose (Lens of the Eye)	20 mSv/a averaged over 5 years and 50 mSv/y
Equivalent Dose (Skin)	500 mSv/y
Equivalent Dose (Hands and Feet)	500 mSv/y

Constraints

Restrictions on the dose to individuals from a source

Upper bounds for optimization

Basic level of protection for the most highly exposed individuals

Limits the range of options considered in optimisation

OCCUPATIONAL EXPOSURES
PLANNED EXPOSURE SITUATION

- Worker doses assessed by direct monitoring or calculation
- Dose limits must be observed
- Design/planning by optimisation below constraints
  - Constraints defined at the design/planning stage
  - Constraints usually set at operational level
  - Responsibility for setting constraints lies with those who are responsible for worker exposure
- Large operations generally set their own constraints
- Smaller operations may require guidance from expert bodies or regulatory authorities

Public Exposures
Planned Exposure Situation

Exposure Situations	Exposure Types: Occupational	Exposure Types: Public	Exposure Types: Medical
Planned		Dose Limits Constraints	
Existing			
Emergency			

Public Exposures
Planned Exposure Situation

“Normal” radiological protection

Public Dose Limits	
Effective Dose (Whole Body)	1 mSv/y
Equivalent Dose (Lens of the Eye)	15 mSv/y
Equivalent Dose (Skin)	50 mSv/y

Constraints

Restrictions on the dose to individuals from a source

Upper bounds for optimization

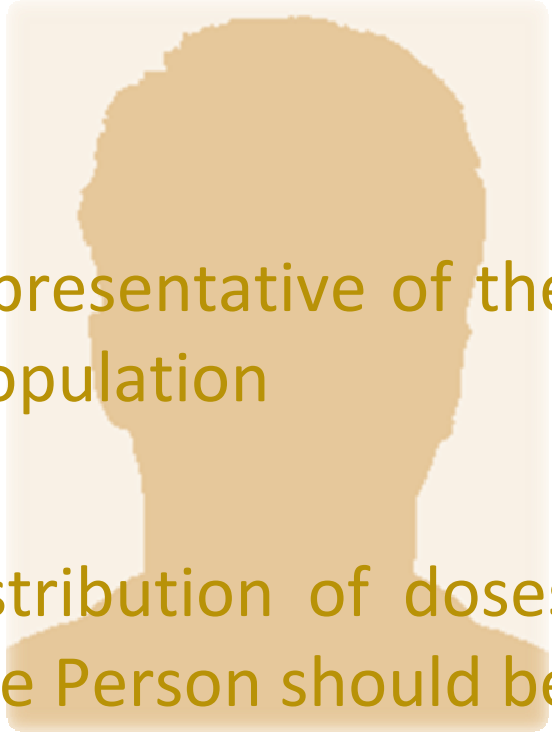
Basic level of protection for the most highly exposed individuals

An upper bound on public doses from a planned operation

Public Exposures
Planned Exposure Situation

Doses to all individuals cannot be monitored

Use Representative Person:



An individual receiving a dose that is representative of the more highly exposed individuals in the population

Generally, each source will cause a distribution of doses over many individuals; the Representative Person should be used to represent the more highly exposed individuals

Occupational and Public Exposures
Existing Exposure Situation

Exposure Situations	Exposure Types: Occupational	Exposure Types: Public	Exposure Types: Medical
Planned			
Existing	Reference Levels	Reference Levels	
Emergency			

Public Exposures
Existing Exposure situation

Complex, cannot be managed with RP considerations alone (address health, environmental, economic, social, psychological, cultural, ethical, political, etc.)

