

AIFM, AIRP, ANPEQ - Workshop interassociativo Roma 19/06/2015  
**La dimensione etica della professione  
nella radioprotezione e nella fisica medica**



**Ricordo di Giovanni Silini:**

**un radiobiologo che ha gettato le  
basi dell'etica in radioprotezione**

Luigi Frittelli, *Roma*

# Una riflessione personale (aggiunta dopo la giornata del 19/6/2015)

***Povera e nuda vai, Filosofia - dice la turba al vil guadagno intesa”***

Era il ricordo del liceo suscitato in me dal confronto tra la vivacità intellettuale dei congressi negli anni in cui Giovanni Silini scrisse la sua Sievert Lecture e la monotonia degli incontri professionali delle Associazioni in questi ultimi anni

Ma la giornata di oggi ha cancellato questo ricordo

E di questo ringrazio Francesco e Marie-Claire



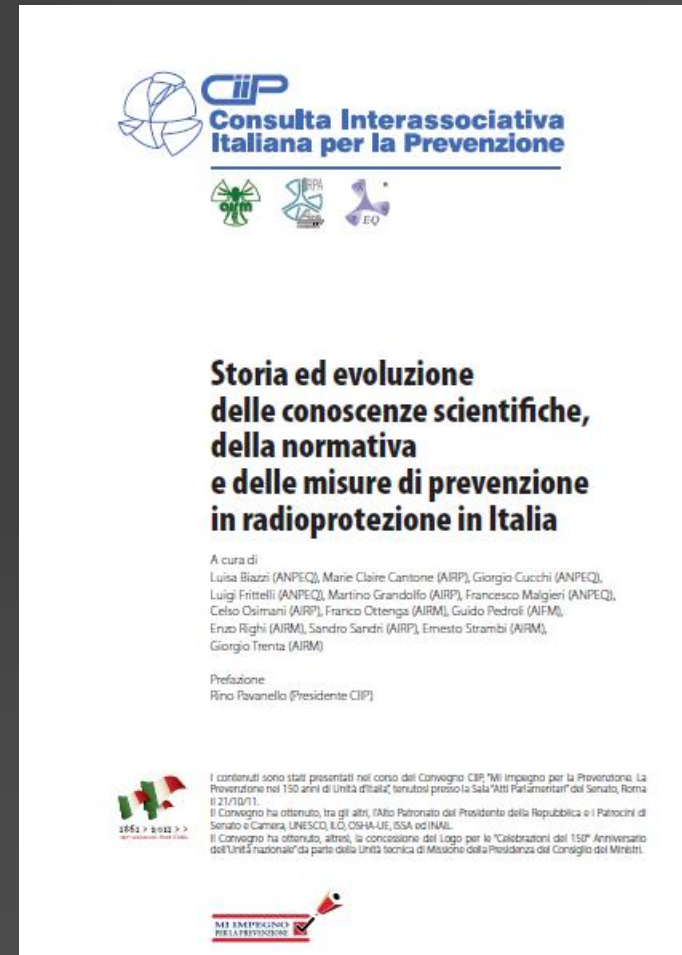
# Nota sulla presentazione

- Nel testo vengono richiamati i seguenti file pdf, di cui si consiglia la lettura per una completa comprensione della Sievert Lecture anche alla luce delle idee di quei tempi sulla radioprotezione
  - Slide 11: Sievert.pdf
  - Slide 12: nea6920-ICRP-recommendations.pdf
  - Slide 15: Conclusions of the Working Group on Biological implications of optimization in radiation protection.pdf
  - Slide 16: ETC\_55.pdf
  - Slide 19: Silini.pdf



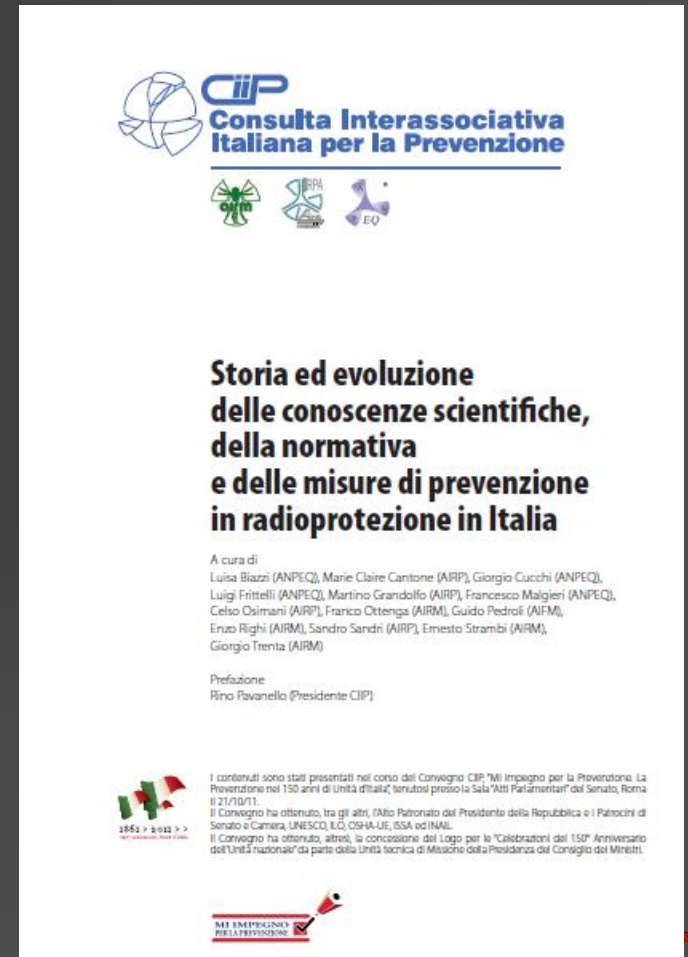
# Citazioni d'interesse nella Storia della radioprotezione in Italia della CIIP (Silini viene citato solo una volta)

- ICRP
- “Gli italiani che nel corso degli anni sono stati chiamati a far parte della Commissione sono stati Carlo Polvani (Comitato 4), Luigi Frittelli (Comitato 4), Carlo Perussia (Comitato 3) e Giovanni Silini, per numerosi mandati membro prima del Comitato 1 e poi della Main Commission.”

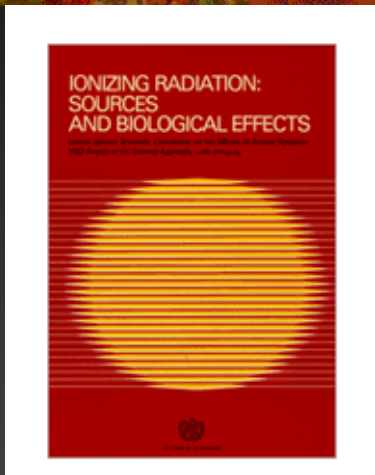


# Citazioni d'interesse nella Storia della radioprotezione in Italia della CIIP

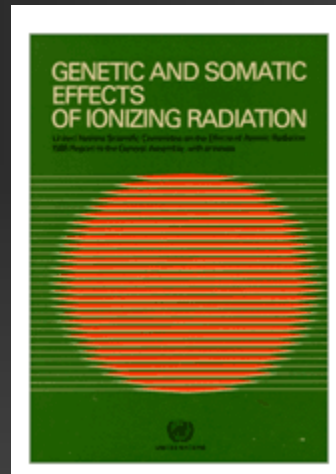
- UNSCEAR
- Le Nazioni Unite promossero la costituzione dell'UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) la cui attività era essenzialmente diretta al censimento e monitoraggio, su scala planetaria, delle principali fonti di radiazioni e sui loro effetti.;



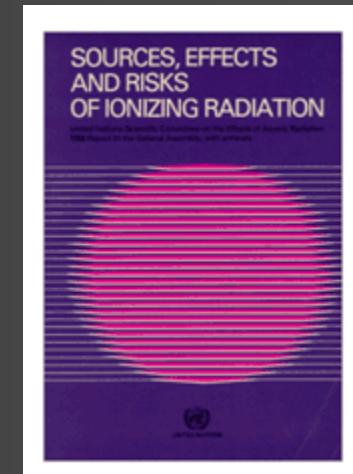
# Giovanni Silini Segretario dell'UNSCEAR (1981\_1988)



Rapporto 1982



Rapporto 1986



Rapporto 1988

## UNSCEAR 1988 REPORT

ANNEX D

Exposures from the Chernobyl accident

“Sono l’unica persona al mondo che ha letto i rapporti dell’UNSCEAR nella loro interezza”

Rapporto Chernobyl

# Impatto del Rapporto UNSCEAR 1988 sulla ICRP60

R.Clarke, NEA\_2011

In the 1990 Recommendations there was a review of non-stochastic, now renamed “deterministic” effects in organs and tissues and estimates were given for the thresholds of these effects. There was also a rigorous review of the stochastic effects in exposed individuals. There was a longer list than in 1977 of organs and tissues for which risks were quantified, some 13 organs plus gonads. Now the Commission gave nominal probability coefficients for stochastic effects; **for fatal cancer the risk was  $5.0 \cdot 10^{-2} \text{ Sv}^{-1}$**  for a population of all ages and the risk of **severe hereditary effects was  $1.0 \cdot 10^{-2} \text{ Sv}^{-1}$** . The Commission now gave separate risk factors for workers; **a fatal cancer risk of  $4.0 \cdot 10^{-2} \text{ Sv}^{-1}$**  and a **hereditary risk of  $0.6 \cdot 10^{-2} \text{ Sv}^{-1}$** .

# Impatto del Rapporto UNSCEAR 1988 sulla ICRP60

These estimates represented a significant increase over those from 1977 and caused some major changes to protection philosophy. The principal reason for the increased cancer risk estimates was that in 1977 an **additive model** had been used for estimating the risks, i.e., the radiation risks were assumed to be induced independent of the naturally occurring cancers. However, by the latter part of the 1980s there were more solid tumours recorded in the Japanese survivors, indicating there is a longer “latent period” for solid tumours compared to leukaemia, and the increased numbers led to the conclusion that the radiation-induced tumours were consistent with a **multiplicative model**, whereby the tumours induced by radiation arise as a percentage increase of

those naturally arising. This led to an increased estimate of the tumours that would arise in the future as natural cancer rates generally increase as a high power of attained age.



# La valutazione del rischio nella ICRP60 (1990) e nella ICRP103 (2007)

Table 6 gives the comparison of detriment adjusted nominal risks from 1990 and 2007. If the fatal cancer risk is taken alone for a population of all ages it is  $4 \cdot 10^{-2} \text{ Sv}^{-1}$  in 2007 (i.e., not adding in the weighted allowance for non-fatal cancers) compared to  $5 \cdot 10^{-2} \text{ Sv}^{-1}$  in 1990.

Table 6. **Detriment-adjusted nominal risk coefficients ( $10^{-2} \text{ Sv}^{-1}$ ) for stochastic effects after exposure to radiation at low dose rate**

Exposed population	Cancer (detriment weighted)		Heritable effects		Total	
	ICRP 103	ICRP 60	ICRP 103	ICRP 60	ICRP 103	ICRP 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

It is seen therefore that the fatal cancer, and the total detriment nominal risk coefficients are **about 25% lower** in the 2007 Recommendations compared to 1990.

# La Sievert Lecture del 1992

## Il Sievert Award

A partire dal 1973, ciascun congresso IRPA è stato aperto dalla Sievert Lecture presentata dal vincitore del Sievert Award, premio in onore di Rolf M. SIEVERT, pioniere della fisica delle radiazioni e della radioprotezione.

Chi riceve il premio deve avere fornito notevoli e qualificati contributi nel campo della radioprotezione e presenta la Sievert Lecture all'apertura del Congresso Internazionale dell'IRPA.

Le Associazioni affiliate all'IRPA propongono le nomine per il Sievert Award ed un Comitato dell'IRPA, sotto la presidenza del vice-presidente dell'Associazione Internazionale seleziona due candidati. La decisione finale a chi attribuire il premio è del Consiglio Direttivo dell'IRPA.

I vincitori del Sievert Award sino al Congresso di Montreal sono stati:

- 1973: Prof. Bo Lindell (Svezia)
- 1977: Prof. W.V.Meyneord (U.K.)
- 1980: Dr. Lauriston S. Taylor (USA)
- 1984: Sir Edward Pochin (U.K.)
- 1988: Prof. Dr. Wolfgang Jacobi (FRG)
- 1992: Prof. Giovanni Silini (Italia)

# La Sievert Lecture del 1992 (file sievert.pdf)



SIEVERT LECTURE 1992



XA04N2819

INIS-XA-N--247

## ETHICAL ISSUES IN RADIATION PROTECTION

Giovanni Silini

BOLOGNA, Settembre 1992

## La Sievert Lecture del 1992

- Per la prima volta vengono discussi gli aspetti etici alla base del Sistema di radioprotezione definito dalla ICRP con la Pubblicazione ICRP60 del 1990, che ha profondamente innovato nei contenuti e nella filosofia rispetto alla Pubblicazione ICRP26 del 1977.
- Una sintesi dell'evoluzione del sistema di radioprotezione dalla ICRP26 alla ICRP60 e da questa alla attuale ICRP103 del 2007 è nella pubblicazione di R.Clarke, "Evolution of ICRP Recommendations 1977, 1990, 2007" (File nea6920-ICRP-recommendations.pdf) la cui lettura permette di valutare nella loro completezza e nel loro valore le considerazioni di Giovanni Silini nella Sievert Lecture, che per molti versi hanno anticipato nel 1992 le conclusioni raggiunte nella ICRP103 del 2007.

# La Sievert Lecture del 1992

- L'Introduction **ne definisce gli obiettivi, riassunti nella** Conclusions
  - to discuss first the adequacy of the existing scientific information for the purpose of setting safety standards;
  - then to consider the foundation of the underlying main general assumption;
  - and finally, to discuss a few aspects of the three general principles.
    - Justification of a practice
    - Optimization of protection
    - Individual dose limitation
- All this, of course, in the light of ethical considerations.

## CONCLUSIONS

- My personal feeling at present, from a global perspective, is that adoption of the system, imperfect though it may be, by all countries would be likely to save more doses than might be saved by further marginal improvements in countries where the system is already well in operation. If this feeling is correct, then we should continue working, as we have done in the past, in order to develop the system rationally, while trying all the time to behave reasonably.
- Acknowledgements.
- I am greatly indebted to a number of friends who discussed with me some of the points or made useful comments to the original manuscript. They are: dr. C. Bresciani, dr. L. Frittelli, dr. O. Ilari, prof. B. Lindell and dr. F. Sella.

# In quei tempi di vivace dibattito sui principi e le metodiche della radioprotezione

## Conclusions of the Working Group on:

### BIOLOGICAL IMPLICATIONS OF OPTIMIZATION IN RADIATION PROTECTION

An appalling discrepancy exists between the cautious approach to the development of peaceful uses of nuclear energy and the reckless accumulation of nuclear weapons that now represent the greatest threat ever faced by humanity (Declaration on Prevention of Nuclear War, Pontifical Academy of Sciences, 23-24 September 1982).

This unprecedented danger does not preclude a continuous obligation to reduce the possibly harmful effects of the medical and industrial uses of ionizing radiation. A Study Group was therefore appointed by the Pontifical Academy of Sciences to review present measures of radiation protection and their biological bases.

#### I. GENERAL CONSIDERATIONS

##### 1) *Exposure to natural sources of radiation*

Cosmic rays, gamma radiation from the earth crust and naturally occurring radioactive substances in food and water are essentially unavoidable sources of radiation. The annual doses that individuals receive from these sources vary substantially from place to place and time to time. Whether mankind is adapted to these doses and not affected by them still remains an open question; in this respect no differences have yet been detected between populations exposed to different levels of background radiation. However, present assumptions about the dose-response relationships do not make it likely that the expected effects could be detected at the low exposure levels in question.

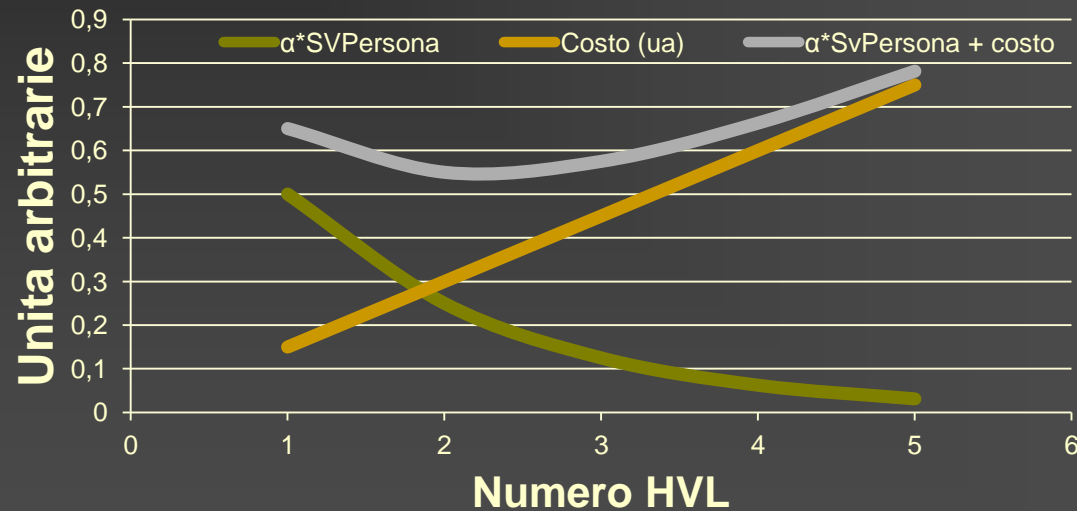
##### 2) *Biological effects of ionizing radiation*

Ionizing radiation can damage living cells. The most important

- La Pontificia Commissione per le Scienze esprime il proprio parere sulle tecniche di ottimizzazione (file Conclusions of the Working Group on Biological implications of optimization in radiation protection.pdf)

In quei tempi di vivace dibattito sui principi e le metodiche della radioprotezione

Si discute sulla analisi costi benefici e sul valore di alfa valore monetario da attribuire al Svpersona



Il valore di alfa viene ancora calcolato (file eTC55.pdf)



# In quei tempi di vivace dibattito sui principi e le metodiche della radioprotezione

- Vengono trasferiti nel dlgs 241/00 i principi della ICRP60, come presenti nella Direttiva 96/29, con qualche anticipazione dei contenuti della direttiva 59/2013 ispirata dalla ICRP103
  - Limiti di dose a 20 mSv e 1 mSv
  - Non significatività radiologica delle pratiche che comportano 10  $\mu$ Sv/anno per la dose individuale e di 1 Svpersona /anno per la dose collettiva
  - Applicazione pratica dell'ottimizzazione con il rispetto delle norme di buona tecnica applicabili



# Molte delle considerazioni di Silini sono state recepite nella ICRP103

- La ICRP 60 (1990) ha fortemente innovato rispetto alla ICRP26 (1977) ponendo la base per l'evoluzione nella ICRP103 (2007)
- Riavvicinamento concettuale dei limiti di dose per i lavoratori e la popolazione
- Sostanziale riduzione del rischio individuale associato ai valori numerici dei limiti
- Implicita cancellazione della dose collettiva dal processo decisionale
- Formalizzazione dei vincoli al processo di ottimizzazione, con minore enfasi sui processi quantitativi
- Inserimento del processo di giustificazione in un più ampio contesto decisionale
- La protezione radiologica dell'ambiente

“Quando sarò ricordato nel futuro sarà per i miei studi storici”  
(file silini.pdf)”

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Amministratore

**GIOVANNI SILINI**

Sabato 20 aprile 2013 - ore 17.00  
Lovere, Auditorium di Villa Milesi



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# ISOE INFORMATION SHEET

## MAN-SIEVERT MONETARY VALUE SURVEY (2012 UPDATE)

ISOE European Technical Centre - Information Sheet No. 55 (2012)

In order to balance the costs associated with radiological protection options and their benefits in terms of exposure reduction the International Commission on Radiation Protection has suggested the use of cost benefit or cost effectiveness analysis in which options' benefits or effectiveness are given a monetary value according to a monetary reference value of the avoided unit of exposure: the man-sievert value, often referred as "alpha value".