Develop a protection strategy

Protective actions directed at exposure pathways

Protect people with the highest exposures, in parallel reduce all individual exposures to ALARA

Include self-help protective actions

Reference levels (e.g. for post-accident recovery)

Initially in lower part of 1-20 mSv/a

Long term objective ~1 mSv/a, and rehabilitate areas to allow people to return to their normal habits

Occupational Exposures
Emergency Exposure Situation

Exposure Situations	Exposure Types: Occupational	Exposure Types: Public	Exposure Types: Medical
Planned			
Existing			
Emergency	Reference Levels		

Occupational Exposures
Emergency Exposure Situation

Exposure of workers responding to an emergency is generally deliberate and controlled, although this is not always the case so some flexibility is needed

Category 1: urgent action at the site

Doses may voluntarily exceed limits for planned exposure situations

Make every effort to keep doses < 1 Sv, although higher may be justified for life-saving actions

Category 2: early protective actions and action to protect public

Protection consistent with the system for planned exposure situations, where feasible

Category 3: recovery operations

Subject to the system for occupational exposure in planned exposure situations

Public Exposures
Emergency Exposure Situation

Exposure Situations	Exposure Types: Occupational	Public	Medical
Planned			
Existing			
Emergency		Reference Levels	

Public Exposures

Emergency Exposure Situation

Develop a protection strategy considering all exposure pathways and all relevant protection options

Reference Level on residual dose

20-100 mSv, set by national authorities

May not be applicable for low-probability high-consequence events

Triggers (observable or measureable) initiate action in the early phase

Consider termination of emergency actions & transition to rehabilitation

Medical Exposures

Exposure Situations	Exposure Types: Occupational	Exposure Types: Public	Exposure Types: Medical
Planned			Diagnostic Reference Levels *(Dose Constraints)*
Existing			
Emergency			

Radiological Protection in Medicine

Justification

Most benefit and risk apply to the patient

Optimization

ALARA is management of the radiation dose to the patient commensurate with the medical purpose

Diagnostic reference levels (not constraints)

Dose Limitation

Does not apply to medical exposures of patients

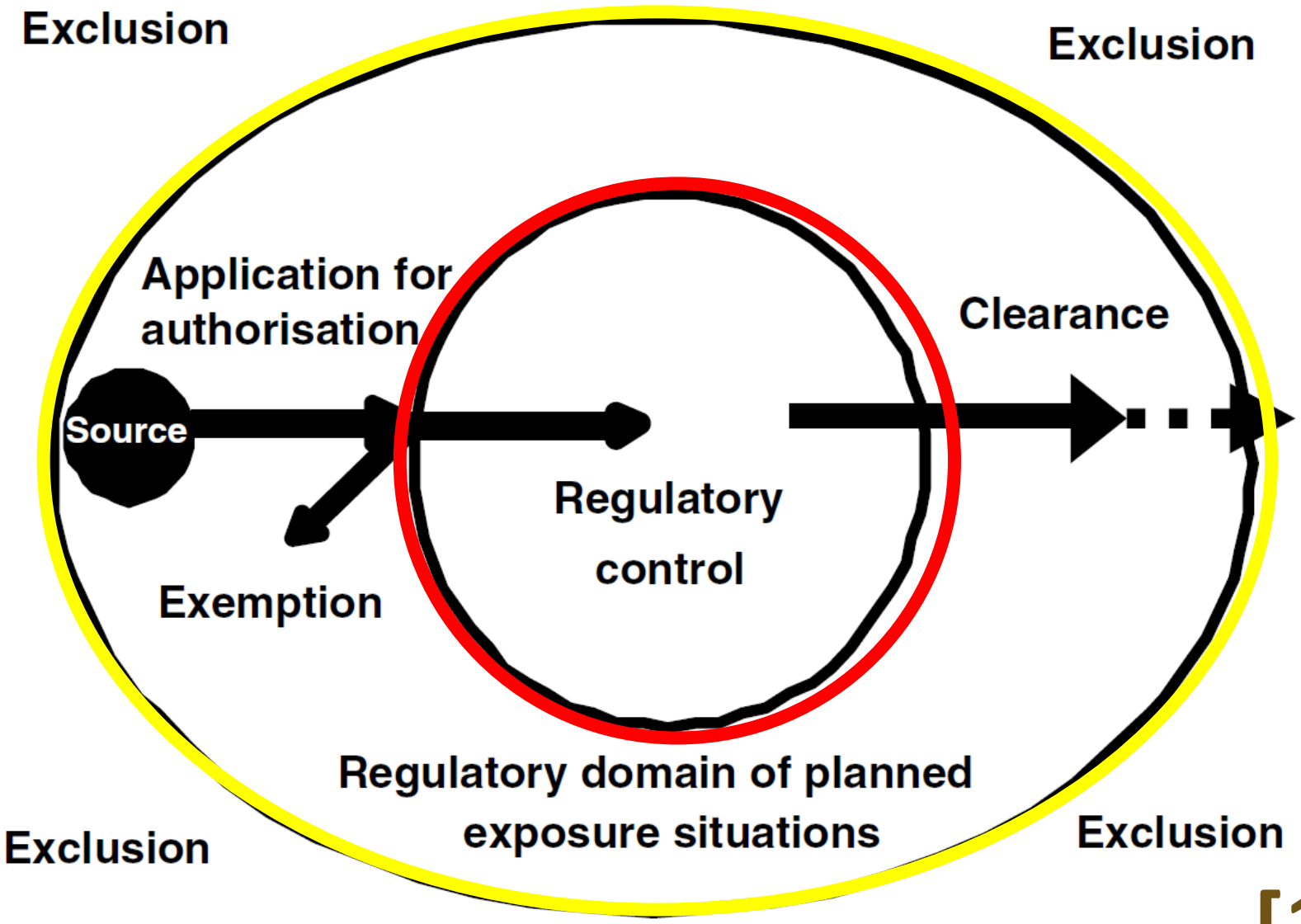
Three Levels of Justification

1. Is the proper use of radiation in medicine doing more good than harm to society?

2. A specified procedure with a specified objective
   - e.g. chest x-ray for diagnostic purposes for patients showing relevant symptoms

3. Application to a specific patient
   - i.e. Do more good than harm to the patient

EXCLUSION, EXEMPTION, CLEARANCE



[10]

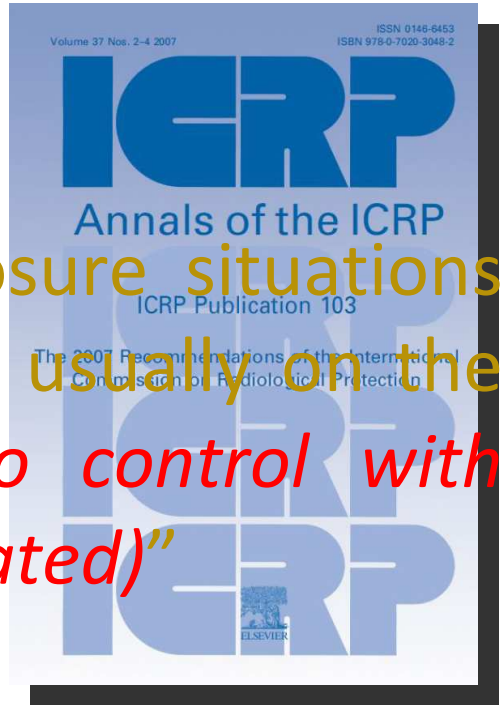
RADIATION REGULATION

"there is no need for ICRP to mandate specific numerical guidance on scope, such as radioactivity concentration that should be regulated"

"The application of regulatory control should achieve a net benefit in protection; otherwise, regulatory control is not justified"

[10]

ICRP 103



EXCLUSION: "exclusion of certain exposure situations from radiological protection legislation, usually on the basis that *they are not amenable to control with regulatory instruments (cannot be regulated)*"

EXEMPTION: "the exemption from some or all radiological protection regulatory requirements for situations where such controls are regarded as unwarranted, often on the basis that *the effort to control is judged to be excessive compared to the associated risk (need not be regulated)*"

[10]

EXCLUSION

UNCONTROLLABLE EXPOSURES

EXPOSURES WHICH ARE NOT AMENABLE TO CONTROL, REGARDLESS OF THEIR MAGNITUDE

EXEMPTION - DE MINIMIS

DE MINIMIS NON CURAT LEX

DE MINIMIS NON CURAT PRAETOR

THERE IS NO “DE MINIMIS DOSE”!!!