In 1997, the ISOE European Technical Centre performed a first international survey among regulatory bodies and nuclear facilities to check the actual use of such a tool in the different countries. A second survey has been performed in 2002 to update the first survey.

The main conclusions, as well as the values used have been made available through the ETC ISOE Information Sheet No. 18 and No. 34 downloadable from the ETC Web site (<http://isoe.cepn.asso.fr/>).

Today, it appears useful to check whether the values have evolved or not. Therefore a third survey has been performed in 2009 among all the ISOE participants. The following tables show a synopsis of the 2002 and 2009 results. The graphs present the 2009 values and the 2002 values when there have been no answers in 2009. It is noticeable that the "alpha values" have not been drastically modified except in Sweden where they have been multiplied by 2.

**Table 1. Adoption by regulatory bodies in charge of radiological protection of a system of man-sievert reference monetary values**

Country	2002 Survey		2009 Survey	
	Existence of man-sievert monetary value system	$\alpha$ -values per man-mSv (in Euro)	Since	$\alpha$ -values per man-mSv (in Euro)
Armenia	under consideration			
Belgium	No value		No value	
Canada	1997 ALARA guidelines referring to the concept to be published	79.06 EUR (100 CAD) as an international reference	No value 2004 ALARA guidelines referring to the concept	
China	under consideration			
The Czech Republic	RP Decree No. 307/2002 of 13/06/2002	20.08-100.39 EUR (500-2500 CZK) depending on individual dose level and exposure situation	RP Decree No. 307/2002 of 13/06/2002	20.08-100.39 EUR (500-2500 CZK) depending on individual dose level and exposure situation in process of updating
Finland	1984 recommended value 1991 recommended value	15.44 EUR (20 USD) 77.21 EUR (100 USD)		
France	No value		No value	
Germany	No value		No value	
Japan	No value		No value	
Korea	under consideration		2008	0-1mSv: 13.13 EUR (17 USD), 1-5mSv: 61.77 EUR (80 USD), 5-10mSv: 270.23 EUR (350 USD), $\geq 10$ mSv: 1312.54 EUR (1700 USD). As given by Constant Price in the year of 2000 set in 2008
Mexico			No value	
Netherlands	1995 recommended value	453.78 EUR (1000 NLG)		
Romania	Approval of the $\alpha$ -value proposed by Cernavoda NPP 169.86 EUR (220 USD)		2010	570 EUR



**Table 2. Corporate or NPP alpha values for occupational exposure: single values**

Country	Nuclear Power Plant / Utility	2002 Survey		2009 Survey	
		Since	$\alpha$ -value per man-mSv (in Euro)	Since	$\alpha$ -value per man-mSv (in Euro)
Bulgaria	Kozloduy NPP	No value		No value	
Belgium	ELECTRABEL	No value		No value	
Canada	Gentilly NPP	seventies	789.70 EUR (1000 CAD)		
Finland	Olkiluoto NPP	1998	170 EUR	No value	
	Loviisa NPP			No value	
Hungary	Paks NPP	1999	87.84 EUR (25000 HUF) will be updated in 2003		
Mexico	Laguna Verde NPP			1990	404.20 EUR (520 USD)
Romania	Cernavoda NPP	2003	171.01 EUR (220 USD)	2010	570 EUR
Slovenia	Krsko NPP	2003	1000 EUR		
South Africa	Koeberg NPP	2003	1010.49 EUR (1300 USD)	2003	1010.49 EUR (1300 USD)
Spain	Vandellos 2 NPP, Jose Cabrera NPP	No value		No value	
	Almaraz NPP Santa Maria NPP Trillo NPP			No value	
	Asco NPP	2002	1554.61 EUR (2000 USD)	No value	
Sweden	Barsebäck NPP	2002	531.22 EUR (4500 SEK)		
	Ringhals NPP, Oskarshamn NPP	2002	531.22 EUR (4500 SEK)	2008	1179.76 EUR (10000 SEK)
	Forsmark NPP	471.90 EUR (4000 SEK) In process of updating		2008	1179.76 EUR (10000 SEK)
USA	Entergy Nuclear Operations, Inc. (except Vermont Yankee NPP)			No value	
	Consumers Energy Co. (Palisades NPP)				
	First Energy Nuclear Operating Co. (FENOC)			Under review	

Country	Nuclear Power Plant / Utility	2002 Survey		2009 Survey	
		Since	$\alpha$ -value per man-mSv (in Euro)	Since	$\alpha$ -value per man-mSv (in Euro)
	South Carolina Electric & Gas Co. (SGEC)				466.31 EUR (600 USD)
	Detroit Edison Co. (DTE-Energy)				777.18 EUR (1000 USD)
	Florida Power & Light Co. (FPL)				
	FPL Energy Point Beach, LLC (FPL-Energy)				
	Maine Yankee Power Co. (MYPCO)				
	Pacific Gas & Electric Co. (PG&E)				
	Progress Energy (Pro-Energy) (Brunswick, Robinson NPPs)				
	Public Service Electric & Gas Nuclear (PSE&G)				
	TXU Generating Company Lp				
	Nuclear Management Co., LLC (NMCCO) (Monticello NPP)				932.62 EUR (1200 USD)
	Nebraska Public Power District (NPPD)				971.48 EUR (1250 USD)
	Dominion Nuclear Connecticut, Inc. (Millstone, North Anna NPPs)				
	Duke Energy Power Co., LLC				1088.05 EUR (1400 USD)
	Progress Energy (Pro-Energy) (Shearon Harris NPP)				
	Omaha Public Power District (OPPD)				1165.77 EUR (1500 USD)
	Entergy Nuclear Operations, Inc. (Vermont Yankee NPP)				
	Nuclear Management Co., LLC (NMCCO) (Prairie Island NPP)				



Country	Nuclear Power Plant / Utility	2002 Survey		2009 Survey	
		Since	$\alpha$ -value per man-mSv (in Euro)	Since	$\alpha$ -value per man-mSv (in Euro)
	Arizona Public Service Co. (APS)				1554.36 EUR (2000 USD)
	Dominion Nuclear Connecticut, Inc. (Kewaunee NPP)				
	PPL Susquehanna, LLC				
	Southern Nuclear Operating Co., Inc. (except Farley NPP)				
	Constellation Energy (Nine Mile Point NPP)				
	AmerenUE				1942.95 EUR (2500 USD)
	Constellation Energy (Except Nine Mile Point NPP)				
	Dominion Nuclear Connecticut, Inc. (Surry NPP)				
	Energy NorthWest (ENERGY-NW)				
	Southern Nuclear Operating Co., Inc. (Farley NPP)				
	Tennessee Valley Authority (TVA)			2331.55 EUR (3000 USD) Depending on management goals	
	Progress Energy (Pro-Energy) (Crystal River NPP)				
	Indiana Michigan Power Co. (IMP)				2536.10 EUR (3263,2 USD)
Wolf Creek Nuclear Operating Corp. (WCNOC)	3108.73 EUR (4000 USD)				

Exchange rate of the 25 September 2012

no answer

For the USA in 2010,  $\alpha$ -values per man.mSv are between 466.31 and 6217.46 EUR (600 to 8000 USD) with an average of 1865.24 EUR (2400 USD).

**Table 3. Corporate or NPP alpha values for occupational exposure: set of values**

Country	Nuclear Power Plant / Utility	2002 Survey		2009 Survey	
		Since	$\alpha$ -values per man-mSv (in Euro)	Since	$\alpha$ -values per man-mSv (in Euro)
Canada	Darlington NPP <i>the values of the system depends on the type of worker category</i>	(?)	from 79.16 to 1583.28 EUR (from 100 to 2000 CAD) *		
Czech Republic	Dukovany NPP <i>depending on indiv. dose level and exposure situation</i>			1999	Average effective dose < 1/10 limits (5 mSv): 19.99 EUR (500 CZK) 1/10 limits (5 mSv) < average effective dose < 3/10 limits (15 mSv): 39.98 EUR (1000 CZK) Average effective dose > 3/10 limits (15 mSv): 99.94 EUR (2500 CZK)
	Temelin NPP <i>depending on indiv. dose level and exposure situation</i>			1999	Average effective dose < 1/10 limits (5 mSv): 60.10 EUR (1500 CZK) 1/10 limits (5 mSv) < average effective dose < 3/10 limits (15 mSv): 120.19 EUR (3000 CZK) Average effective dose > 3/10 limits (15 mSv): 300.48 EUR (7500 CZK)
France	EDF <i>the values of the system depends on annual individual dose level</i>	2003	0 - 10 mSv: 650 EUR 10 - 16 mSv: 1300 EUR 16 - 20 mSv: 1800 EUR	2003	0 - 10 mSv: 650 EUR 10 - 16 mSv: 1300 EUR 16 - 20 mSv: 1800 EUR
Germany	VGB proposal agreed on by all utilities for testing <i>the values of the system depends on annual individual dose level</i>	In process of updating			
Korea	KHNP			2007	0 - 1 mSv: 13.22 EUR (17.10 USD) 1 - 5 mSv: 123.72 EUR (160 USD) 5 - 10 mSv: 417.57 EUR (540 USD) $\geq 10$ mSv: 2165.17 EUR (2 800 USD)
Netherlands	Borssele NPP <i>the values of the system depends on individual dose level</i>	2002	<10 mSv: 500 EUR >10 mSv: 1000 EUR In process of updating		

Country	Nuclear Power Plant / Utility	2002 Survey		2009 Survey	
		Since	$\alpha$ -values per man-mSv (in Euro)	Since	$\alpha$ -values per man-mSv (in Euro)
Spain	Cofrentes NPP <i>the values of the system depends on the unit annual collective dose level and on individual dose level</i>	1994	Total collective dose (3 years average): <1250 man.mSv: 1000 EUR >1250 man.mSv: 5000 EUR Individual dose: <10 mSv: 1000 EUR >10 mSv: 5000 EUR	2002	< 10 mSv/year: 1000 EUR 10-50 mSv/year: 5000 EUR
Switzerland	Beznau NPP <i>the values of the system depends on individual dose level per job</i>	1995	< 10 mSv: 413.46 EUR (500 CHF) > 10 mSv: 4134.62 EUR (5000 CHF)		No value
UK	Sizewell NPP <i>the values of the system depends on annual individual dose level</i>	?	use of the NRPB data set from 12.56 to 25.12 EUR (10 to 20 GBP)		No value
USA	STPNOC (South Texas NPP) <i>the values of the system depends on annual individual dose level</i>	2002	<10 mSv: 388.59 EUR (500 USD) >10 mSv: 1942.95 EUR (2500 USD)		<10 mSv: 388.59 EUR (500 USD) >10 mSv: 1942.95 EUR (2500 USD)
	CONNYANKEE (Haddam Neck NPP)	2002	From 77.72 to 1554.36 EUR (from 100 to 2000 USD)		From 77.72 to 1554.36 EUR (from 100 to 2000 USD)
	EXELON			2009	1554.36 EUR x INPO Quartile ranking (2000 USD x INPO Quartile ranking)

Exchange rate of the 25 September 2012

\* ex: general workers: 158.33 EUR (200 CAD); reactor maintenance crew: 1187.46 EUR (1500 CAD)

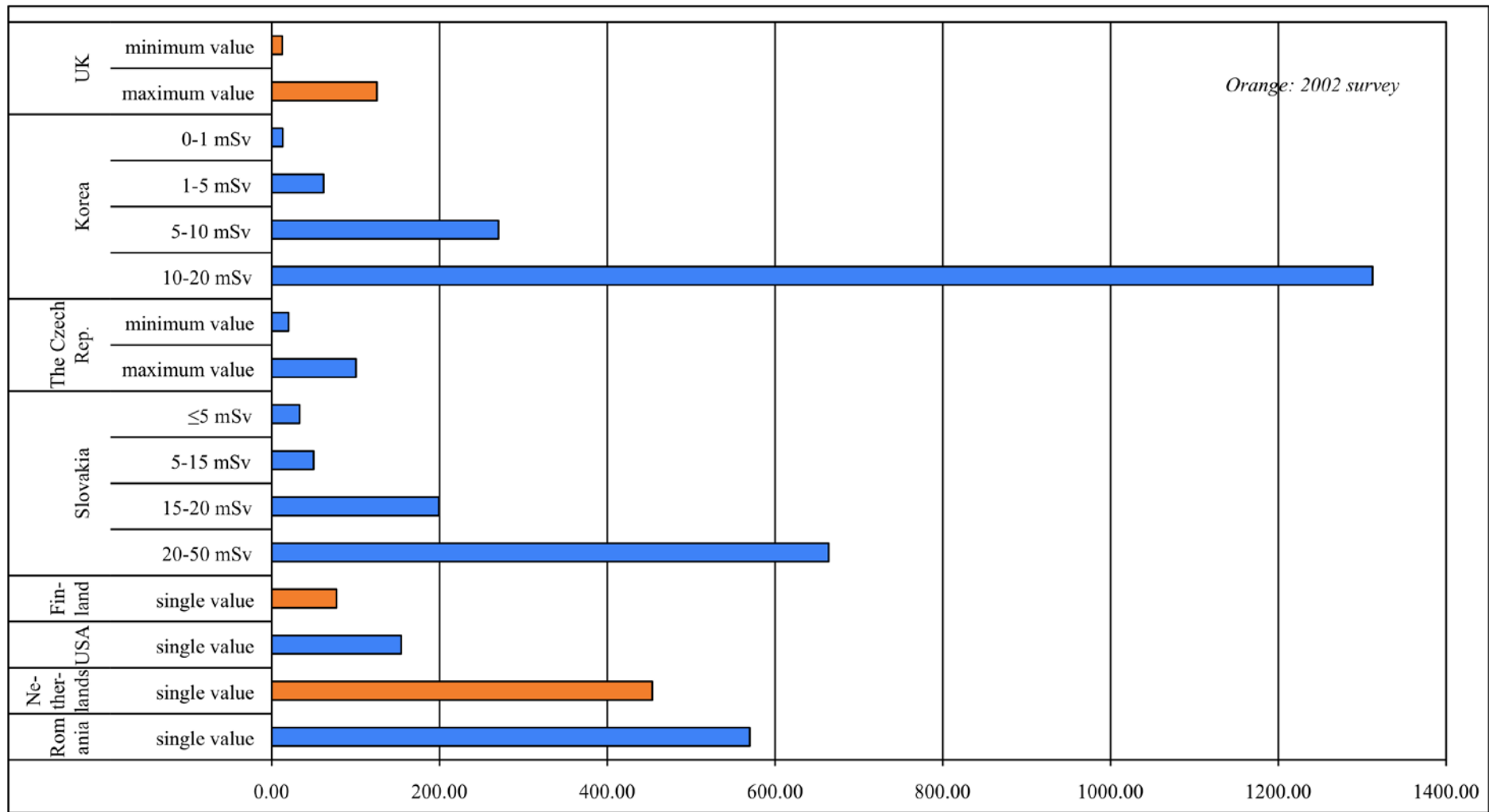
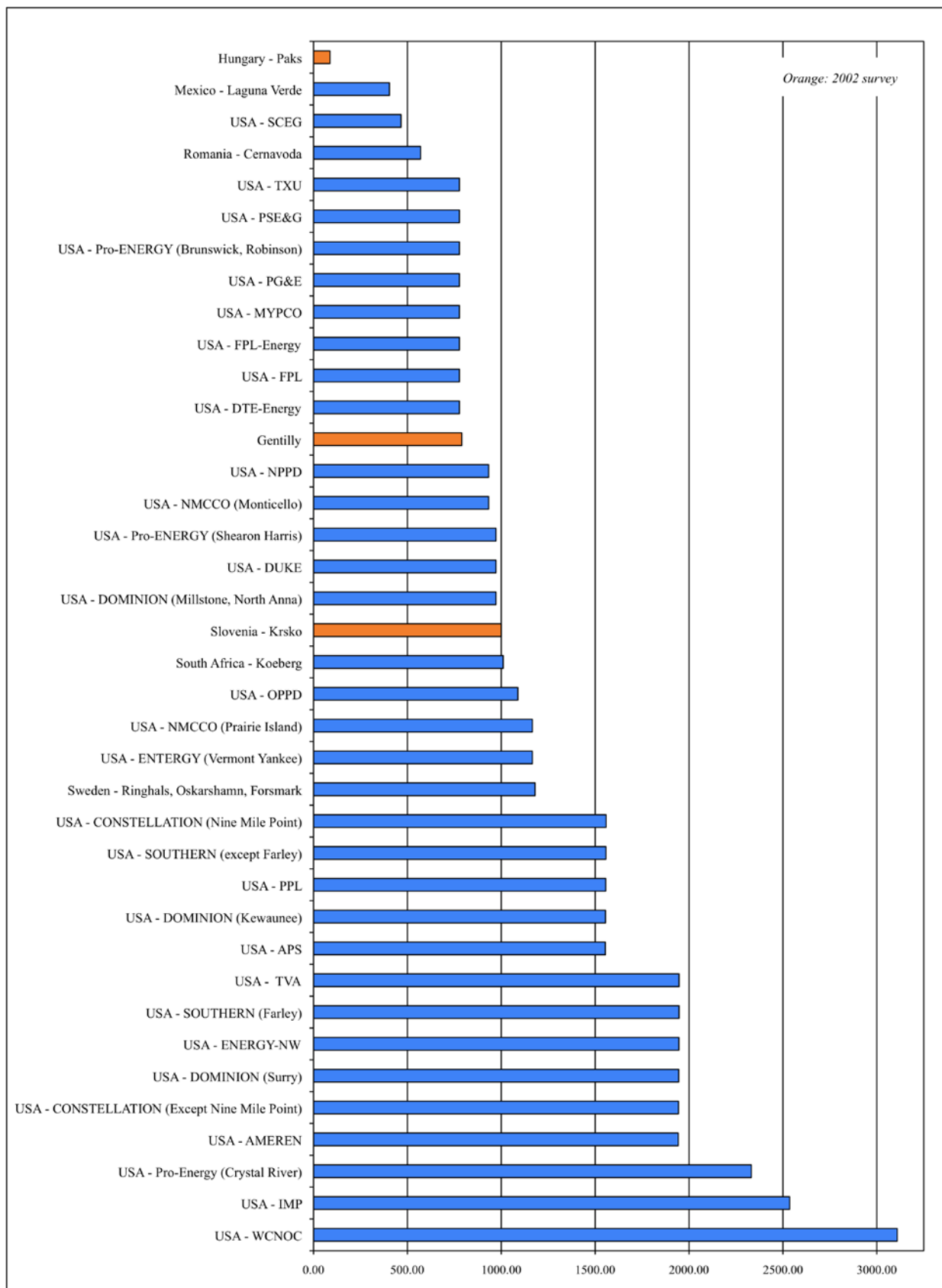
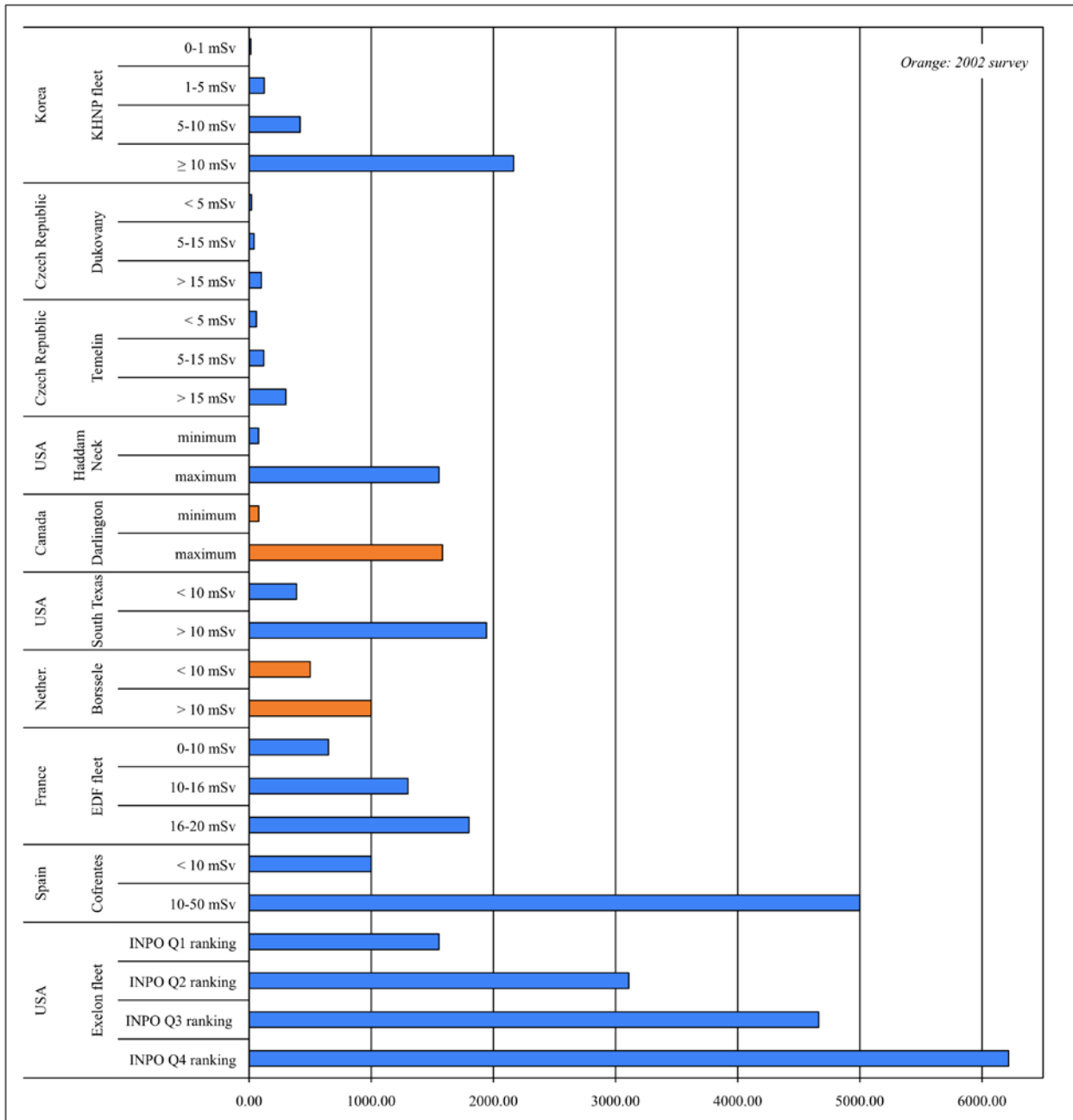