EXEMPTION GENERIC PRINCIPLES

(i) the attributable expected individual risks must be sufficiently low as not to warrant regulatory concern

(ii) Radiological protection must be optimised taking account of the effort required to regulate

(iii) Practice is justified

(iv) Practice is inherently safe

EXEMPTION HISTORY: IN THE ’70s

- Initially related to waste sea dumping international discussions
- IAEA 1984
- IAEA/WHO/NEA/ART.31 1985
- IAEA/NEA 1988: "Principles for the exemption of radiation sources and practices from regulatory control"

[16]

EXEMPTION HISTORY: IAEA AND NEA

1988: IAEA and NEA

Tens of microSv were indicated, based on natural background considerations.

Taking a nominal risk factor of approximately 5E-2/Sv for whole-body exposure as a broad average over age and sex, the level of trivial individual effective dose would be of the order of magnitude of 10–100 microSv/year

“EXEMPTION PRINCIPLE” HISTORY

1970s: sea dumping convention

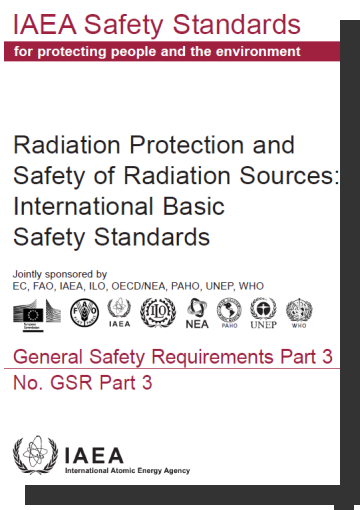
1984: IAEA

1990: ICRP 60

1988: IAEA+NEA

1996: BSS IAEA → GSR, part 3

IAEA REQUIREMENT 8

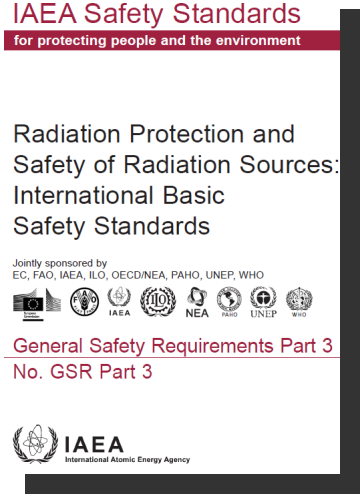


Requirement 8: Exemption and clearance

The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control.

[1]

IAEA REQUIREMENT 8



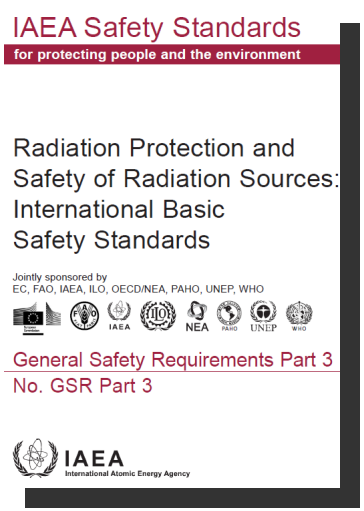
Exemption

3.10. The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards, including the requirements for notification, registration or licensing, using as the basis for this determination the criteria for exemption specified in Schedule I or any exemption levels specified by the regulatory body on the basis of these criteria.

3.11. Exemption shall not be granted for practices deemed to be not justified.

[1]

IAEA SCHEDULE I



CRITERIA FOR EXEMPTION

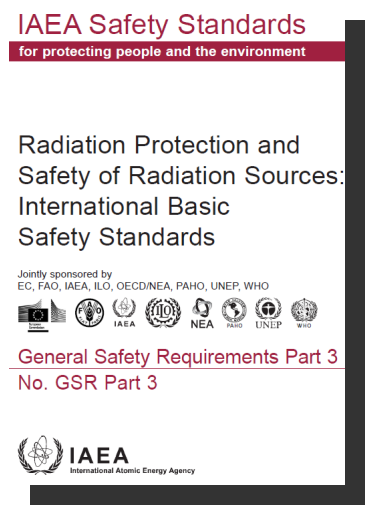
I.1. The general criteria for exemption of a practice or a source within a practice from some or all of the requirements of these Standards are that:

(a) Radiation risks arising from the practice or from a source within the practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations arising that could lead to a failure to meet the general criterion for exemption; or

(b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable measures for regulatory control would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

[1]

IAEA SCHEDULE I



I.2. A practice or a source within a practice may be exempted without further consideration from some or all of the requirements of these Standards under the terms of para. I.1(a) provided that under all reasonably foreseeable circumstances the effective dose expected to be incurred by any individual (normally evaluated on the basis of a safety assessment) owing to the exempt practice or the exempt source within the practice is of the order of 10 μSv or less in a year. To take into account low probability scenarios, a different criterion could be used, namely that the effective dose expected to be incurred by any individual for such low probability scenarios does not exceed 1 mSv in a year.

[1]

“EXEMPTION PRINCIPLE” HISTORY

1970s: sea dumping convention

1984: IAEA

1990: ICRP 60

1988: IAEA+NEA

1996: BSS IAEA → GSR, part 3

1996: BSS EU 96/29 → EU 59/2013

ART.31 – EUROPEAN COMMISSION

Commission of the European Communities

radiation protection - 65

Principles and Methods for Establishing Concentrations and Quantities (Exemption values) Below which Reporting is not Required in the European Directive

Doc. XI-028/93

Radiation Protection 122

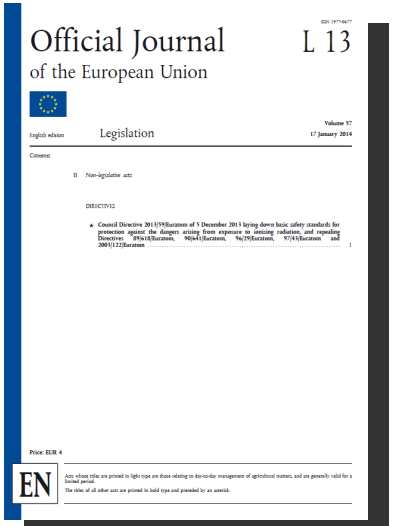
PRACTICAL USE OF THE CONCEPTS OF CLEARANCE AND EXEMPTION – PART I

Guidance on General Clearance Levels for Practices

Recommendations of the Group of Experts established under the terms of Article 31of the Euratom Treaty

European Commission

EU DIRECTIVE 59-2013


Official Journal
of the European Union
L 13
Legislation
Volume 57
17 January 2014
EN

Article 3

Exclusion from the scope

This Directive shall not apply to:

(a) exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level;

(b) exposure of members of the public or workers other than air or spacecrew to cosmic radiation in flight or in space;

(c) aboveground exposure to radionuclides present in the undisturbed earth's crust.

[2]

59-2013: ART. 24


Official Journal
of the European Union
L 13
Legislation

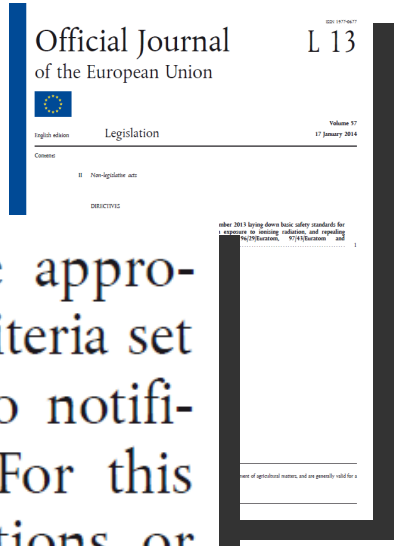
Article 24

Graded approach to regulatory control

1. Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.

[2]

59-2013: ART. 24

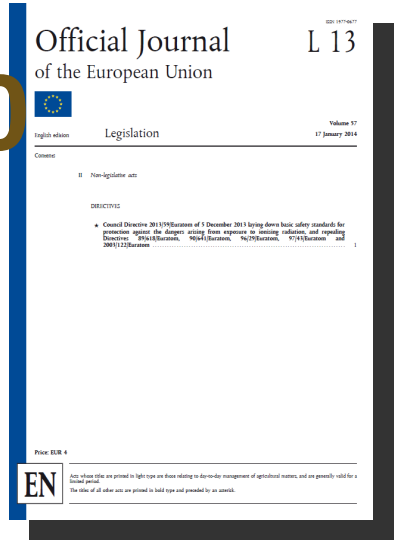


2. Without prejudice to Articles 27 and 28, where appropriate, and in accordance with the general exemption criteria set out in Annex VII, regulatory control may be limited to notification and an appropriate frequency of inspections. For this purpose, Member States may establish general exemptions or allow the competent authority to decide to exempt notified practices from the requirement of authorisation on the basis of the general criteria specified in Annex VII; in the case of moderate amounts of material, as specified by Member States, the activity concentration values laid down in Annex VII, Table B, column 2 may be used for this purpose.