Figure 1. Alpha values adopted by the Regulatory bodies (Euro per man.mSv)



**Figure 2. Corporate or NPP alpha values for occupational exposure: single value (Euro per man.mSv)**



**Figure 3. Corporate or NPP alpha values for occupational exposure: set of values (Euro per man.mSv)**

Radiological Protection

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# **Evolution of ICRP Recommendations 1977, 1990 and 2007**

**Changes in Underlying Science and Protection Policy  
and their Impact on European  
and UK Domestic Regulation**

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NEA No. 6920

NUCLEAR ENERGY AGENCY  
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## FOREWORD

In May 2009, the NEA Committee on Radiation Protection and Public Health (CRPPH) Expert Group on Occupational Exposure (EGOE) proposed to undertake a case study to address the implementation of the new ICRP Publication 103 recommendations as regards operational radiological protection at nuclear installations, and focusing on the use of dose constraints. In discussing this proposal, the Committee also held a more general discussion of the approaches and measures being considered in order to broadly implement the new ICRP Publication 103 recommendations. As part of this discussion, the delegation from the United States asked how much it had “cost” to implement ICRP Publication 60 recommendations, which were issued in 1990. The basis of the question was that in 1990, the United States had recently completed a lengthy update of its own national radiological protection regulation and did not feel that it would be appropriate to reopen the system just after having closed it. As such, the United States did not implement the recommendations of ICRP Publication 60, but in May 2009 was considering whether it should implement those of ICRP Publication 103. As part of these considerations, the “cost-effectiveness” of such a change was being studied, and the assistance and experience of the other members of the CRPPH was seen as potentially very valuable to these discussions.

The Committee agreed that a discussion of this issue could be useful to the full NEA/CRPPH membership, perhaps not directly in terms of the “monetary costs” of implementation, but rather in terms of the areas that were addressed and updated, and the resources that were necessary. The CRPPH thus charged the NEA Secretariat to work with the EGOE to develop this issue further. The Secretariat suggested to the CRPPH Bureau that a good starting point for this work would be a report detailing the scientific and philosophical changes that had taken place in moving from ICRP Publication 26 to Publication 60, and subsequently from ICRP Publication 60 to Publication 103. In addition, these same evolutions could be characterised in terms of the regulatory changes that were necessary to ensure implementation. The CRPPH Bureau agreed with this approach, and Professor Roger Clarke, former Chair of the ICRP Main Commission, and Ms. Wendy Bines, former UK regulator, were commissioned to develop this report.

It should be noted that the section of this report on regulatory evolution is somewhat limited in its context, reflecting regulatory approaches only from the perspective of the United Kingdom. The CRPPH noted, however, that the UK regulations are subject to the European Commission Basic Safety Standard Directive, as are those of all other European Union countries. As such, the Committee felt that the documented views were sufficiently broadly representative to be of use for the CRPPH as a whole.

#### **ACKNOWLEDGEMENTS**

The CRPPH and the NEA Secretariat would like to thank Professor Roger Clarke and Ms. Wendy Bines for the high quality of this final report.

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# **I. CHANGES IN UNDERLYING SCIENCE AND PROTECTION POLICY**

**Roger H. Clarke<sup>1</sup>**

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1. Emeritus member, ICRP, contact: [clarke.rogerh@btinternet.com](mailto:clarke.rogerh@btinternet.com).





## **I.1. INTRODUCTION**

The ICRP has produced recommendations three times in the last 30 years and the purpose of this review is to highlight some of the major changes that have taken place over that period. The starting point is the 1977 Recommendations in Publication 26 and this paper seeks to identify the major changes in the underlying science and the development in protection policy that led to the 1990 Recommendations in Publication 60. Next, the changes in the scientific understanding and the evolution of protection policy that occurred between the 1990 Recommendations of Publication 60 and the 2007 Recommendations in Publication 103 are summarised.



**PART I.A**  
**SCIENCE AND PROTECTION POLICY**

**Publication 26 to Publication 60**



## I.2. BIOLOGICAL RISKS

In the 1977 Recommendations, the ICRP introduced the distinction between “stochastic” effects and “non-stochastic” effects of radiation exposure. While it gave no risk figures for non-stochastic effects, it gave quantitative estimates of the stochastic risk of radiation exposure for the first time. The Commission derived cancer risk factors for: red bone marrow, bone, bone surfaces, lung, thyroid, breast and “all other tissues”. The whole body mortality risk factor **for radiation induced cancer was concluded to be  $10^{-2} \text{ Sv}^{-1}$** , as an average for both sexes and all ages. The average risk factor for **hereditary effects was taken as  $0.4 \cdot 10^{-2} \text{ Sv}^{-1}$**  as expressed in the first two generations. It was recognised that the estimates would vary between workers and a population of all ages, but the Commission felt the difference was not large enough to warrant the use of separate values for protection.

In the 1990 Recommendations there was a review of non-stochastic, now renamed “deterministic” effects in organs and tissues and estimates were given for the thresholds of these effects. There was also a rigorous review of the stochastic effects in exposed individuals. There was a longer list than in 1977 of organs and tissues for which risks were quantified, some 13 organs plus gonads. Now the Commission gave nominal probability coefficients for stochastic effects; **for fatal cancer the risk was  $5.0 \cdot 10^{-2} \text{ Sv}^{-1}$**  for a population of all ages and the risk of **severe hereditary effects was  $1.0 \cdot 10^{-2} \text{ Sv}^{-1}$** . The Commission now gave separate risk factors for workers; **a fatal cancer risk of  $4.0 \cdot 10^{-2} \text{ Sv}^{-1}$  and a hereditary risk of  $0.6 \cdot 10^{-2} \text{ Sv}^{-1}$** .

These estimates represented a significant increase over those from 1977 and caused some major changes to protection philosophy. The principal reason for the increased cancer risk estimates was that in 1977 an **additive model** had been used for estimating the risks, i.e., the radiation risks were assumed to be induced independent of the naturally occurring cancers. However, by the latter part of the 1980s there were more solid tumours recorded in the Japanese survivors, indicating there is a longer “latent period” for solid tumours compared to leukaemia, and the increased numbers led to the conclusion that the radiation-induced tumours were consistent with a **multiplicative model**, whereby the tumours induced by radiation arise as a percentage increase of

those naturally arising. This led to an increased estimate of the tumours that would arise in the future as natural cancer rates generally increase as a high power of attained age.

There were also reviews of the risks of exposure to radon gas and irradiation of the skin as well as of exposure *in utero*-malformations, mental retardation and leukaemia.

### **Detriment**

In Publication 26, the Commission introduced the concept of detriment to identify and, where possible, to quantify all the deleterious effects of exposure. In general, the detriment is the expectation of harm taking account not only of the probability of each type of deleterious effect but also the severity of the effect. The total population detriment due to radiation of a given exposure was to take account of the total risk of hereditary damage that may be expressed in all subsequent generations in addition to the somatic cancer risk.

In Publication 60, the definition of detriment was elaborated so as to include not only the fatal cancer risk for an organ but also a weighted allowance for non-fatal cancers plus an estimate of the incidence of severe hereditary effects, all of which were also weighted for the relative length of life lost. The resulting figures are shown in Table 1. The comparable figure from Publication 26, although never quoted, is about  $1.8 \cdot 10^{-2} \text{ Sv}^{-1}$ .

**Table 1. Nominal probability coefficients for stochastic effects in Publication 60 ( $10^{-2} \text{ Sv}^{-1}$ )**

<b>Exposed population</b>	<b>Fatal cancer</b>	<b>Non-fatal cancer</b>	<b>Severe hereditary effects</b>	<b>Total detriment</b>
Adult workers	4.0	0.8	0.8	<b>5.6</b>
Whole population	5.0	1.0	1.3	<b>7.3</b>

The primary use made of the detriment estimates in Publication 26 and later publications is for producing **tissue weighting factors** ( $w_T$  values) described in Section I.3 below.

### I.3. BASIC DOSIMETRIC QUANTITIES

#### Dose equivalent to equivalent dose

The fundamental dosimetric quantity for radiological protection is the absorbed dose,  $D$ . In Publication 26 the quantity that better predicted the severity and probability of deleterious effects from radiation was the dose equivalent,  $H$ , defined at a point in tissue and given by the equation:

$$H = DQN \dots\dots\dots(1)$$

where  $D$  is the absorbed dose,  $Q$  is the quality factor and  $N$  is the product of all other modifying factors specified by the Commission. Such factors might take account of, for example, absorbed dose rate and fractionation. In fact, the Commission recommended a value of 1 for  $N$  which it retained until Publication 60.

The quality factor,  $Q$ , was intended to allow for the effect on the detriment of the microscopic distribution of absorbed energy. It is defined as a function of the collision stopping power ( $L_{co}$ ) in water at the point of interest. The ICRP specified the relationship between  $Q$  and  $L_{co}$  and for a spectrum of radiation, an effective value,  $\bar{Q}$ , of  $Q$  at the point of interest can be calculated.

When Publication 60 was prepared, the Commission decided that the point quantities  $H$ ,  $Q$ , and  $\bar{Q}$  were used in metrology and radiobiology, for protection purposes it was more appropriate to *average* the dose over an organ or tissue. Hence, Publication 60 defined absorbed dose as the average dose over an organ as an indicator of the probability of subsequent stochastic effects in that organ. This averaging is dependent upon a linear relationship between dose and risk, the dose-response relationship, without which the additivity of doses from internal and external sources would not be possible.

Because of this, the Commission then introduced the quantity **equivalent dose**,  $H_T$ , and the **radiation weighting factor**,  $w_R$ . The total equivalent dose in tissue  $T$  is then

$$H_T = \sum_R W_R \cdot D_{T,R} \dots\dots\dots(2)$$

where  $D_{T,R}$  is the average absorbed dose in tissue T from radiation R. The radiation weighting factor takes account of the quality of the incident radiation on the body and was considered by the Commission better to reflect the biological information such as RBE (**relative biological effectiveness**) than the averaging of  $\bar{Q}$  calculated at multiple points in an organ or tissue to derive a value of  $\bar{Q}$ . The values recommended in Publication 60 are given in Table 2.

For radiation types and energy which are not included in Table 2, it suggested an approximation of  $w_R$  can be obtained by calculation, at 10 mm in the ICRU sphere, of

$$\bar{Q} = \frac{1}{D} \int_0^{\infty} Q(L) D(L) dL \dots\dots\dots (3)$$

where  $D(L)dL$  is the absorbed dose between unrestricted linear energy transfer L and  $L + dL$  and  $Q(L)$  is the quality factor of radiation at 10 mm in the ICRU sphere. The relationship between Q and L is given in Table 3.

The Commission recognised that, for neutrons, it may be more convenient, practically, to have a smooth function rather than step functions. As an approximation to  $w_R$  for neutrons the Commission allowed the following relationship:

$$W_R = 5 + 17e^{-\frac{[\ln(2E)]^2}{6}} \dots\dots\dots (4)$$

**Table 2. Radiation weighting factors in Publication 60 and  $\bar{Q}$  in Publication 26**

Type and energy range	$w_R$	$\bar{Q}$
Photons, all energies	1	1
Electrons, muons, all energies	1	1
Neutrons* < 10 keV	5	
Neutrons* 10 keV to 100 keV	10	
Neutrons* > 100 keV to 2 MeV	20	
Neutrons* > 2 MeV to 20 MeV	10	
Neutrons* > 20 MeV	5	
Protons, other than recoil protons, energy > 20 MeV	5	1
Alpha particles, fission fragments, heavy nuclei	20	20

\* In Publication 26,  $\bar{Q}$  for neutrons was recommended to be 10 for unknown energies, otherwise to be calculated and a value of 2.3 was given for thermal neutrons.



Table 3. Relationship between  $Q$  and  $L$

Publication 26

$L_{\infty}$ in water (keV $\mu\text{m}^{-1}$ )	$Q$
<3.5	1
7	2
23	5
53	10
>175	20

Publication 60

Unrestricted linear energy transfer, $L$ (keV $\mu\text{m}^{-1}$ )	$Q(L)$
$\leq 10$	1
$> 10 \leq 100$	$0.32 L - 2.2$
$> 100$	$300/\sqrt{L}$

**Effective dose equivalent to effective dose**

Publication 26 introduced the quantity later named as **effective dose equivalent**,  $E$ , when the Commission stated that its recommended dose limitation was based on the principle that the risk should be equal whether the whole body is irradiated uniformly or whether there is non-uniform irradiation. The basis for equalising that risk was the estimate of the relative detriment in different organs and tissues.

The Commission simplified the name, without any change in the concept, in Publication 60 to effective dose,  $E$ . It is the doubly weighted sum of the absorbed doses in organs or tissues:

$$E = \sum_T w_T \sum_R w_R D_{T,R} \dots \dots \dots (5)$$

It is apparent from this that radiation weighting factors are tissue independent and tissue weighting factors are radiation independent.

For intakes of radionuclides, in Publication 26, the Commission defined **committed dose equivalent** to a given organ or tissue from a single intake of radioactive material as the integral of effective dose up to 50 years after intake. When added over all tissues this became **committed effective dose**. By Publication 60, it had refined the time to 50 years for workers or up to age 70 for members of the public.

The respective  $w_T$  values in Publication 26 and 60 are given in Table 4. It has to be remembered that these weighting factors are normalised to 1.0 and that the detriment estimate had increased by a factor of more than 3 so that the absolute risk to, say, the breast remained constant, although its  $w_T$  was reduced by 3.

Table 4. **Tissue weighting factors in Publications 26 and 60**

*Publication 26*

Organ	$w_T$
Thyroid Bone surfaces	0.03
Lung Bone marrow	0.12
Breast	0.15
Remainder	0.3
Gonads	0.25

*Publication 60*

Organ	$w_T$
Skin Bone surface	0.01
Bladder Breast Liver Oesophagus Thyroid Remainder	0.05
Bone marrow Colon Lung Stomach	0.12
Gonads	0.2

**Treatment of remainder tissues**

In Publication 26, the Commission recommended that a  $w_T$  value of 0.06 be allocated to each of the five organs or tissues of the remainder having the highest dose equivalents, those tissues being those defined in the ICRP phantom. This meant that **effective dose was a non-additive quantity** as different organs would appear in the highest irradiated remainder list, depending on the external radiation energy or the radionuclide in the body.



tissue) and collective effective dose as the integrals over all exposed individuals and over all time; when integration is not over all time, the quantity is described as being truncated at a defined time.

### **Annual limits on intake (ALI) to dose coefficients for radionuclides**

In Publication 26, the dose calculations for workers were presented as ALIs, these annual limits on intake replacing the earlier values of maximum permissible concentrations (MPCs). The ICRP Committee 2 decided against calculating any corresponding figures for the public, since it was thought to be too complex a process.

After the publication of the 1990 Recommendations, the ICRP swiftly produced new figures for ALIs for workers, using the new  $w_T$  values. However, there was a major change taking place as the Commission had decided that in the future it would produce dose coefficients for intakes of radionuclides and external radiations. The reason was that dose per unit intake ( $\text{Sv Bq}^{-1}$ ) or per unit fluence was considered to be more useful and assisted the addition of internal and external doses. The Commission also asked Committee 2 to develop dose coefficients for members of the public, which it subsequently did.

#### I.4. PHILOSOPHY OF PROTECTION

It was in Publication 26 that the Commission observed that most decisions about human activities are based on an implicit form of balancing costs and benefits leading to the conclusion that the conduct of a chosen practice is “worthwhile”. Less generally, it was recognised that the conduct of the chosen practice should be adjusted to maximise the benefit to the individual or society. The Commission felt that it was becoming possible to formalise these decision-making procedures in radiation protection. This led to the introduction of the Commission’s **system of dose limitation**, the main features of which were:

- (a) no practice shall be adopted unless its introduction produces a positive net benefit;
- (b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and
- (c) the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.

These became the principles now known as those of **justification, optimisation and limitation**.