3. Notified practices which are not exempted from authorisation shall be subject to regulatory control through registration or licensing.

[2]

59-2013: ART. 24, 26 AND 30


Official Journal
of the European Union
L 13
Legislation
Volume 57
17 January 2014
Contents
II Non-legislative acts
DIRECTIVES
Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
Price: EUR 4
EN

Article 24

Graded approach to regulatory control

Article 26

Exemption from notification

Article 30

Release from regulatory control

[2]

59-2013: ANNEX VII

3. **General exemption and clearance criteria**

(a) The general criteria for the exemption of practices from notification or authorisation or for the clearance of materials from authorised practices are as follows:

(i) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and

(ii) the type of practice has been determined to be justified; and

(iii) the practice is inherently safe.

→ Clearance tables (bulk amounts and moderate amounts, natural radionuclides)

[2]

59-2013: ANNEX VII

Official Journal of the European Union L 13
Legislation

(e) For the purpose of exemption from notification or for the purpose of clearance, where amounts of radioactive substances or activity concentrations do not comply with the values laid down in Table A or Table B, an assessment shall be made in the light of the general criteria (i) to (iii) above. For compliance with the general criterion (i), it shall be demonstrated that workers should not be classified as exposed workers, and the following criteria for the exposure of members of the public are met in all feasible circumstances:

— For artificial radionuclides:

The effective dose expected to be incurred by a member of the public due to the exempted practice is of the order of 10 μSv or less in a year.

— For naturally-occurring radionuclides:

The dose increment, allowing for the prevailing background radiation from natural radiation sources, liable to be incurred by an individual due to the exempted practice is of the order of 1 mSv or less in a year. The assessment of doses to members of the public shall take into account not only pathways of exposure through airborne or liquid effluent, but also pathways resulting from the disposal or recycling of solid residues. Member States may specify dose criteria lower than 1 mSv per year for specific types of practices or specific pathways of exposure.

For the purpose of exemption from authorisation, less restrictive dose criteria may be applied.

[2]

“EXEMPTION PRINCIPLE” HISTORY

1970s: sea dumping convention

1984: IAEA

1990: ICRP 60

1988: IAEA+NEA

1996: BSS IAEA → GSR, part 3

1996: BSS EU 96/29 → EU 59/2013

2000: D. Lgs. 241/2000 → ?

D. Lgs. 230/95 e ss.mm.ii.


SERIE GENERALE

GAZZETTA UFFICIALE

DELLA REPUBBLICA ITALIANA

PARTE PRIMA — Roma - Mercoledì, 19 agosto 2015

AVVISO ALLE AMMINISTRAZIONI

SOMMARIO

LEGGI ED ALTRI ATTI NORMATIVI

DECRETI PRESIDENZIALI

DECRETI, DELIBERE E ORDINANZE MINISTERIALI

Art. 2 Principi concernenti le pratiche

6. In applicazione dei principi generali di cui ai commi 3 e 4, con i decreti di cui all'articolo 1, comma 2, sono esentate dalle disposizioni del presente decreto, senza ulteriori motivazioni, le pratiche che soddisfino congiuntamente il principio di cui al comma 1, ed i seguenti criteri di base:
   a) i rischi radiologici causati agli individui dalla pratica devono essere sufficientemente ridotti da risultare trascurabili ai fini della regolamentazione;
   b) l'incidenza radiologica collettiva della pratica deve essere sufficientemente ridotta da risultare trascurabile ai fini della regolamentazione nella maggior parte delle circostanze;
   c) la pratica deve essere intrinsecamente senza rilevanza radiologica, senza probabilità apprezzabili che si verifichino situazioni che possono condurre all'inosservanza dei criteri definiti nelle lettere a) e b).