The 1977 Recommendations were concerned with routine operations and during the years up to 1990 the ICRP extended its advice away from the central core of dose limitation to deal with other exposure situations. These include: **radon**, for which a philosophy was developed that did not include dose limits; **criteria for solid waste disposal**, where exposures are not certain to occur and events are probabilistic, so that again dose limits are not applicable; and **principles for protection of the public in emergencies**, where again dose limits do not apply. In the 1990 Recommendations the Commission tried to draw together all of these different situations in a **system of radiological protection**.

The Commission, in Publication 60, adopted a process-based system of protection making the new distinction between **practices** and **intervention**. This was explained by considering that some activities increase overall exposure to radiation by introducing new sources, pathways and individuals, or by modifying the network from existing sources to man. Those activities which **add** radiation

exposures or risks are called “practices”. Other human activities can **decrease** the overall exposure by removing the source, modifying the pathways or reducing the number of exposed individuals. Those activities which subtract radiation exposures are called “intervention”.<sup>2</sup>

## **Practices**

For practices, the system of protection recommended by the Commission was based on the following general principles:

- (a) 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. (The justification of a practice.)
- (b) 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 judgments. (The optimisation of protection.)
- (c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)

These principles were broader than those in 1977 and introduced two new concepts: the need to consider risk of accidents and thus **potential exposures**; and the requirement for a **constraint** in optimisation.

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2. It is of interest to note that the draft of the 1990 Recommendations, which was made widely available for comment in 1989, did not use this process-based approach but one which recognised situations with the terms **planned, potential and pre-existing** for setting a framework of protection. However, this attracted much criticism in the comments and was abandoned.

Little more was said about justification in 1990 than was said in 1977. The Commission did however point out that radiological protection considerations are only one aspect of decision-making over the introduction of a new practice.

### **Intervention**

In some situations, the sources, pathways, and exposed individuals are all in place when a decision on control has to be taken. In this case, the reduction in dose was to be achieved by intervention. An important group of such situations was the exposure from natural sources of radiation. Accidents and emergencies would have been considered as sources of potential exposure when assessing a practice but, if they occur, they may require intervention.

Intervention cannot usually be applied at the source and has to apply in the environment or to people. Countermeasures forming the intervention have disadvantages, so they must be justified as doing more good than harm. The Commission recommended that their scale should be optimised to maximise the benefit. The dose limits applied to practices are not relevant in the decision-making on intervention, but the Commission had not decided, in Publication 60, on the levels of dose at which intervention is justified.

The system of radiological protection recommended by the Commission for Intervention was thus based on the following general principles:

- (a) The proposed intervention should do more good than harm, i.e. the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention.
- (b) The form, scale, and duration of the intervention should be optimised so that the net benefit of the reduction of dose, i.e. the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised.

Principles (a) and (b) would lead to intervention levels which gave guidance on the situations in which intervention is appropriate. However, there would be some level of projected dose above which, because of serious deterministic effects, intervention would almost always be warranted.

## I.5. OPTIMISATION OF PROTECTION

Once the practice was justified, the doses and risks had to be optimised within the dose or risk limits specified for individuals. However, **optimisation is a source-related** process while **limits apply to the individual** to ensure protection from all sources under control.

It was in Publication 26 that for the principle of optimisation the Commission advocated the use of **cost-benefit analysis** for deciding what is reasonably achievable in dose reduction below the recommended limits. For this purpose the question was whether or not the activity is being performed at a sufficiently low level of collective dose equivalent (and usually, therefore, of detriment) so that any further reduction in dose would not justify the incremental cost required to accomplish it. In making this determination, the cost-benefit analysis shifted from a consideration of the *total* benefit of the activity to the *change* in net benefit that might be involved in requiring the activity to be performed at one level of dose rather than another.

In order to determine whether a reduction in exposure was “reasonably achievable”, the Commission said it was necessary to consider, on the one hand the increase of benefit from such a reduction, and on the other the increase of cost involved in its achievement. In the differential cost-benefit analysis, intended to maximise the net benefit, the independent variable was the collective dose equivalent,  $S$ , from the practice. It follows that the optimisation condition was fulfilled at a value  $S^*$  such that the increase in the cost of protection per unit dose equivalent balanced the reduction of detriment per unit dose equivalent.

The Commission offered that the formal cost-benefit analysis may be helped by the assignment of a monetary value to the unit of collective dose equivalent. The Commission **never recommended such a monetary value** because, it said, in practice it is very difficult to quantify even some of the components of the detriment, although several estimates of the cost equivalent of a man sievert have been published, and, with all their limitations, they have provided possible quantitative inputs to the decision-making process.



In the 1990 Recommendations, the ICRP was recognising that it had to move away from the purely mathematical methods of optimisation. The process, it said, was complicated by the various factors to be included and the diverse methods of dealing with them. They were said to range from simple common sense to complex techniques of multi-attribute analysis. It said that the judgments involved in the optimisation of protection are not purely quantitative; they involve preferences between detriments of different kinds and between the deployment of resources and health effects.

The Commission introduced, in Publication 60, the new concept of a constraint to dose or risk. A constraint is an individual-related criterion, but applied to a single source in order to ensure that dose or risk limits are not exceeded. A dose constraint would therefore be set at a fraction of the dose limit as a boundary on the optimisation of that source. The Commission considered that a constraint should be set on the basis of general knowledge about the performance of the source or by a generic optimisation. For potential exposures, risk constraints should be established in the same way. A constraint was therefore seen as a regulatory requirement, rather than as a design target or an operational investigation level. Despite introducing the idea of a constraint, the Commission did not give guidance on its use or application until the 2007 Recommendations.

## I.6. DOSE LIMITS

### Publication 26

In Publication 26, there was little discussion on the basis for setting dose limits and there was no justification for the risk associated with the limits. The Commission said that it believed a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognised as having high standard of safety, which were generally considered to be those in which the **average annual mortality** due to occupational hazards did not exceed  $10^{-4}$ . Non-fatal accidents were recognised but the Commission compared fatal accident rates and the risk of radiation induced fatal malignancy.

The Commission noted that for uniform exposure of the whole body, where the Commission's annual dose equivalent limit of 50 mSv had been applied, the annual dose distributions were commonly log-normal with an arithmetic mean of about 5 mSv. Using its then risk factor, and noting that this was an upper estimate, the Commission concluded that this average dose gave an **average risk in radiation occupations** that was comparable with the risk in other safe industries. The Commission compared average radiation fatal risk with average accident fatality rates, not the risks to those most exposed.

In 1977, the establishment of the dose limits was of secondary concern to the cost-benefit analysis and use of collective dose. This can be seen in the convoluted wording used by the ICRP in setting its dose limit for members of the public. Publication 26 states that "the assumption of a total risk of the order of  $10^{-2} \text{ Sv}^{-1}$  would imply restriction of the lifetime dose to the individual member of the public to 1 mSv per year. The Commission's recommended limit of 5 mSv in a year, as applied to critical groups, has been found to give this degree of safety and the Commission recommends its continued use".

The annual effective dose equivalent dose limits were 50 mSv for workers and 5 mSv for the public. The non-stochastic limits were set out in Section I.3.

## Publication 60 – acceptability of risk

During the 1980s, it was becoming clear that the risks from radiation exposure were higher than adopted in Publication 26 and calls grew for a reduction in the dose limits. The Commission's initial response was to emphasise the process of optimisation which was more important than limits and if the process were correctly carried out, then the resulting exposures would be acceptable.<sup>3</sup>

However, by 1990 the Commission had reviewed the biological evidence (Section 2) and it was clear that the risks had increased so the Commission had to address the setting of new limits.

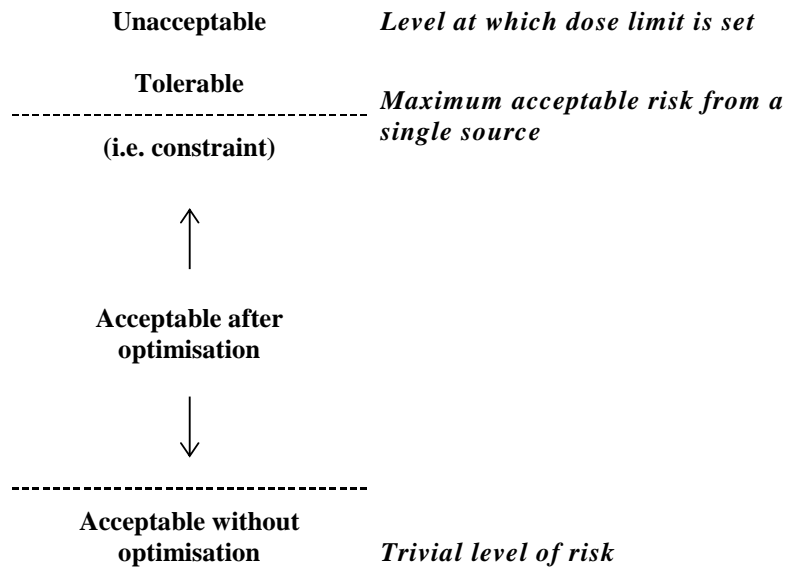
The setting of radiation protection standards requires judgments on two very different issues. Firstly, it is necessary to adopt a set of risk estimates for the effects on health per unit of exposure to ionising radiation that are applicable for radiological protection purposes. Secondly, apart from what might be called the scientific challenges, biological and epidemiological, there is the challenge of what is meant by risk.

All human activities or lack of activities carry some risk. Some of the activities are accepted by most people even if the risks are rather high, e.g. traffic accidents. Other activities are not accepted because the risks are considered unjustifiably high in relation to the ensuing benefits even after reasonable attempts at risk reduction. Radiation protection purposes the relevant circumstances would be normal occupational or private life in what might be considered a safe society. The ICRP has found it useful to use three words to indicate the degree of tolerability of an exposure or risk. They are necessarily subjective in character and must be interpreted in relation to the type and source of exposure under consideration. The first word is “**unacceptable**”, which is used to indicate that the exposure would not be acceptable on any reasonable basis in the normal operation of a practice of which the use was a matter of choice. Such exposures might have to be accepted in abnormal situations, such as those during accidents. Exposures that are not unacceptable are then subdivided into those that are “**tolerable**”, meaning they are not welcome, but can reasonably be tolerated, and “**acceptable**”, meaning that they can be accepted without further improvement, i.e. when protection has been optimised. This is illustrated in Figure 1.

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3. In the 1987 Como Statement, the Commission acknowledged that the fatal cancer risks may have increased by about a factor of 2, but considered that the dose limits were not the controlling factor in the restriction of doses. This is because optimisation will keep doses far below the dose limits.

Figure 1. Schematic diagram of the acceptability of risk



In this framework, the ICRP set the **dose limit** at a level of risk selected at the **boundary** in the region **between “tolerable” and “unacceptable”** for the situation in which dose limits apply, i.e. the control of specified practices. The limit then protects the individual from all sources under control by ensuring the total risk is not unacceptable. There will also be a level of risk that is trivial, and the source will automatically be considered acceptable. If the risk is above the trivial level then optimisation of protection from the source must be undertaken. It follows that the optimisation process for **any single source must be constrained to the maximum acceptable individual risk** so that the risk from that single source does not cause concern and the combined risk from all sources under control does not become unacceptable.

### **Workers**

For workers, it might be concluded that a continuing annual probability of death of 1 in 100 would be clearly unacceptable, since the individual would be almost certain to die from the occupation. On the other hand, an annual probability of death of 1 in 1 000 can hardly be called totally unacceptable provided the individual at risk knows of the situation, has some commensurate benefit as a result, and everything reasonable has already been done to reduce the risk. The ICRP concluded that, broadly, a risk of death of 1 in 1 000 per year is about the most that

is ordinarily accepted under modern conditions for workers, and adopted it as the dividing line between what is just tolerable and what is intolerable (unacceptable).

In order to recommend limits to exposure and constraints on optimisation, it is necessary to compare the risks of exposure with the risk acceptance criteria derived above. The attributable fatal cancer rate as a result of working from age 18 to 65, i.e. 47 years at annual doses of 10, 20, 30 and 50 mSv were calculated. The attributable fatality probability as a function of age tends to follow the probability of death from cancer for an individual aged 18 because of the use of a multiplicative model. The peak risk rate therefore arises at an age in the late 70s. The question to be asked was what is to be compared with the numerical criterion that the level of unacceptable risk is  $10^{-3}$  per year.

This criterion ( $10^{-3}$  per year) would be exceeded at an age in the mid-50s for someone receiving an annual dose of 50 mSv and in the early-60s for someone receiving 20 mSv per year. The peak risk occurs in the 70s, but is a peak risk in the later years of life as important as added risks earlier in life? Or, should the integrated lifetime risk be considered, or perhaps the annual average risk of fatality?

The relative importance of these different attributes had to be judged when making a decision on acceptability. On the basis of the data presented above, ICRP Publication 60 recommended dose limits of an average of **20 mSv per year over five years (100 mSv in five years) with no more than 50 mSv in a single year.**<sup>4</sup> At this rate of exposure, the lifetime risk of induced fatal cancer is nearly 4%, which with added weighted allowances for non-fatal cancers and hereditary defects is 5%, which may be compared with the lifetime risk, inferred by the maximum tolerable risk of  $10^{-3}$  per year, of 4.7% for work from age 18 to 64, and the natural risk of dying of cancer of towards 25%. The **average annual** attributable fatal cancer risk is  $7 \cdot 10^{-4}$ . These levels of risk seem to correspond to the most that will be tolerated and were therefore used by the ICRP to mark the borderline of unacceptability.

### *Members of the public*

In the case of members of the public, the ICRP found it much more difficult to decide what may be the level of unacceptability. A risk of 1 in 1 000 000 per year

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4. The author notes that when deciding on the occupational dose limit, the ICRP drafting group proposed the single value of 20 mSv in a year. This provoked a debate and the only vote, to the author's knowledge, in the main Commission. There were 6 votes for the proposed limit and 6 against in the 12 Main Commission members. The then Chairman, Dan Beninson, favoured the single 20 mSv limit, but would not use his casting vote to decide on the recommendation. To allow the retention of 50 mSv in a year, averaging was proposed and the period of five years was agreed.

was thought to be commonly regarded as trivial, whereas risks imposed on the public were perhaps challenged at levels of risk approaching 1 in 10 000 per year. The ICRP has used the same approach for the public as for occupational exposure to consider the different results of exposure over a lifetime received at rates from below 1 up to 5 mSv y<sup>-1</sup>. Although suggestions of upper limits to acceptable levels of imposed risk have been made, it is clear that again judgments have to be made about whether the time at which that risk is received is important. Added risks late in life may be less important than risks added in earlier years. On the basis of considering these risk levels and the variation in natural background radiation (excluding radon for high levels of which intervention is recommended), the ICRP has recommended a dose limit of 1 mSv in a year, with a higher value being allowed in special circumstances, provided the average over five years does not exceed 1 mSv per year.

The dose limit for the public represents the ICRP's judgment of the borderline to the level of unacceptability. The associated average annual fatal risk is about 3 in 100 000 per year on the basis of the risk factors derived by the ICRP, and the lifetime fatal cancer risk at this rate of exposure is 0.4% which represents an increase of about 2% of the natural probability of dying of cancer.

## I.7. CONDITIONS OF WORK AND CLASSIFICATION OF WORKPLACES

### Publication 26

For the purposes of the 1977 Recommendations occupational exposure was defined as comprising all the dose equivalents and intakes incurred by a worker during periods of work (excluding those due to medical and natural radiation). Since the scale and form of the problems of radiation protection of workers vary over very wide ranges, there were seen to be practical advantages in introducing a system of classification of conditions of work. Conditions of work were divided into two classes:

- **Working condition A:** this described conditions where the annual exposures might exceed three-tenths of the then dose equivalent limits.
- **Working condition B:** this described conditions where it is most unlikely that the annual exposures will exceed three-tenths of the then dose equivalent limits.

The value of three-tenths of the basic limits for occupational exposure was thus a reference level used in the organisation of protection. It was not a limit. Where the exposure was unconnected with the work, and where the work was in premises not containing the radiation sources giving rise to the exposure, the working condition was to be such that the limits applicable to members of the public are observed.

The main aim of the definition of working condition A was to ensure that workers who might otherwise reach or exceed the dose-equivalent limits were **subject to individual monitoring** so that their exposures could be restricted if necessary. In working condition B, **individual monitoring was not necessary**, although it might sometimes have been carried out as a method of confirmation that conditions are satisfactory.

The practical application of this system of classification of working conditions was intended to be greatly simplified by the introduction of a

corresponding system of classification of workplaces. The minimum requirement was to define **controlled areas** where continued operation would give rise to working condition A and to which access would be limited. The demarcation of controlled areas would depend on the operational situation and it would often be convenient to use existing structural boundaries. The controlled area in any case was to be large enough to make it most unlikely that the annual dose-equivalents to workers outside the controlled area would exceed three tenths of the limits. ICRP 26 also thought it sometimes convenient to specify a further class of workplace called a “**supervised area**”, and has a boundary chosen so as to make it most unlikely that the annual dose equivalents outside the supervised area would exceed one-tenth of the limits.

There was no simple parallelism between the classification of areas and the classification of working conditions, because the classification of areas took no account of the time spent by workers in the area during the course of the year and because conditions were rarely uniform throughout an area.

### **Publication 60**

The Commission changed its recommendations on classified area definitions and working conditions in 1990. It now said that a **controlled area** was one in which normal working conditions, including the possible occurrence of minor mishaps, required the workers to follow well-established procedures and practices aimed specifically at controlling radiation exposures. A **supervised area** was one in which the working conditions were kept under review but special procedures were not normally needed. The definitions were best based on operational experience and judgment. Account was to be taken both of the expected levels of exposure and of the likely variations in these exposures. In areas where there was no problem of contamination by unsealed radioactive materials, designated areas could sometimes be defined in terms of the dose rates at the boundary. The aim should be to ensure that anyone **outside the designated areas would not need to be regarded as occupationally exposed.**

The dose limits recommended by the Commission are intended to apply to all workers, but the use of designated areas was to enable the actual doses received **outside the designated areas** to be kept **below the dose limits for public** exposure. The dividing line between controlled areas and supervised areas, if the latter were used, was commonly set with the aim of ensuring that the doses to workers in the supervised areas could confidently be predicted to be less than 3/10 of the occupational dose limits. The Commission in 1990 regarded this definition as being **too arbitrary** and recommended that the designation of controlled and supervised areas should be decided either at the design stage or locally by the operating management on the basis of operational



experience and judgment. This judgment was to take account of the expected level and the likely variations of the doses and intakes, and the potential for accidents.

In previous recommendations, the Commission had defined two types of **working conditions** based on the expected level of individual annual dose. This was originally intended to help in the choice of workers to be subject to individual monitoring and special medical surveillance. In the years before the 1990 Recommendations, it had become apparent that neither of these decisions was best linked to a crude classification of working conditions based on expected dose and in Publication 60 the Commission no longer recommended such a classification.

## I.8. PREGNANT WORKERS

In Publication 26, the Commission stated that when women of reproductive capacity were occupationally exposed under the limits recommended, and when this exposure was received at an approximately regular rate, it was unlikely that any embryo could receive more than **5 mSv during the first two months** of pregnancy. Having regard to the circumstances in which such exposures could occur, the Commission believed that this procedure would provide appropriate protection during the essential period of organogenesis. It further declared that it was likely that any pregnancy of more than 2 months' duration would have been recognised by the woman herself or by a physician. The Commission recommended that, when pregnancy had been diagnosed, arrangements should be made to ensure that the woman could continue **to work only in the then recommended working condition B** (Section 7).