[3]

D. Lgs. 230/95 e ss.mm.ii.


SERIE GENERALE

GAZZETTA UFFICIALE

DELLA REPUBBLICA ITALIANA

AVVISO ALLE AMMINISTRAZIONI

SOMMARIO

Le pratiche devono essere:

1. Giustificate
2. Rischio radiologico individuale ridotto
3. Incidenza radiologica collettiva ridotta
4. Instrinsecamente senza rilevanza radiologica

Allegato I

SERIE GENERALE

GAZZETTA UFFICIALE

DELLA REPUBBLICA ITALIANA

PARTE PRIMA — Roma - Mercoledì, 19 agosto 2015

AVVISO ALLE AMMINISTRAZIONI

SOMMARIO

LEGGI ED ALTRI ATTI NORMATIVI

DECRETO LEGISLATIVO 20 luglio 2015, n. 139.

Disciplina sanzionatoria delle violazioni delle disposizioni del Regolamento (UE) n. 1177/2010, che modifica il Regolamento (CE) n. 2006/2004, relativo ai diritti dei passeggeri che viaggiano via mare e per vie navigabili interne. (15G00144) . . . Pag. 1

DECRETO LEGISLATIVO 6 agosto 2015, n. 130.

Attuazione della direttiva 2013/11/UE sulla risoluzione alternativa delle controversie dei consumatori, che modifica il regolamento (CE) n. 2006/2004 e la direttiva 2009/22/CE (direttiva sull'ADR per i consumatori). (15G00147) . . . . . Pag. 10

DECRETI PRESIDENZIALI

DECRETO DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 3 agosto 2015.

Sospensione del sig. Massimiliano Scarabeo dalla carica di consigliere regionale della regione Molise. (15A06948) . . . . . Pag. 25

DECRETI, DELIBERE E ORDINANZE MINISTERIALI

Ministero dell'economia e delle finanze

DECRETO 20 luglio 2015.

Riparto delle risorse di cui all'articolo 8, comma 1, del decreto-legge 19 giugno 2015, n. 78. (15A06540) . . . . . Pag. 26

0. Criteri di non rilevanza radiologica delle pratiche

0.1. In conformità ai criteri di base di cui all'articolo 2 del presente decreto, una pratica può essere considerata, senza ulteriori motivazioni, priva di rilevanza radiologica, in particolare per gli effetti di cui agli articoli 30 e 154, purché i seguenti criteri siano congiuntamente soddisfatti in tutte le possibili situazioni:

a) la dose efficace cui si prevede sia esposto un qualsiasi individuo della popolazione a causa della pratica esente è pari o inferiore a 10 μSv all'anno;

b) la dose collettiva efficace impegnata nell'arco di un anno di esecuzione della pratica non è superiore a circa 1 Sv·persona, oppure una valutazione relativa all'ottimizzazione della protezione mostra che l'esenzione è l'opzione ottimale.

“EXEMPTION PRINCIPLE” HISTORY

1970s: sea dumping convention

1984: IAEA

1990: ICRP 60

1988: IAEA+NEA

1996: BSS IAEA → GSR, part 3

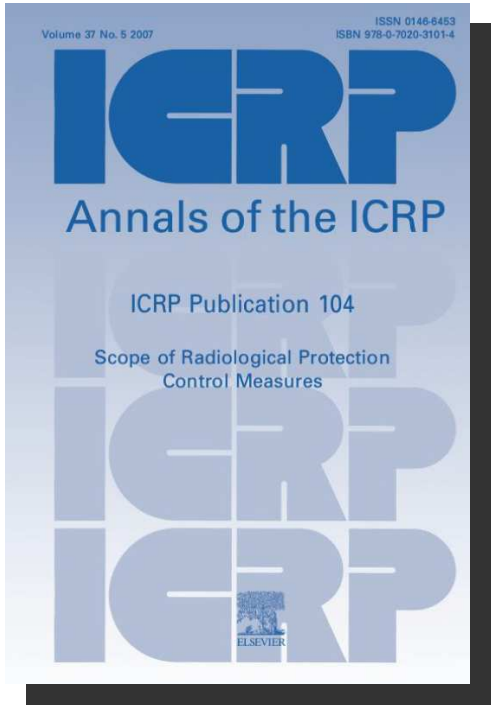
1996: BSS EU 96/29 → EU 59/2013

2000: D. Lgs. 241/2000 → ?