In the 1990 Recommendations, the basis for the control of the occupational exposure of women who are not pregnant was the same as that for men. The Commission's policy was that the methods of protection at work for women who may be pregnant should provide a standard of **protection for any conceptus broadly comparable with that provided for members of the general public**. The Commission considered that its policy would be adequately applied if the mother is exposed, prior to a declaration of pregnancy, under the system of protection recommended by the Commission, including the recommended dose limits for occupational exposure. On this basis the Commission recommended no special occupational dose limit for women in general.

Once pregnancy has been declared, the Commission recommended that the conceptus should be protected by applying a supplementary **equivalent-dose limit to the surface of the woman's abdomen (lower trunk) of 2 mSv for the remainder of the pregnancy and by limiting intakes of radionuclides to about 1/20 of the ALI**. The Commission emphasised that the use of its system of protection, particularly the use of source-related dose constraints, would usually provide an adequate guarantee of compliance with this limit without the need for specific restrictions on the employment of pregnant women. The principal criterion would then be that the employment should be of a type that does not carry a significant probability of high accidental doses and intakes.

However, the 2 mSv criterion was unclear and the Commission clarified its intent in Publication 73. The adoption of a rigid dose limit for the conceptus of a pregnant woman who was occupationally exposed would pose practical problems. The early part of a pregnancy was covered by the normal protection of workers, which was essentially the same for males and females. Once the pregnancy has been declared, and notified to the employer, additional protection of the conceptus should be considered. The Commission considered that its existing advice has sometimes been interpreted too rigidly. It now recommended that the working conditions of a pregnant worker, **after the declaration of pregnancy, should be such as to make it unlikely that the additional equivalent dose to the conceptus will exceed about 1 mSv during the remainder of the pregnancy.**

In the interpretation of this recommendation, the Commission commented that it was important not to create unnecessary discrimination against pregnant women and re-emphasised its view that “the use of its system of protection, particularly the use of source-related dose constraints, would usually provide an adequate guarantee of compliance (with this recommendation), without the need for specific restrictions on the employment of pregnant women”.

## **I.9. EXCLUSION AND EXEMPTION FROM REGULATORY CONTROL**

Publication 26 made no mention of the scope of protection and gave no criteria for exempting materials from regulatory control. In the 1990 Recommendations the Commission stated that it believed that the exemption of sources is an important component of the regulatory functions. It noted that the International Atomic Energy Agency (IAEA) and the OECD Nuclear Energy Agency (NEA) had issued advice on this subject to their member states in IAEA Safety Series 89.

There are two grounds for exempting a source or an environmental situation from regulatory control. One is that the source gives rise to small individual doses and small collective doses in both normal and accident conditions. The other is that no reasonable control procedures can achieve significant reductions in individual and collective doses. The Commission's view was that a basis for exemption on the grounds of trivial dose is much sought after, but very difficult to establish. Apart from the difficulty of deciding when an individual or a collective dose is small enough to be disregarded for regulatory purposes, there is a considerable difficulty in defining the source.

However the IAEA/NEA report had come to conclusions on exemption criteria. One of the key recommendations was concerning collective dose in the optimisation process when it recognised that the cost of regulatory effort should be included in the cost-benefit analysis. If the cost of the collective dose was less than the minimum cost of investigating the source, i.e. a few thousand dollars, and the individual doses were trivial, the source could be presumed optimised. In Publication 64, the Commission accepted the conclusions of that report and stated that the grounds for exemption are that the source gives rise to small individual doses (of the order of 10  $\mu$ Sv per year) and the protection is optimised, i.e. regulatory provisions will produce little or no improvement in dose reduction. If the collective dose is small, e.g. on the order of one man-sievert per year, protection was usually to be assumed to be optimised.

## I.10. EMERGENCIES

In the 1977 Recommendations, the Commission recognised that situations may occur infrequently during normal operations when it may be necessary to permit a few workers to receive dose equivalents in excess of the recommended limits. In such circumstances, called *planned special exposures*, external exposures and intakes of radioactive material were to be permitted provided the sum of the dose-equivalent from the external exposure and the committed dose equivalent from the intake of radionuclides did not exceed **twice the relevant annual limit in any single event**, i.e. 100 mSv and, **in a lifetime, five times this limit** i.e. 250 mSv. The Commission wished to emphasise that external exposures or intakes of this magnitude were only justified when alternative techniques, which did not involve such exposure of workers, were either unavailable or impracticable.

By 1990, the Commission dropped the planned special exposures and the dose restrictions. It had established principles for intervention and only stated that for occupational exposures, emergencies involving significant exposures of emergency teams are rare, so some relaxation of the controls for normal situations could be permitted in serious accidents without lowering the long-term level of protection. This relaxation should not permit the exposures in the control of the accident and in the immediate and urgent remedial work to give effective doses of more than about 0.5 Sv except for life-saving actions, which could rarely be limited by dosimetric assessments. The equivalent dose to skin should not be allowed to exceed about 5 Sv, again except for life saving. Once the emergency was under control, remedial work should be treated as part of the occupational exposure incurred in a practice.

As far as the public was concerned, under conditions in which accidental exposures occur, questions arose as to what remedial actions may be available to limit the subsequent dose. In such cases, the hazard or social cost involved in any remedial measure was to be justified by the reduction of risk that would result. Because of the great variability of the circumstances in which remedial action might be considered, it was not possible for the Commission to recommend unique “intervention levels” that would be appropriate for all occasions. The Commission retained the dose ranges for countermeasures that it recommended in its 1984 Publication 40.

### **I.11. SUMMARY OF CHANGES – PUBLICATIONS 26 TO 60**

There were a number of significant changes to the form of ICRP Recommendations between 1977 and 1990. Firstly there was an increase in the carcinogenic risk factors which was also reflected in a larger estimate of radiation detriment. More organs and tissues were specifically identified to be given their own tissue weighting factor while the Commission, by 1990, had moved away from the use of quality factors in favour of radiation weighting factors which it believed were more biologically plausible and related to measured RBEs.

The philosophical basis was also broadened from a “system of dose limitation”, to a “system of radiological protection”. The main thrust of the 1990 Recommendations was, however, the revision of the risk and detriment estimates (the biological Annex B was just longer than the Recommendations<sup>5</sup>), followed by the justification for the new dose limits. Annex C at 30 pages was exploring the significance of the effects of radiation exposure so as to assess “acceptability”.

Between Publications 26 and 60 the Commission also brought the treatment of radon, at home and at work, into the system by estimating the effective dose equivalent for radon gas concentrations. There was a Derived Air Concentrations (DAC) for the workplace that corresponded to the annual effective dose equivalent limit of 50 mSv while for homes, a radon concentration corresponding to 20 mSv per year was suggested as an action level. Advice for the protection of the public in the event of accidents and emergencies was also given for the first time.

A summary of the numerical values published by the ICRP from Publication 26 to Publication 60 is given in Table 5.

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5. Annex B was 70 pages compared with 66 pages for the recommendations.

**Table 5. Comparison of protection criteria  
between the 1977 and the 1990 Recommendations**  
(numbers in brackets refer to ICRP publication numbers)

Categories of exposure	1977 Recommendations (Publication 26)	1990 Recommendations (Publication 60)
<b>INDIVIDUAL DOSE LIMITS</b>		
<b>Occupational exposure</b> including recovery operations Any individual organ, except: <ul style="list-style-type: none"> <li>• lens of the eye</li> <li>• skin</li> <li>• hands and feet</li> <li>• pregnant women, remainder of pregnancy</li> </ul>	50 mSv/year <sup>d</sup>  500 mSv/year <sup>e</sup>  300 mSv/year <sup>e</sup> 20 Sv (in a lifetime) <sup>e</sup> – Working condition B (<15 mSv/year, so < ~ 10 mSv) <sup>d</sup>	20 mSv/year <sup>a</sup> averaged over defined periods of 5 years <sup>c</sup>  <b>Dropped</b>  150 mSv/year <sup>b</sup> 500 mSv/year <sup>b</sup> 500 mSv/year <sup>b</sup> 2 mSv to the surface of abdomen or 1 mSv from intake of radionuclides
<b>Public exposure (1985 Paris Statement)</b>      Any individual organ <ul style="list-style-type: none"> <li>• lens of the eye</li> <li>• skin</li> </ul> <b>(1978 Stockholm Statement)</b>	5 mSv/year <sup>d</sup> 1 mSv/year, but it is permissible to use a subsidiary limit of 5 mSv in a year for some years provided that the average annual effective dose equivalent over a lifetime does not exceed the principal limit of 1 mSv/year 50 mSv/year <sup>e</sup> – wT of 0.01	1 mSv in a year In special circumstances a higher value is allowed as long as the average over 5 years does not exceed 1 mSv/yr      <b>Dropped</b> 15 mSv/year <sup>b</sup> 50 mSv/year <sup>b</sup>
<b>DOSE CONSTRAINTS</b>		
<b>Occupational exposure</b> <b>Public exposure</b> <ul style="list-style-type: none"> <li>• general</li> </ul>	None None	≤ 20 mSv/year <sup>a</sup> < 1 mSv/year <sup>a</sup>

*Notes:*

- a. Effective dose.
- b. Equivalent dose.
- c. With the further provision that the effective dose should not exceed 50 mSv in any one year. Additional restrictions apply to the occupational exposure of pregnant women. When applied to the intake of radionuclides, the dose quantity is committed effective dose.
- d. Effective dose equivalent.
- e. Dose equivalent.
- f. Averted dose.
- g. Derived air concentration.

**Table 5. Comparison of protection criteria  
between the 1977 and the 1990 Recommendations**  
(numbers in brackets refer to ICRP publication numbers) (*continued*)

Categories of exposure	1977 Recommendations (Publication 26)	1990 Recommendations (Publication 60)
<b>ACCIDENTS/EMERGENCIES</b>		
<b>Occupational exposure (40)</b>		
• life-saving (informed volunteers)	–	No dose restrictions
• other urgent rescue operations	500 mGy whole body 5 Gy individual organs	~500 mSv <sup>a</sup> ; ~5 Sv (skin)
• other rescue operations	–	–
<b>Public exposure (40)</b>		
• foodstuffs		
• distribution of stable iodine	5-50 mSv in the first year <sup>d, f</sup> 50-500 mSv (thyroid) <sup>e, f</sup>	<b>No change</b>
• sheltering	5-50 mSv in 2 days <sup>d, f</sup>	
• temporary evacuation	50-500 mSv in 1 week <sup>d, f</sup>	
• permanent relocation	100 mSv first year <sup>m</sup> or 1Sv in a lifetime <sup>d, f</sup>	
<b>EXISTING EXPOSURE</b>		
<b>Radon</b>	Action level	
• at home (39)	200 Bq m <sup>-3</sup> (was set to be 20 mSv/year <sup>d</sup> )	<b>No change</b>
• at work (32)	DAC <sup>g</sup> 1 500 Bq m <sup>-3</sup> (was set at the dose limit, 50 mSv/year <sup>d</sup> )	<b>No change</b>

*Notes:*

- a. Effective dose.
- b. Equivalent dose.
- c. With the further provision that the effective dose should not exceed 50 mSv in any one year. Additional restrictions apply to the occupational exposure of pregnant women. When applied to the intake of radionuclides, the dose quantity is committed effective dose.
- d. Effective dose equivalent.
- e. Dose equivalent.
- f. Averted dose.
- g. Derived air concentration.



## **PART I.B**

# **SCIENCE AND PROTECTION POLICY**

### **Publication 60 to Publication 103**

Since Publication 60, there has been a series of publications that has provided additional guidance for the control of exposures from radiation sources. When the 1990 Recommendations are included, these reports specify some 30 different numerical values for restrictions on individual dose for differing circumstances. Furthermore, these numerical values are justified in many different ways. There is, however, more continuity than change in the 2007 Recommendations; some recommendations from 1990 are to remain because they work and are clear; others have been updated because understanding has evolved; some items have been added because there has been a void; and some concepts are better explained because more guidance is needed. In addition the Commission began to develop policy guidance for protection of the environment in Publication 91. The major changes are reviewed below.



## I.12. BIOLOGICAL RISKS

In Publication 103, the Commission said that its extensive review of the vast body of literature on the health effects of ionising radiation has not indicated that any fundamental changes are needed to the system of radiological protection.

### **Detriment**

As in Publication 60, the detriment for a tissue, T, is defined as:

$$D_T = (R_{F,T} + q_T R_{NF,T}) l_T \dots \dots \dots (7)$$

where  $R_F$  is the nominal risk of fatal disease,  $R_{NF}$  is the nominal risk of non-fatal disease,  $q$  is a non-fatal weight (between 0 and 1) reflecting the reduced quality of life associated with living with a serious illness, and  $l$  is the average life lost due to the disease relative to normal life expectancy, expressed relative to the average over all cancers. The quality of life factor is a function of the lethality ( $k$ ) of the disease and a subjective judgment accounting for pain, suffering, and adverse effects of treatment.

The computations in Publication 60 were based on nominal mortality risk coefficients,  $R_F$ , and  $q$  was taken to be equal to the lethality fraction  $k$ .  $R_{NF}$  is therefore  $(1 - k) R_F/k$ . Thus, the ICRP Publication 60 cause-specific detriment is:

$$(R_F + k (1 - k)R_F /k)l = R_F (2-k)l \dots \dots \dots (8)$$

Cancer survivors generally experience adverse effects on their quality of life. Thus, in Publication 103, the Commission judges that cancers should be weighted not only by lethality but also for pain, suffering, and any adverse effects of cancer treatment. To achieve this, a factor termed  $q_{min}$  is applied to the non-lethal fractions of cancers to produce an adjusted lethality fraction termed  $q_T$ . The formula used to calculate  $q_T$  with an adjustment for non-lethal detriment is:

$$q_T = q_{min} + k_T (1 - q_{min} ) \dots \dots \dots (9)$$

where  $k_T$  is the lethality fraction and  $q_{min}$  is the minimum weight for non-lethal cancers.

## Nominal risk coefficients

Table 6 gives the comparison of detriment adjusted nominal risks from 1990 and 2007. If the fatal cancer risk is taken alone for a population of all ages it is **4 10<sup>-2</sup> Sv<sup>-1</sup> in 2007** (i.e., not adding in the weighted allowance for non-fatal cancers) compared to **5 10<sup>-2</sup> Sv<sup>-1</sup> in 1990**.

Table 6. **Detriment-adjusted nominal risk coefficients (10<sup>-2</sup> Sv<sup>-1</sup>) for stochastic effects after exposure to radiation at low dose rate**

Exposed population	Cancer (detriment weighted)		Heritable effects		Total	
	ICRP 103	ICRP 60	ICRP 103	ICRP 60	ICRP 103	ICRP 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

It is seen therefore that the fatal cancer, and the total detriment nominal risk coefficients are **about 25% lower** in the 2007 Recommendations compared to 1990. There are two main reasons for these changes. Firstly, the cancer risk estimates in 2007 were derived from incidence data whereas in 1990 the starting point was mortality data. It was felt that the use of incidence data was more reliable than mortality data as incidence is more certainly diagnosed while in the case of mortality, cancer may be the underlying cause of death, but not the primary cause and some cancers may be missed in the reporting. The mortality fraction of cancers is also felt to be more certain when derived from initial incidence data.

Secondly, there was a major revision of the estimates of hereditary diseases induced by exposure. The major finding was that the total hereditary risk is 0.3-0.5% per gray to the first generation following irradiation. This is less than one tenth of the risk of fatal carcinogenesis following irradiation. Since it is now believed to take some hundreds of generations for defects to reach equilibrium, the risk to the first few generations is still about 10% of the carcinogenic risk to the parents.

There are some problems in comparing genetic risk coefficients with those for cancers. This is because of the fact that cancer risk coefficients quantify the probability of harmful effects of radiation to the exposed individuals themselves, and genetic risk coefficients quantify the probability of harmful effects to the descendants of those exposed. In the case of genetic risk coefficients, the inclusion of risk up to two generations in the calculations can be justified on the basis that people are generally interested in the well-being of their children and grandchildren. The estimate restricted to the first post-radiation generation has the advantage that it is more comparable to those for cancers and therefore the Commission believes it deserves serious consideration.

### I.13. BASIC DOSIMETRIC QUANTITIES

The Commission continued with the quantities that it had defined in Publication 60 and reaffirmed its use of equivalent dose so that there was no mention of dose equivalent or  $\bar{Q}$ .

#### Radiation and tissue weighting factors

The values of  $w_R$  for neutrons and protons given in these recommendations differ from those given in Publication 60. The numerical values of  $w_R$  are specified in terms of type and in the case of neutrons in terms of energy of radiation either incident on the human body or emitted by radionuclides residing in the body. The values of  $w_R$  shown in Table 7 are selected by judgment from a broad range of experimental RBE data which are relevant to stochastic effects. The values of RBE have been used for  $w_R$  selection and are assigned fixed values for radiological protection purposes.

All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s). The continuous function in neutron energy  $E_n$  (MeV) is recommended for the calculation of the radiation weighting factors for neutrons and is given in Equation 10. This function has been derived empirically and is consistent with existing biological and physical knowledge.

Table 7. Recommended radiation weighting factors in 2007

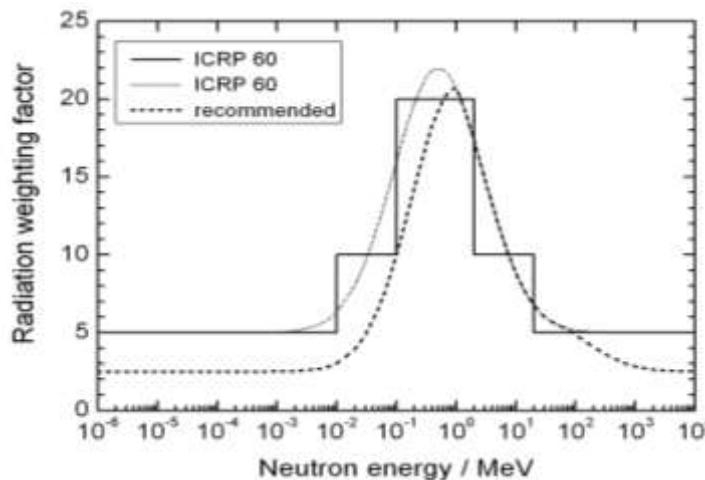
Radiation type	Radiation weighting factor, $w_R$
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	Equation 9

$$w_R = \begin{cases} 2.5 + 18.2 e^{-\ln(E_n)^2/6} & , \quad E_n < 1 \text{ MeV} \\ 5.0 + 17.0 e^{-\ln(2E_n)^2/6} & , \quad 1 \text{ MeV} \leq E_n \leq 50 \text{ MeV} \\ 2.5 + 3.25 e^{-\ln(0.04E_n)^2/6} & , \quad E_n > 50 \text{ MeV} \end{cases} \dots\dots\dots (10)$$

The Publication 60 recommended histogram, together with the continuous function that was permitted, are compared to the Publication 103 values of Equation 9 in Figure 2.

The major change to  $w_R$  for **protons is a reduction from five to two** reflecting a better understanding of the dosimetry. For neutrons there is again a **reduction of about a factor of two for thermal and intermediate energy neutrons**. This is due to the recognition that the  $w_R$  values in 1990 more closely followed the value of  $\bar{Q}$  at a depth of 1 cm into the ICRU sphere and did not properly reflect the dose to deeper organs in the human when there is a significant proton component in the degraded neutron spectrum that has significantly lower biological significance.

Figure 2. Radiation weighting factors,  $w_R$ , as recommended in Publications 60 and 103



The organs and tissues for which  $w_T$  values are specified in the 2007 Recommendations are in Table 8. They represent mean values for humans averaged over both sexes and all ages and thus do not relate to the characteristics of particular individuals. The major differences from the values in Publication 60 are **increases by about a factor of two for breast and remainder tissues**, whilst the **gonads are decreased by about a factor of two**.