2007: ICRP 103 AND 104

EXCLUSION IN ICRP 104

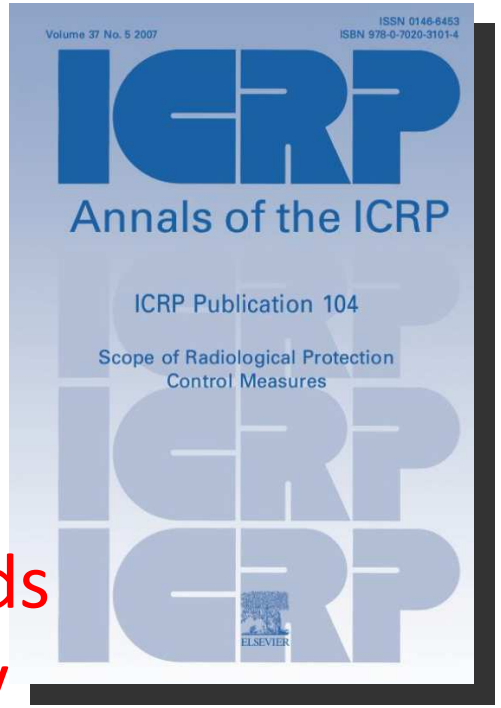
APPLICATION OF THE **JUSTIFICATION** PRINCIPLE:



"it *calls for ascertaining the exposure situations that can be justifiably regulated with controls or, conversely, those that are uncontrollable or unamenable to regulatory control and should therefore be excluded from control regulations*"

[10]

EXEMPTION IN ICRP 104



APPLICATION OF THE **OPTIMISATION** PRINCIPLE :

"requires determining the intensity of regulatory efforts by defining what needs to be regulated with the full regulatory system, including regulatory controls, or, conversely, what does not need to be fully regulated because optimum protection of the situation does not warrant full, or in some cases any, regulatory control and could therefore be exempted from some or all of the requirements"

[10]

CONSIDERATIONS

1. Exemption has been extensively embedded in the Italian Regulation (mainly through the “graded approach” process)
2. Exemption is not only a ‘technical’ criterion
3. “Radiological significance criteria” in ALLEGATO I correspond to TOTAL EXEMPTION from regulation
4. Those criteria should not be used as reference levels for any other phase of radiological activities licensing than exemption or clearance

AIRP PALERMO 2012 - GIUFFRIDA

Deve un'installazione radiologica rispettare il criterio di esenzione?

AIRP PALERMO 2012 - GIUFFRIDA

L'utilizzo del criterio di esenzione per l'autorizzazione di nuove pratiche o per l'ottimizzazione della dose pubblica è errato concettualmente ed è una falsa soluzione ad un (altro) problema

AIRP PALERMO 2012 - GIUFFRIDA

Pratica radiologica senza rilevanza radiologica!

PUBLIC EXPOSURE OPTIMISATION ?

Dose limit to the public: 1 mSv/y

Dose constraint: below 1 mSv/y

Optimisation process to 10 microSv/y?

Is optimisation concluded only in non-radiological significance conditions?

[4]

CONCLUSIONS - 1

- Radiation risks at high-dose exposures are rather well known and can be assessed using “absorbed dose”
- Low-dose exposures risks are assessed based (also) on information obtained from high-dose exposures
- Estimates of radiation risks at low-dose exposures are complex and bear huge uncertainties and doubts
- Radiation risks at low-dose exposures can be assessed using the “effective dose” concept, within the current RP system
- A RP system and a Regulatory System have different scopes and purposes: “protection” and “regulation”

CONCLUSIONS - 2

- The field of applicability of a Regulation should be based on radiation risk triviality and on practical considerations
- Many Recommendations converge towards a “10 microSv” concept for triviality
- Exemption is largely embedded in the Italian Regulation in various phases of authorisations
- Exemption criteria should not be used as optimisation levels or as constraints (misuse!)
- The implementation of the 59/2013 is an opportunity for further clarifications in the Italian Regulation

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Thank you







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