Table 8. 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

\* Remainder tissues: adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (♂), small intestine, spleen, thymus, uterus/cervix (♀).

### Remainder tissues

The  $w_T$  for the remainder tissues (0.12) applies to the arithmetic mean dose of the 13 organs and tissues for each sex listed in the footnote to Table 3 of ICRP Publication 103. This essentially means that each remainder tissue has a weighting factor of just under 0.01 and therefore less than that of the named organs with the lowest values in Table 6 of ICRP Publication 103. The so-called splitting rule in the treatment of the remainder in Publication 60 is therefore no longer used, and hence the **effective dose is now an additive quantity for the first time since it was introduced in Publication 26.**

### Collective dose

In Publication 60, very little was said about the calculation and use of collective dose. The Commission became increasingly concerned about the misuse of the quantity (Publication 77) and in Publication 103 it clarified the use of collective dose. In addition to the reduction of the magnitude of individual exposures, a reduction of the number of exposed individuals should also be considered. The collective effective dose has been and remains a key parameter for optimisation of protection for workers. However, the individual dose distribution in the workforce should be taken into account so as to ensure that there is no inequity in the optimisation process.

The definition of collective quantities, as in Section I.3 above, has led in some cases to the incorrect use of collective effective dose for summing up radiation exposures over a wide range of doses, over very long time periods and over large geographical regions, and to calculate on this basis, radiation-related detriments. However, such a use of collective effective dose would only be meaningful if there were sufficient knowledge of the risk coefficients for the detrimental radiation effects in all dose ranges which contribute to the collective dose and an accurate assessment of the doses over space and time. Owing to the large uncertainties, such knowledge of risk coefficients is not available in the very

low dose range, nor are the dose estimates accurate at long distances from the source or in the far future.

The Commission now considers that, in the low dose range, the risk factors have a high degree of uncertainty. This is particularly the case for very low individual doses which are only small fractions of the radiation dose received from natural sources. The use of collective effective dose under such conditions for detailed risk estimates is not a valid procedure.

To avoid aggregation of low individual doses over extended time periods and wide geographical regions the range in effective dose and the time period should be limited and specified. In the calculation and interpretation of collective effective dose, the following aspects should be considered and critically reviewed in order to avoid a misuse of collective effective dose:

- number of exposed individuals;
- age and sex of exposed persons;
- range of individual doses;
- dose distribution in time; and
- geographical distribution of exposed individuals.

The collective effective dose due to individual effective dose values between  $E_1$  and  $E_2$  is defined in Equation 11:

$$S(E_1, E_2, T) = \int_{E_1}^{E_2} E (dN/dE)_{\Delta T} dE \dots \dots \dots (11)$$

where  $(dN/dE)dE$  denotes the number of individuals who are exposed to an effective dose between  $E$  and  $E+dE$  within the time period  $\Delta T$ . When the range of individual doses spans several orders of magnitude, the distribution should be characterised by dividing it into several ranges of individual dose, each covering no more than two or three orders of magnitude, with the population size, mean individual dose, and uncertainty being considered separately for each range. When the collective effective dose is smaller than the reciprocal of the relevant risk detriment, the risk assessment should note that the most likely number of excess health effects is zero. Thus if the detriment figure is  $5\% \text{ Sv}^{-1}$ , and the collective dose is less than 20 man Sv, the likely number of health effects is zero.



## I.14. PHILOSOPHY OF PROTECTION

The Commission's process of consolidation of previous guidance and recommendations has indicated that some changes to the structure and terminology of the system of protection, as set out in Publication 60, were desirable in order to improve clarity and utility. In particular, the distinction between practices and interventions may not have been clearly understood in the wider radiological protection community. Additionally, there were exposure situations which were difficult to categorise in this manner.

The Commission in 2007 replaced the previous process-based categorisation of practices and interventions to one that is **situation-based** with three exposure situations intended to cover the entire range of exposure situations. The Commission hopes that by using these three types of exposure situations, it will clarify the application of its system of protection. The three situations are:

- *Planned exposure* situations, which are situations involving the planned introduction and operation of sources. (This type of exposure situation includes situations that were previously categorised as practices.)
- *Emergency exposure* situations, which are unexpected situations such as those that may occur during the operation of a planned situation, or from a malicious act, requiring urgent attention.
- *Existing exposure* situations, which are exposure situations that already exist when a decision on control has to be taken, such as those caused by natural background radiation.

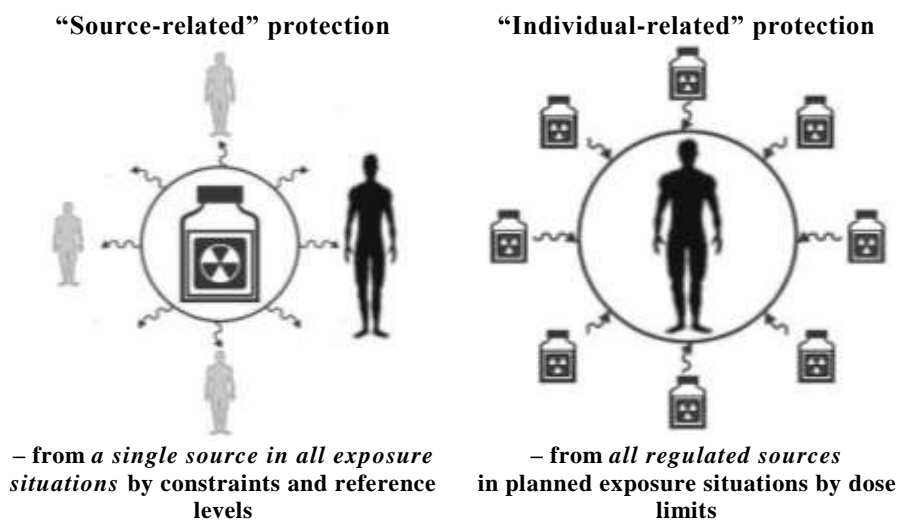
The three key principles of radiological protection are retained in the revised recommendations. In the 1990 Recommendations, the Commission gave principles of protection for practices separately from intervention situations. The Commission continues to regard these principles as fundamental for the system of protection, and has now formulated a set of principles that apply to planned, emergency, and existing controllable situations. In the new recommendations, the Commission also clarifies how the fundamental

principles apply to radiation sources and to the individual, as well as how the source-related principles apply to all controllable situations. This is illustrated schematically in Figure 3.

Two principles are *source related* and apply in all situations:

- **The principle of justification:** Any decision that alters the radiation exposure situation should do more good than harm.  
This means that by introducing a new radiation source or by reducing existing exposure, one should achieve an individual or societal benefit that is higher than the detriment it causes.
- **The principle of optimisation of protection:** the likelihood of incurring exposures, the number of people exposed and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.  
This means that the level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm. In order to avoid severely inequitable outcomes of this optimisation procedure, there should be restrictions on the doses or risks to individuals from a particular source (dose or risk reference levels and constraints).

Figure 3. **Dose constraints and reference levels contrasted with dose limits to protect workers and members of the public from *single* sources and *all regulated* sources**



The **dose constraint** is now seen as a prospective source-related restriction on the individual dose from a source, which provides a basic level of protection for the most highly exposed individuals from a source, and serves as an upper bound on the dose in optimisation of protection for that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.

The **reference level**, in emergency or existing controllable exposure situations, represents the level of dose or risk, above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration.

One principle is *individual related* and applies only in planned situations:

- **The principle of application of dose limits:** The total dose to any individual from all planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

Dose limits are determined by the national regulatory authority on the basis of international recommendations and apply to workers and to members of the public in planned exposure situations. Dose limits do not apply to medical exposure of patients, or to public exposures in emergency situations, or to existing exposure situations.

The Commission continues to distinguish amongst three categories of exposure: occupational exposures, public exposures, and medical exposures of patients. If a female worker has declared that she is pregnant, additional controls have to be considered in order to attain a level of protection for the embryo/foetus broadly similar to that provided for members of the public.

## **I.15. OPTIMISATION: DOSE CONSTRAINTS AND REFERENCE LEVELS**

Optimisation is always aimed at achieving the best level of protection under the prevailing circumstances through an ongoing, iterative process that involves:

- evaluation of the exposure situation, including any potential exposures (the framing of the process);
- selection of an appropriate value for the constraint or reference level;
- identification of the possible protection options;
- selection of the best option under the prevailing circumstances; and
- implementation of the selected option.

In all situations, the process of optimisation with the use of constraints or reference levels is applied in planning protective actions and in establishing the appropriate level of protection under the prevailing circumstances. The doses to be compared with the dose constraint or reference levels are usually prospective doses, i.e. doses that may be received in the future, as it is only those doses that can be influenced by decisions on protective actions. They are **not** intended as a form of **retrospective dose limit**.

A necessary stage in applying the principle of optimisation of protection is the selection of an appropriate value for the dose constraint or the reference level. The relevant national authorities will often play a major role in this process. The first step is to characterise the relevant exposure situation in terms of the nature of the exposure, the benefits from the exposure situation to individuals and society and the practicability of reducing or preventing the exposures. The ICRP considers that comparison of these attributes with the characteristics described in Table 9 should enable the selection of the appropriate band for the constraint or the reference level.

The specific value for the constraint may then be established by a process of generic optimisation that takes account of national or regional attributes and

preferences together, where appropriate, with a consideration of international guidance and good practice elsewhere.

The revised recommendations **emphasise the key role of the principle of optimisation**. This principle should be applied in the same manner in all exposure situations. Restrictions are applied to doses to a nominal individual (the reference person), namely dose constraints for planned exposure situations and reference levels for emergency and existing exposure situations. Options resulting in doses greater in magnitude than such restrictions should be rejected at the planning stage. Importantly, these restrictions on doses are applied prospectively, as with optimisation as a whole. If following the implementation of an optimised protection strategy, it is subsequently shown that the value of the constraint or reference level is exceeded, the reasons should be investigated but this fact alone should not necessarily prompt regulatory action. The Commission expects that this emphasis on a common approach to radiological protection in all exposure situations will aid application of the Commission's recommendations in the various circumstances of radiation exposure.

The relevant national authorities will often play a major role in selecting values for dose constraints and reference levels. Guidance on the selection process is provided in the revised 2007 Recommendations. This guidance takes account of numerical recommendations made previously by the Commission.

The optimisation of protection, as set out in Publication 103, is a forward-looking iterative process aimed at preventing or reducing future exposures. It takes into account both technical and socio-economic developments and requires both qualitative and quantitative judgments. The process should be systematic and carefully structured to ensure that all relevant aspects are taken into account. **Optimisation is a frame of mind**, always questioning whether the best has been done in the prevailing circumstances, and whether all that is reasonable has been done to reduce doses. It also requires commitment at all levels in all concerned organisations as well as adequate procedures and resources.

**Table 9. Framework for source-related dose constraints and reference levels with examples of constraints for workers and the public from single dominant sources for all situations that can be controlled (effective dose in a year)**

<b>Projected effective dose<sup>a</sup> (mSv)</b>	<b>Characteristics of the situation</b>	<b>Radiological protection requirements</b>	<b>Examples</b>
<b>&gt;20 to 100<sup>b, c</sup></b>	Sources not controllable, or where actions to reduce doses would be disproportionately disruptive. Controlled by action on the exposure pathways.	Individuals should receive information on risk and on the actions to reduce doses. Assessment of individual doses.	Reference level for evacuation in a radiological emergency.
<b>&gt;1 to 20</b>	Individuals usually receive direct benefit from the situation but not from the exposure itself. Controlled at source or by action in the exposure pathways.	General information made available to enable individuals to reduce their doses. For planned situations, individual monitoring and training should take place.	Constraints set for occupational exposure. Constraints set for comforters and carers. Reference level for radon in dwellings.
<b>1 or less</b>	Individuals get no direct benefit but society benefits. Controlled by action on the source planned in advance.	General information on the level of exposure should be made available. Periodic checks should be made on the exposure pathways as to the level of exposure.	Constraints set for public exposure in planned situations.

a Acute or annual dose.

b In exceptional situations, informed volunteer workers may receive doses above this band to save lives, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions.

c Situations in which the dose threshold for deterministic effects in relevant organs or tissues could be exceeded should always require action.

Societal values usually influence the final decision on the level of radiological protection. Therefore, while this report should be seen as providing decision-aiding recommendations mainly based on scientific considerations on radiological protection, the Commission's advice will be expected to serve as an input to a final (usually wider) decision-making process, which may include other societal concerns and ethical aspects, as well as considerations of transparency. This decision making process may often include the participation of relevant stakeholders rather than radiological protection specialists alone.

Planned exposure situations encompass sources and situations that have been appropriately managed within the Commission's previous recommendations for practices. Protection during the medical uses of radiation is also included in this type of exposure situation. The process of planning protection in planned exposure situations should include consideration of deviations from normal operating procedures including accidents and malicious events. Exposures arising in such circumstances are referred to as potential exposures by the Commission. Potential exposures are not planned but they can be anticipated. The designer and the user of a source must therefore take actions to reduce the likelihood of a potential exposure happening, such as assessing the probability of an event and introducing engineering safeguards commensurate to this probability.

## I.16. DOSE LIMITS

Recommendations for planned exposure situations are substantially unchanged from those provided in Publication 60 and subsequent publications. The dose limits for occupational and public exposures for practices are retained for application to regulated sources in planned exposure situations.

The dose limits for individuals is retained from Publication 60 in Publication 103. It is to be noted that, because the estimates of **fatal cancer** and **detriment** have **decreased** by about 25% per unit effective dose, by retaining the numerical values for dose limits the Commission has **increased the level of protection** afforded by the limits by 25%. Otherwise, a reduction in risk per unit exposure would have increased the occupational dose limit, for example, by 25% (for the same level of protection) to an average of 25 mSv per year, and the public to 1.25 mSv per year.



## I.17. EMERGENCY AND EXISTING SITUATIONS (RADON)

Emphasis on optimisation using reference levels in emergency and existing exposure situations focuses attention on the projected level of dose remaining after implementation of protection strategies. This expected level of dose should be below the selected value of the reference level. These exposure situations often involve multiple exposure pathways which mean that protection strategies involving a number of different protective actions will have to be considered. The process of optimisation will, however, continue to use the dose averted by specific countermeasures as an important input into the development of optimised strategies.

Emergency exposure situations include consideration of emergency preparedness and emergency response. Emergency preparedness should include planning for the implementation of optimised protection strategies which have the purpose of reducing exposures, should the emergency occur, to below the selected value of the reference level. During emergency response, the reference level would act as a benchmark for evaluating the effectiveness of protective actions and as one input into the need for establishing further actions.

Existing exposure situations include naturally occurring exposures as well as exposures from past events and practices conducted outside the Commission's recommendations and past accidents. In this type of situation, protection strategies will often be implemented in an interactive, progressive manner over a number of years.

### **Radon**

Indoor radon in dwellings and workplaces is an important existing exposure situation and is one where the Commission has made specific recommendations in 1994 in Publication 65 which updated the recommendations in Publications 32 and 39. In essence the epidemiology of the mine workers gave the **same risk per unit exposure**, but **the risk per mSv was now five times the values used before** Publication 60. Thus the domestic action level (Table 5) of 200 Bq m<sup>-3</sup> now corresponded to the risk of an effective dose of 4 mSv/year, not that of 20 mSv assumed in Publication 39.

Similarly for workers the DAC of 1 500 Bq m<sup>-3</sup> (Table 5) no longer equated with the risk associated with an effective dose of 50 mSv/year but 10 mSv/year.

In Publication 65, the Commission considered that simple remedial measures were almost certainly warranted to avoid an effective dose from radon of 10 mSv/year. This gave action levels of 600 Bq m<sup>-3</sup> at home and 1 500 Bq m<sup>-3</sup> at work. The Commission recommended national authorities derived optimised action levels of their own which would take account of the local situation, and 600 Bq m<sup>-3</sup> in homes and 500-1 500 Bq m<sup>-3</sup> in workplaces.

Since then, several epidemiological studies have confirmed that **the health risk from radon exposure is now assessed to be about double** that estimated in 1994 (ICRP Statement, November 2009). This has led the Commission to revise its recommendations in Publication 103.

The Commission reaffirms that radon exposure in dwellings due to unmodified concentrations of radium-226 in the earth's crust, or from past practices not conducted within the Commission's system of protection, is an existing exposure situation. Furthermore, the Commission's protection policy for these situations continues to be based on setting a level of annual dose of around 10 mSv from radon where action would almost certainly be warranted to reduce exposure. Taking account of the new findings, the Commission has therefore revised the upper value for the reference level **for radon gas in dwellings** from the value in the 2007 Recommendations of 600 Bq m<sup>-3</sup> to **300 Bq m<sup>-3</sup>**. National authorities should consider setting lower reference levels according to local circumstances. All reasonable efforts should be made, using the principle of optimisation of protection, to reduce radon exposures to below the national reference level.

Taking account of differences in the lengths of time spent in homes and workplaces of about a factor of three, a level of radon gas of around 1 000 Bq m<sup>-3</sup> defines the entry point for applying occupational protection requirements for existing exposure situations. In Publication 103, the Commission considered that the internationally established value of 1 000 Bq m<sup>-3</sup> might be used globally in the interest of international harmonisation of occupational safety standards. The Commission now recommends **1 000 Bq m<sup>-3</sup>** as the **entry point** for applying occupational radiological protection requirements in existing exposure situations. The situation will then be managed as a planned exposure situation.

The Commission reaffirms its policy that, for planned exposure situations, any workers' exposure to radon incurred as a result of their work, however small, shall be considered as occupational exposure.

## **I.18. PROTECTION OF THE ENVIRONMENT**

In Publication 26 it was said that although the principal objective of radiation protection is the achievement and maintenance of appropriately safe conditions for activities involving human exposure, the level of safety required for the protection of all human individuals is thought likely to be adequate to protect other species, although not necessarily individual members of those species. The Commission therefore believes that if man is adequately protected, then other living things are also likely to be sufficiently protected.

In the 1990 Recommendations, the Commission retained the same view: it believes that the standard of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed, but not to the extent of endangering whole species or creating imbalance between species. At the present time, the Commission concerns itself with mankind's environment only with regard to the transfer of radionuclides through the environment, since this directly affects the radiological protection of man.

The revised 2007 Recommendations acknowledge the importance of protecting the wider environment. The Commission has previously concerned itself with mankind's environment only with regard to the transfer of radionuclides through it, mainly in the context of planned exposure situations. In such situations, the Commission continues to believe that the standards of environmental control needed to protect the general public would ensure that other species are not placed at risk. To provide a sound framework for environmental protection in all exposure situations, the Commission proposes use of reference animals and plants. In order to establish a basis for acceptability, additional doses calculated to these reference organisms could be compared with doses known to have specific biological effects and with dose rates normally experienced in the natural environment. The Commission, however, does not propose to set any form of "dose limits" for environmental protection.

## I.19. SUMMARY OF CHANGES – PUBLICATIONS 60 TO 103

In the 2007 Recommendations, the Commission sought to clarify and extend its previous recommendations. The risks from exposure to ionising radiation are slightly lower than in 1990 but there was a **major decrease in the hereditary risk estimates**, leading to changes in the  $w_T$  values. Some reductions in  $w_R$  values were recommended.

The system of protection was changed **from a process-led** (practice and intervention) **to a situation-led** (planned, emergency and existing) philosophy with a greater emphasis on source-related control compared to the 1990 concentration on the individual-related dose limits.

In 2007, the Commission de-emphasised the mathematical approach to optimisation that had existed since its introduction in 1977 and recommended a **more qualitative approach to optimisation**, stating that it is a frame of mind, always questioning whether the best has been done in the prevailing circumstances. As part of this, the Commission recommended the disaggregation of collective dose to enable the doses to whom, when and where to be presented separately in any optimisation considerations. The Commission has recommended a **framework for constraints and reference levels** to facilitate decision-making by national authorities.

The retention in 2007 of the **dose limits** established in 1990 has **increased the level of protection by about 25%** because the risk per unit exposure has decreased by this amount.

The current recommended values for protection criteria in 2007 are compared in Table 10 with those provided by the previous recommendations in Publication 60 and the derivative publications. The comparison shows that the current recommendations are essentially the same as the previous 1990 Recommendations for planned exposure situations.

In the case of existing and emergency exposure situations, the current recommendations generally encompass the previous values but are wider in their scope of application. It should be noted that in some cases the values cited are in

different quantities; for example, in emergency exposure situations the criteria in Publication 60 are specified in terms of averted dose (intervention levels) whereas the criteria in the current Recommendations are specified in terms of residual dose (reference levels). The Commission has recently **revised downwards the reference level for radon** in homes and the level for occupational exposure that would require the application of the system of protection.

The Commission has now embraced protection of the environment as a subject for radiological protection. It has recently published advice on reference animals and plants.

**Table 10. Comparison of protection criteria between the 1990 and the 2007 Recommendations**  
(numbers in brackets refer to ICRP publication numbers)

Categories of exposure (publications)	1990 Recommendations and subsequent publications	2007 Recommendations
<b>PLANNED EXPOSURES</b>		
<i>Individual dose limits<sup>a</sup></i>		
Occupational exposure (60, 68) including recovery operations	20 mSv/year average over defined periods of 5 years <sup>c</sup>	No change
– lens of the eye	150 mSv/year <sup>b</sup>	No change
– skin	500 mSv/year <sup>b</sup>	No change
– hands and feet	500 mSv/year <sup>b</sup>	No change
– pregnant women, remainder of pregnancy (60) (75, 96)	2 mSv to the surface of abdomen or 1 mSv from intake of radionuclides 1 mSv to the embryo/foetus	<b>Dropped</b> <b>No change</b>
Public exposure (60)	1 mSv in a year In special circumstances a higher value is allowed as long as the average over 5 years does not exceed 1 mSv/yr	<b>No change</b>
– lens of the eye	15 mSv/year <sup>b</sup>	<b>No change</b>
– skin	50 mSv/year <sup>b</sup>	<b>No change</b>
<i>Dose constraints</i>		
Occupational exposure (60)	≤20 mSv/year	<b>No change</b>
Public exposure (77, 81, 82)	<1 mSv/year	To be <1 mSv/year according to the situation
– general		<b>No change</b>
– radioactive waste disposal	≤0.3 mSv/year	
– long-lived radioactive waste disposal	≤0.3 mSv/year	
– prolonged exposure	<~1 & ~0.3 mSv/year <sup>e</sup>	
– prolonged component from long-lived nuclides	≤0.1 mSv/year <sup>g</sup>	<b>No change</b>

Table 10. Comparison of protection criteria between the 1990 and the 2007 Recommendations  
(numbers in brackets refer to ICRP publication numbers) (continued)

Categories of exposure (publications)	1990 Recommendations and subsequent publications	2007 Recommendations
<b>EMERGENCY EXPOSURES</b>		
	<b>Intervention levels<sup>a, d, f</sup></b>	<b>Reference levels<sup>a, f</sup></b>
Occupational exposure (60, 96)	No dose restrictions <sup>h</sup>	No dose restrictions if benefit to others outweighs rescuer's risk <sup>i</sup>
– life-saving (informed volunteers)		1 000 or 500 mSv <sup>i</sup>
– other urgent rescue operations	~500 mSv; ~5 Sv (skin) <sup>h</sup>	≤100 mSv <sup>i</sup>
– other rescue operations		
Public exposures (63, 96)		
– foodstuffs	10 mSv/year <sup>j</sup>	
– distribution of stable iodine	50-500 mSv (thyroid) <sup>b, j</sup>	
– sheltering	5-50 mSv in 2 days <sup>j</sup>	
– temporary evacuation	50-500 mSv in 1 week <sup>j</sup>	
– permanent relocation	100 mSv first year or 1Sv <sup>j</sup>	
– all countermeasures combined in an overall protection strategy		In planning, typically between 20 and 100 mSv/year according to the situation
<b>EXISTING EXPOSURES</b>		
	<b>Action levels<sup>a</sup></b>	<b>Reference level<sup>a, 1</sup></b>
Radon (65)		
– at home	3-10 mSv/year (200-600 Bq m <sup>-3</sup> )	<10 mSv/year (300 Bq m <sup>-3</sup> )
		<b>Entry point<sup>a, 1</sup></b>
– at work	3-10 mSv/year (500-1500 Bq m <sup>-3</sup> )	(to occupational protection regime) 10 mSv/year (1 000 Bq m <sup>-3</sup> )

*Notes:*

- a Effective dose unless otherwise specified.
- b Equivalent dose.
- c With the further provision that the effective dose should not exceed 50 mSv in any one year. Additional restrictions apply to the occupational exposure of pregnant women. When applied to the intake of radionuclides, the dose quantity is committed effective dose.
- d Averted dose.
- e The dose constraint should be less than 1 mSv and a value of no more than about 0.3 mSv would be appropriate.
- f Intervention levels refer to averted dose for specific countermeasures. Intervention levels remain valuable for optimisation of individual countermeasures when

planning a protection strategy, as a supplement to reference levels for evaluation of protection strategies; these refer to residual dose.

- g To be considered if dose assessment methodologies to ensure compliance under any conceivable situation of combination of doses are not available.
- h Publication 60.
- i Publication 96. Effective doses below 1 000 mSv should avoid serious deterministic effects; below 500 mSv should avoid other deterministic effects.
- j Publication 63.
- k Reference levels refer to residual dose and are used to evaluate protection strategies, as opposed to the previously recommended intervention levels which referred to averted doses from individual protective actions.
- l ICRP statement on Radon, 2009, see: [www.icrp.org](http://www.icrp.org).





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## **II. IMPACT ON EUROPEAN AND UK DOMESTIC REGULATION**

**Wendy Bines**



## II.1. INTRODUCTION

Within the European Union, the ICRP Recommendations are reflected in Basic Safety Standards for radiation protection directives made under the Euratom Treaty. Member States, which include the United Kingdom (UK), are obliged to implement directives through their national legislation. In the United Kingdom, as elsewhere, no single piece of legislation has implemented the requirements of the Euratom Basic Safety Standards Directives. However, Ionising Radiations Regulations prepared and enforced by the Health and Safety Commission (HSC) and Executive (HSE) (the UK regulator for occupational exposure to ionising radiation) have implemented the majority of the provisions.

Publication 26 led directly to the adoption by the European Community in 1980 of Directive 80/836/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, commonly known as the Basic Safety Standards (BSS) Directive (and subsequently amended by Directive 84/467/Euratom). The European Commission's Communication on the 1980 Directive as amended in 1984 commented: "The ICRP publications on which the Council Directives are based were written with a view to enabling the competent international organisations and national authorities to prepare legislative texts. Seen in this light, ICRP Publication 26 does not modify the key principles of ICRP Publication 9, or those of the 1976 Directive. The Council Directive of 1980, which takes into account the information available in Publication 26, should not require fundamental changes in the legislations of Member States."

In the United Kingdom, the Ionising Radiations Regulations 1985 (IRR85) were introduced to implement most provisions of the 1980 BSS Directive, though certain provisions can be traced only to domestic legislative origins because of the need to consolidate some of the provisions of two earlier sets of regulations. This earlier legislation had been solely concerned with the protection of factory workers against ionising radiations from sealed sources and machines or apparatus generating X-rays, though site licence conditions had contained equivalent provisions for nuclear installations. The extension of radiation protection legislation to include educational and research establishments as well as hospitals, previously covered only by codes of practice, was therefore a significant development.

In 1993, in response to Publication 60, the European Commission published proposals for a revised BSS Directive which was adopted on 13 May 1996 (Directive. 96/29/Euratom).

Key changes in the 1996 BSS Directive from the 1980 one were seen as:

- use of the new ICRP concepts of practices and intervention;
- a lower principal dose limit which could be averaged over five years but with the facility, if Member States so wished, to decide on an annual limit instead;
- mandatory requirement for “prior authorisation” of certain activities;
- explicit treatment of natural radiation sources; and
- explicit treatment of “intervention”, i.e. emergency preparedness.

The main piece of UK implementing legislation for the 1996 BSS Directive was the Ionising Radiations Regulations 1999 (IRR99).

The ICRP’s recommendations on biological risk underpin the BSS directives and national implementing legislation, but implicitly rather than explicitly.

**PART II.A**  
**REGULATORY EXPERIENCE**

**Publication 26 to Publication 60**





## II.2. BASIC DOSIMETRIC QUANTITIES

The BSS Directives, and thus national implementing legislation, followed the ICRP's lead on dosimetric quantities. **The European Commission's Communication<sup>6</sup> on the 1980 Directive**, and amending 1984 Directive, commented in its general remarks: "The concept of effective dose equivalent which is a characteristic of the recommendations contained in the ICRP Publication 26, is introduced in the 1980 Directive. This concept is used in the case of partial body exposure. The aim is to define, for a given partial body exposure, a virtual equivalent whole body dose which would involve the same risk. Used by the ICRP for determining the annual limits of intakes, the concept is not, however, always susceptible to direct application in routine surveillance. However, in the event of accidents, it may be useful to estimate the effective dose equivalent on the basis of data compiled in reconstituting [sic] the accident."

**The European Commission's Communication on the 1996 Directive** commented: "equivalent dose" and "effective dose". The directive uses the protection quantities recommended by the ICRP Publication 60. They replace the previous quantities "dose equivalent" and "effective dose (equivalent)". It is noted that the ICRP recommends that "it is appropriate to treat as additive the weighted quantities used by the ICRP but assessed at different times, despite the use of different values of weighting factors. The ICRP does not recommend that any attempt be made to correct earlier values. It is also appropriate to add values of dose equivalent to equivalent dose and values of effective dose equivalent to effective dose without any adjustment."

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6. A communication is a *sui generis* document, essentially guidance and non-binding.

## II.3. PHILOSOPHY OF PROTECTION

### The 1980 BSS Directive and UK IRR85

The Euratom BSS Directives have reflected the developing ICRP philosophy of protection. Thus **the 1980 BSS Directive** contained the following provisions:

“The limitation of individual and collective doses resulting from controllable exposures shall be based on the following general principles:

- (a) every activity resulting in an exposure to ionising radiation shall be justified by the advantages which it produces;
- (b) all exposures shall be kept as low as reasonably achievable [NOTE: The additional words *economic and social factors being taken into account* did not appear in the directive itself, only in the European Commission’s Communication on the directives.];
- (c) without prejudice to Article 11 [NOTE: planned special exposures] the sum of the doses and committed doses received shall not exceed the dose limits laid down in this Title for exposed workers, apprentices and students and members of the public.”

Article (a) is amended in 1984, in order to clarify that justification was generic rather than potentially site-specific, to read: “the various types of activity resulting in an exposure to ionising radiation shall have been justified in advance by the advantages which they produce”.

**The European Commission’s Communication on the 1980 Directive** and amending 1984 Directive, said in its general remarks: “The basic principles of justification and optimisation of exposures, which were formulated in ICRP Publication 26 and which are reproduced in ... the 1980 Directive, are clearly only of general value, something which must be taken into account when introducing them into national legislative and administrative provisions. The third principle (dose limits), for its part, can be transformed into national legislation in a binding form without restrictions.” In its comments on the specific justification provision, the communication noted: “Compliance with this principle is adequately

demonstrated in respect of a type of activity by the existence or laying down of regulations specifically concerning the type of activity.”

**The UK IRR85** did not contain a specific reference to justification because it was considered that the principle was covered essentially by default, in line with the European Commission’s comment. The preface to the *Approved Code of Practice*<sup>7</sup> supporting the IRR85 made the point: “The basic principle in the Regulations, that all necessary steps shall be taken to reduce, so far as reasonably practicable, the extent to which people are exposed to ionising radiations, reflects principles (a) and (b) and means that it is not sufficient merely to observe dose limits. Thus, those whose undertakings cause people to be exposed to ionising radiation have a duty to weigh the costs of the possible health detriment from exposure against the costs of reducing or eliminating that exposure (taking into account possible risks to health and safety arising from alternative methods of carrying out the work), to the extent of questioning whether a particular use of ionising radiation can be justified at all.”

Optimisation, dose limitation and emergencies are covered in later sections.

It is of interest to note that the UK IRR85 covered occupational exposure to radon. This was not an explicit requirement of the 1980 BSS Directive (as amended), although the European Commission’s Communication implicitly endorsed this interpretation by saying: “It [the scope of the directive] is not intended to apply to natural radioactivity other than in industrial and technical operations. For example, the Directive does not apply directly to radon in dwellings.”

### **The 1996 BSS Directive and UK IRR99**

The 1996 BSS Directive included the following general principles for practices:

“Member States shall ensure that all new classes or types of practices resulting in exposure to ionising radiation are justified in advance of being first adopted or first approved by their economic, social or other benefits in relation to the health detriment they may cause.

Existing classes or types of practice may be reviewed as to justification whenever new and important evidence about their efficacy or consequences is acquired.

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7. In the UK an *Approved Code of Practice* gives practical guidance on how to comply with the law and has a special legal status. If a person holding duties under the regulations is prosecuted for a breach, and it is proved that he did not follow the relevant provisions of the code, then he will have to show that he complied with the regulations in some other way or a court will find him at fault.

In addition, each Member State shall ensure that:

- (a) in the context of optimisation all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account;
- (b) without prejudice to Article 12 [specially authorised exposures], the sum of the doses from all relevant practices shall not exceed the dose limits laid down in this Title for exposed workers, apprentices and students and members of the public.”

Dose constraints were introduced as follows:

“Dose constraints shall be used, where appropriate, within the context of optimisation of radiological protection.”

Control of risk in the case of potential exposures appeared under intervention:

“The implementation and extent of any intervention shall be considered in compliance with the following principles:

- intervention shall be undertaken only if the reduction in detriment due to radiation is sufficient to justify the harm and costs, including social costs, of the intervention;
- the form, scale and duration of the intervention shall be optimised so that the benefit of the reduction in health detriment less the detriment associated with the intervention, will be maximised;
- dose limits, as laid down in Articles 9 and 11, shall not apply to intervention; however, the intervention levels established in application of Article 50(2) constitute indications as to the situations in which intervention is appropriate; furthermore, in cases of long term exposure covered by Article 53, the dose limits set out in Article 9 should normally be appropriate for workers involved in interventions.”

It was originally envisaged that the **UK IRR99** would contain a fairly simple requirement for justification, largely mirroring the requirements of the directive. However, long discussions within government eventually led to a free standing set of regulations backed up by detailed procedures.

Optimisation, dose limitation and emergencies are covered in later sections of this report.

## II.4. OPTIMISATION OF PROTECTION

### The 1980 BSS Directive and UK IRR85

The European Commission's Communication on the 1980 BSS Directive noted that, generally, in routine operations, optimisation need not involve complex calculations. It was implicit in the requirement that "exposures shall be kept as low as reasonably achievable" that scientific consideration should be supplemented by economic and social factors. The techniques for judging the need for further reductions in exposure in the light of what was reasonable were very diverse and included, for instance, formal aids to decision-making, such as cost-benefit analysis, etc., but were more usually based on simple common-sense practices. If an improvement was easy to make and committed only few resources it was sensible, and therefore reasonable, to make the improvement. If the improvement required the major commitment of resources and produced only small reductions of exposure, it was likely to be unreasonable and therefore inappropriate.

Restriction of exposure (optimisation) was not new to UK radiation protection legislation, although previously it had only applied to work in factories. In the UK IRR85 it was seen as the main method of protecting workers, with dose limitation acting almost as a back stop. There was a defined hierarchy of actions. Employers were required to achieve restriction:

- so far as reasonably practicable, by means of engineering controls and design features, which included shielding, ventilation, containment of radioactive substances and minimisation of contamination, also by the provision and use of safety features and warning devices;
- in addition, to provide effective systems of work (i.e. detailed working arrangements, such as permits to work); and
- where appropriate, also provide adequate and suitable personal protective equipment (including respiratory protective equipment).

A mandatory investigation was introduced when a worker's dose reached three-tenths of the annual whole body dose limit for the first time in a calendar

year, which had a powerful effect and resulted in many employers treating 15 mSv as a *de facto* dose limit (though this was not the regulator's intention).

Additionally, employees had a duty to contribute to their own restriction of exposure.

### **The 1996 BSS Directive and UK IRR99**

The advice on optimisation in the **European Commission's Communication on the 1996 BSS Directive** varied little from that on the 1980 Directive, though substituting "professional judgment" for "simple commonsense practices"; however, it noted that the principle should be applied from the design stage, throughout all other stages to eventual decommissioning or disposal of sources.

In respect of the new concept of dose constraints, the point was made that they should not be confused with dose limits. They were essentially a ceiling to the predicted values of individual doses from a source, practice or task which could be determined to be acceptable in the process of optimisation of protection for that source, practice or task. Dose constraints could be established and used by undertakings as a help for optimising protection in the design or in the planning stage. They could also be established by authorities, particularly in the context of public exposure. They could be matters for discussion between undertakings and authorities. The communication also referenced the guide on the utilisation of the newly introduced concept given in a report by a joint group of experts from the OECD Nuclear Energy Agency and from the European Commission, published by the OECD in 1996.

Similarly, the **UK IRR99** saw little change from IRR85, apart from a reordering of requirements within the regulations to improve coherence, other than the addition of a requirement to use dose constraints where appropriate at the planning stage of radiation protection. Guidance stressed that dose constraints were not intended to be used as investigation levels once a decision had been taken about the most appropriate design or plan; in general, the value assigned to dose constraint was intended to represent a level of dose (or some other measurable quantity) which ought to be achieved in a well-managed practice. The mandatory investigation level remained unchanged at 15 mSv, though this was now a default level as employers were free to specify a lower effective dose where they felt it appropriate (as many larger employers had already done).

## II.5. DOSE LIMITS

### **The 1980 BSS Directive and UK IRR85**

The dose limits specified in the **1980 BSS Directive** were consistent with Publication 26. The European Commission's Communication noted that the dose limits were necessary to protect the most highly exposed individuals but they had to be complemented by the application of the second principle (optimisation).

The dose limits in the directive were reproduced in **the UK IRR85**.

### **The 1996 BSS Directive and UK IRR99**

The dose limits specified in the **1996 BSS Directive** were essentially consistent with Publication 60, while allowing for two different approaches for limiting effective dose (whole body dose) to those who worked with ionising radiation. Member States might either continue with a system of annual dose limitation (based on a principal annual limit of 20 mSv) or adopt a system based on the dose received over a five-year period. Whichever system was adopted, no employee aged 18 or over should receive an effective dose greater than 100 mSv in a consecutive five-year period or 50 mSv in any single year.

In respect of dose limits for other persons, the directive allowed for five-year averaging of the annual limit on effective doses of 1 mSv in a year in special cases.

**The European Commission's Communication on the 1996 Directive** noted that compliance with the effective dose limit alone was not always sufficient to prevent the occurrence of deterministic effects in some organs or tissues. It was therefore necessary to ensure compliance with both the effective dose limit and the equivalent dose limits.

There was considerable discussion of the dose limits for employees during the development of **the UK IRR99**. Although there was general preference for retention of an annual dose limit and, because restriction of exposure remained

the main requirement of the regulations, worker exposure was already generally well below the new limits, a minority of employers was reluctant to lose the opportunity for the flexibility offered by a five-year limit. The agreed compromise was, therefore:

- annual dose limits; but
- where an employer was able to demonstrate that, for a particular employee, the annual effective dose limit of 20 mSv was impracticable because of the nature of that person's work, the five-year dose limit could be applied. Various conditions were attached to use of this flexibility, including consultation with the affected employee and giving prior notice to the regulator (who could override the employer's decision). Note: the flexibility has been rarely, if ever, used.

The dose limits for other persons in the UK IRR99 reflected the directive provision for five-year averaging of the annual limit on effective doses of 1 mSv in a year in special cases. It was thought that this special flexibility could be necessary for hospitals and clinics where radiopharmaceuticals were administered to patients. These employers would need to take into account the possibility that members of the public might receive an exposure approaching a dose limit from such patients. This could affect the intended date of release from the hospital or clinic and the nature of the written instructions given to patients on discharge.

It should be noted that exposure of the public was generally constrained through authorisations for the use and disposal of radioactive substances made under different legislation.

Dose limitation for women of reproductive capacity, also pregnant and breastfeeding women, is discussed in Section 7. Planned special exposures are considered in Section 10.



## II.6. CONDITIONS OF WORK AND CLASSIFICATION OF WORKPLACES

### **The 1980 BSS Directive and UK IRR85**

**The 1980 BSS Directive** contained fundamental principles governing operational protection of exposed workers thus:

“Operational protection of exposed workers shall be based on the following principles:

- (a) classification of places of work into different areas;
- (b) classification of workers into different categories;
- (c) implementation of control measures and monitoring relating to these different areas and to the different categories of workers.”

Working areas where the doses were not liable to exceed one-tenth of the annual dose limits for exposed workers did not require any special arrangements for the purposes of radiation protection.

Working areas where the doses were likely to exceed one-tenth of the annual dose limits required arrangements appropriate to the nature of the installation and sources and to the magnitude and nature of the hazards. The directive adopted and reflected the ICRP concepts of controlled and supervised areas and specified monitoring, etc., requirements for each.

The aim of the ICRP concepts of working conditions A and B was ensured by classifying exposed workers as either:

- Category A: those who were liable to receive a dose greater than three-tenths of one of the annual dose limits and who would therefore be subject to individual dose assessment and specific medical classification and surveillance; or
- Category B: those who were not liable to receive this dose.

Exposed workers were to be informed of the health risks involved in their work, the precautions to be taken and the importance of complying with the technical and medical requirements, and were to be given appropriate training in the field of radiation protection.

**The European Commission's Communication on the 1980 BSS Directive** commented: "The practical procedures for classifying working areas and exposed workers are intended to simplify working arrangements and to ensure that workers are aware both of their own status and of the likely conditions in their places of work. The procedures are particularly useful in protecting workers who do not work all the time in a single workplace, e.g. cleaners, maintenance workers and specialist advisers."

**The UK IRR85** somewhat expanded on the directive provisions for controlled and supervised areas through specific requirements for local rules, supervision and radiation protection supervisors. Employees were designated as classified workers using the directive criteria for category A workers. It was seen as essential to consider the potential dose in any given set of circumstances. According to the **Approved Code of Practice** supporting IRR85: "It should be assumed that persons who work with large sources of ionising radiation (i.e. sources that are capable of exposing a person to the equivalent of an overdose within a few minutes) will need to be classified albeit that calculations on the basis of strict adherence to local rules indicate that doses in excess of three-tenths of any relevant dose limit would not occur." Generally, employees could only be declassified at the end of a calendar year.

The regulations did not include a specific equivalent of a category B worker.

#### **The 1996 BSS Directive and UK IRR99**

**The 1996 BSS Directive** did not directly reflect the ICRP's changed definitions for controlled and supervised areas, defining them as follows:

- "Controlled area: an area subject to special rules for the purpose of protection against ionising radiation or of preventing the spread of radioactive contamination and to which access is controlled."
- "Supervised area: an area subject to appropriate supervision for the purpose of protection against ionising radiation."

Workplaces were to be classified into different areas, where appropriate, by reference to an assessment of the expected annual doses and the probability and magnitude of potential exposures.

**The European Commission's Communication on the 1996 BSS Directive** did, however, comment that: "Controlled areas should be established where workers are required to follow rules specially related to radiological protection rather than simply on the basis of a defined fraction of the dose limit. Special rules are required based on considerations of radiological risk, including expected dose to workers, possible spread of contamination and potential exposures."

The directive also retained the distinction between category A and category B workers, amending the criteria to take account of the lower dose limits. As the communication explained: "It is intended to simplify working arrangements and to ensure that workers are aware both of their own status and of the likely conditions in their place of work. It also contributes to ensure that radiation protection arrangements for workers are appropriate to the risks linked with their work and working conditions."

**The UK IRR99** moved away from the prescriptive approach in IRR85 to a more goal-setting requirement for designating areas, relying more on the judgment of the Radiation Protection Adviser (qualified expert) and allowing employers more flexibility. However, to assist smaller employers in particular, clear criteria or reference levels were included, which would remove the need for a detailed prior assessment in straightforward cases. Thus the regulations required:

"Every employer shall designate as a controlled area any area under his control which has been identified by an assessment made by him ... as an area in which:

- (a) it is necessary for any person who enters or works in the area to follow special procedures designed to restrict significant exposure to ionising radiation in that area or prevent or limit the probability and magnitude of radiation accidents or their effects; or
- (b) any person working in the area is likely to receive an effective dose greater than 6 mSv a year or an equivalent dose greater than three-tenths of any relevant dose limit..."

"An employer shall designate as a supervised area any area under his control, not an area designated as being a controlled area:

- (a) where it is necessary to keep the conditions of the area under review to determine whether the area should be designated as a controlled area; or
- (b) in which any person is likely to receive an effective dose greater than 1 mSv a year or an equivalent dose greater than one-tenth of any relevant dose limit..."

The Approved Code or Practice supporting IRR99 contained the following practical guidance on when “special procedures” were likely to be necessary:

“Special procedures should always be necessary to restrict the possibility of significant exposure, and therefore employers should designate controlled areas, in cases where:

- (a) the external dose rate in the area exceeds 7.5  $\mu\text{Sv}$  per hour when averaged over the working day;
- (b) the hands of an employee can enter an area and the 8-hour time average dose rate in that area exceeds 7.5  $\mu\text{Sv}$  per hour;
- (c) there is a significant risk of spreading radioactive contamination outside the working area;
- (d) it is necessary to prevent, or closely supervise, access to the area by employees who are unconnected with the work with ionising radiation while that work is under way; or
- (e) employees are liable to work in the area for a period sufficient to receive an effective dose in excess of 6 mSv a year.

In addition, an area should be designated as a controlled area if the dose rate (averaged over a minute) exceeds 7.5  $\mu\text{Sv}$  per hour and:

- (a) the work being undertaken is site radiography; or
- (b) employees untrained in radiation protection are likely to enter that area, unless the only work with ionising radiation involves a radioactive substance dispersed in a human body and none of the conditions in the previous paragraph apply.”

Both employers and regulators have had some difficulty with the flexibility, seen more as imprecision, of defining the criterion for classification of an area by the need for special procedures.

The approach to classification of employees matched that in the directive and was basically unchanged. Guidance reminded employers of the special restrictions on working conditions for women who had declared themselves to be pregnant or were breastfeeding and of the additional dose limit for women of reproductive capacity.

## **II.7. PREGNANT WORKERS (ALSO WOMEN OF REPRODUCTIVE CAPACITY AND BREASTFEEDING WORKERS)**

### **The 1980 BSS Directive and UK IRR85**

**The 1980 BSS Directive** contained additional dose limits for women as follows:

“For women of reproductive capacity, the dose to the abdomen shall not exceed 13 mSv (1.3 rems) in a quarter.

As soon as pregnancy is declared, measures shall be taken to ensure that exposure of the woman concerned in the context of her employment is such that the dose to the foetus, accumulated over the period of time between declaration of pregnancy and the date of delivery, remains as small as is reasonably practicable and in no case exceeds 10 mSv (1 rem). In general, this limitation can be achieved by employing the women in working conditions appropriate to category B workers.”

Additionally: “Nursing mothers shall not be employed on work involving a high risk of radioactive contamination: if necessary, a special watch will be kept for bodily radioactive contamination.”

Planned special exposures should not be permitted for women of reproductive capacity.

**The UK IRR85** contained dose limits for the abdomen of:

- a woman of reproductive capacity at work (13 mSv in any consecutive three-month interval); and
- a pregnant woman at work (10 mSv during the declared term of pregnancy).

Information, instruction and training requirements included a duty on the employer to ensure that “those of his employees who are engaged in work with ionising radiation and who are women are informed of the possible hazard

arising from ionising radiation to the foetus in early pregnancy and of the importance of informing the employer as soon as they discover they have become pregnant.”

There was some concern that protection of the foetus, achieved through these additional dose limits, only took account of external radiation. Employers were therefore advised, though not legally required, to take special care to restrict intake when a pregnant woman was exposed to a dispersible radioactive substance.

**The Approved Code of Practice supporting IRR85** advised, in the context of classification of workers: “Where dose rates to the abdomen appear to be such that any female employee might receive more than 13 mSv in any consecutive period of three months, then the employer should, in consultation with his radiation protection adviser, make every effort to control exposure so that doses are received more uniformly and do not reach this level. Only if the radiation protection adviser advises that this cannot reasonably be achieved does the question of whether the employee is a woman of reproductive capacity become important in deciding whether she can be exposed in those particular circumstances.” In the context of medical surveillance it said: “When dose rates to the abdomen are not likely to exceed 13 mSv in any three-month interval and the employer has completed the relevant part of the health record to that effect before each review, the question of whether that employee is a woman of reproductive capacity does not arise for the purpose of medical surveillance.”

#### **The 1996 BSS Directive and UK IRR99**

Limitation of doses in **the 1996 BSS Directive** included special protection during pregnancy and breastfeeding (to be applied also to female air crew):

1. “As soon as a pregnant woman informs the undertaking, in accordance with national legislation and/or national practice, of her condition, the protection of the child to be born shall be comparable with that provided for members of the public. The conditions for the pregnant woman in the context of her employment shall therefore be such that the equivalent dose to the child to be born will be as low as reasonably achievable and that it will be unlikely that this dose will exceed 1 mSv during at least the remainder of the pregnancy.
2. As soon as a nursing woman informs the undertaking of her condition she shall not be employed in work involving a significant risk of bodily radioactive contamination.”

Pregnant women and breastfeeding women who were likely to be bodily contaminated were excluded from specially authorised exposures. Information and training for women should include: “the need for early declaration of pregnancy in view of the risks of exposure for the child to be born and the risk of contaminating the nursing infant in case of bodily radioactive contamination”.

**The UK IRR99**, under restriction of exposure rather than dose limitation, required that:

- (a) “in relation to an employee who is pregnant, the conditions of exposure are such that, after her employer has been informed of the pregnancy, the equivalent dose to the foetus is unlikely to exceed 1 mSv during the remainder of the pregnancy; and
- (b) in relation to an employee who is breastfeeding, the conditions of exposure are restricted so as to prevent significant bodily contamination of that employee”.

The dose limit for the abdomen of a woman of reproductive capacity at work was 13 mSv in any consecutive period of three months.

The definition of a woman of reproductive capacity caused much discussion (raised as an equal opportunities matter), the issue being whether the appointed doctor should be required, or allowed, to take account of efforts an individual woman might be making to avoid conception. The agreed compromise was that an appointed doctor would only need to consider whether a woman was of reproductive capacity, and therefore subject to the additional dose limit, if her working conditions made it likely that that she would receive a dose to the abdomen exceeding 13 mSv in any consecutive three-month period and her employer had made an entry in her health record to that effect.

## II.8. EXCLUSION AND EXEMPTION FROM REGULATORY CONTROL

### The 1980 BSS Directive and UK IRR85

The scope of **the 1980 BSS Directive** was defined: “This Directive shall apply to the production, processing, handling, use, holding, storage, transport and disposal of natural and artificial radioactive substances and to any other activity which involves a hazard from ionising radiation.” Unsurprisingly, there was no mention of exclusion or exemption from regulatory control.

In **the UK IRR85** this scope was incorporated in the definition of work with ionising radiation:

“Work with ionising radiation” means any work:

- (a) involving the production, processing, handling, use, holding, storage, moving, transport or disposal of any radioactive substance;
- (b) involving the operation or use of any radiation generator [itself defined as “any apparatus in which charged particles are accelerated in a vacuum vessel through a potential difference of more than 5 kilovolts (whether in one or more steps) except an apparatus in which the only such generator is a cathode ray tube or visual display unit which does not cause under normal operating conditions an instantaneous dose rate of more than  $5 \mu\text{Sv h}^{-1}$  at a distance of 50 mm from any accessible surface”]; or
- (c) in which there is any exposure of a person to an atmosphere containing the short-lived daughters of radon 222 at a concentration in air, averaged over any 8 hour working period, of greater than  $6.24 \times 10 \text{ Jm}^{-3}$  (0.03 working levels [defined as ‘the special unit of potential alpha energy concentration in air, and is any combination of short-lived daughters of radon 222 in unit volume of air such that the total alpha energy concentration for complete decay to lead 210 is  $2.08 \times 10^{-5} \text{ Jm}^{-3}$ ’]).”



## **The 1996 BSS Directive and UK IRR99**

**The 1996 Directive** recognised the concept of clearance for disposal, recycling or reuse, defining clearance levels as: “values, established by national competent authorities, and expressed in terms of activity concentrations and/or total activity, at or below which radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorisation may be released from the requirements of this Directive”.

The directive included criteria for exempting a practice from the requirement to report (notify the competent authorities of the intention to carry out that practice). Although exemption from the requirements of the directive (as opposed to the requirement to report) was not mentioned in the directive, it is interesting to note that **the European Commission’s Communication on the 1996 Directive** contained the statement, hidden away in the remarks on the clearance provisions: “On the other hand, exemption from reporting according to Article 3(2) refers to material which does not need to become subject to regulatory control.”

**The UK IRR99** essentially reproduced the directive requirements for reporting, including the criteria for exemption from reporting. They also contained provisions for exemption certificates:

- “(1) Subject to paragraph (2), the Executive [Health and Safety Executive, the competent authority] may, by a certificate in writing, exempt:
  - (a) any person or class of persons;
  - (b) any premises or class of premises; or
  - (c) any equipment, apparatus or substance or class of equipment, apparatus or substance, from any requirement or prohibition imposed by the Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.
- (2) The Executive shall not grant an exemption unless, having regard to the circumstances of the case and in particular to:
  - (a) the conditions, if any, which it proposes to attach to the exemption; and
  - (b) any other requirements imposed by or under any enactments which apply to the case, it is satisfied that:

- the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and
- compliance with the fundamental radiation provisions underlying regulations... will be achieved.”

NOTE: Authorisation for the use and disposal of radioactive substances and exemption/clearance are covered by other UK legislation.

## II.9. EMERGENCIES

### The 1980 BSS Directive and UK IRR85

The **1980 BSS Directive** made provision for planned special exposures, for use in exceptional circumstances during normal operations when alternative techniques which did not involve such exposure could not be used. Their use was subject to various conditions including authorisation and a ceiling in any year of twice the annual dose limits or, in a lifetime, five times the dose limits. Exceeding a dose limit because of a planned special exposure should not in itself be a reason for excluding the worker from his usual occupation, but subsequent conditions of exposure were subject to the agreement of the approved medical practitioner.

Although planned special exposures were not incorporated in the **UK IRR85**, the principle that it was not appropriate to automatically exclude an overexposed employee from further work with ionising radiation during the remainder of the relevant calendar year was recognised. The regulations therefore made specific provision for dose limitation for overexposed employees, subject to conditions. An employer could allocate a new, *pro rata*, dose limit for the remainder of the calendar year in which that employee had been overexposed (“The employer shall ensure that an employee ... does not, in the remaining part of the calendar year in which he was subjected to the overexposure, receive a dose of ionising radiation greater than that proportion of any dose limit which is equal to the proportion that the remaining part of the year bears to the whole calendar year”). The conditions were:

- (a) The provisions relating to investigation and notification of overexposure should have been fully complied with.
- (b) The work was performed in accordance with any conditions imposed by an employment medical adviser or appointed doctor.

### The 1996 BSS Directive and UK IRR99

The **1996 BSS Directive** again made provision for planned special exposures, now termed specially authorised exposures. Maximum exposure

levels resulting from specially authorised exposures were to be defined for each particular case by the competent authorities, but no ceiling was given for such levels as it might be interpreted as a generally tolerable level.

Under the section on intervention, it also made provision for emergency occupational exposures. It was left to individual Member States to establish relevant exposure levels; an exposure above these special levels could be allowed exceptionally to save human lives, but only for volunteers who had been informed of the risks involved in their intervention.

The **UK IRR99** again eschewed planned special exposures. However, the **Radiation Emergency Preparedness and Public Information Regulations 2001 (REPPIR)** implemented the articles on intervention in the 1996 BSS Directive. They set out a framework for controlling the exposure of employees who were required to intervene in the event of a radiation emergency, defined as an event that was likely to result in a member of the public receiving an effective dose of 5 mSv during the year immediately following the emergency, e.g. to save a life or prevent a large number of people being exposed. During intervention, these employees might receive a dose of ionising radiation in excess of the dose limits in IRR99, termed an “emergency exposure”; they were only permitted for authorised employees who had received appropriate information and training and were properly equipped.

## **II.10. NON-ICRP ISSUES INTRODUCED INTO THE REGULATIONS**

Several significant legislative changes arose not from the ICRP recommendations but from provisions in directives responding to other influences (such as, but not only, concerns expressed by the European Parliament).

### **Approved dosimetry services**

Pre-**IRR85**, employers maintained records of personal doses. This changed, in line with the **1980 BSS Directive** provisions, to requiring employers to use one or more approved dosimetry services to assess the doses received by employees and keep the dose record. This required the regulator to set up an approval system and the dosimetry services to prepare the necessary documentation, etc., for a successful application for approval. The purpose of the approval system was to ensure, as far as possible, that doses were assessed on the basis of accepted national standards. Initially there was no charge for approval, but fees were later introduced.

The approvals system has become more complex over the years, with separate applications being necessary for external radiations, internal radiations and co-ordination and record-keeping. The **Radiation Emergency Preparedness and Public Information Regulations 2001** (REPPPIR) brought in requirements for separate assessment and recording of emergency exposures.

A Central Index of Dose Information was established in 1987 as a national database of dose information. It holds annual summaries of recorded radiation doses for classified persons, used to generate statistical information for the regulator published in regular reports, and facilitates cross-referencing when a classified person changes employer.

### **Radiation protection adviser**

The **1980 BSS Directive** required the use of “qualified experts” in certain situations and for them to be “recognised” by the competent authority. The main qualified expert in the United Kingdom was the radiation protection adviser. Recognition of the radiation protection adviser was achieved under the **UK IRR85** by notification of intention to appoint. Such appointments were new for

factories but not for licensed nuclear establishments nor, in practice, for hospitals or universities since they already made equivalent appointments.

The **1996 BSS Directive** contained similar provisions but an annex to the **European Commission's Communication on the Directive**, published in 1998, contained advice on the training and experience of the qualified expert. Recognising a wide diversity in the approaches of Member States it proposed, *inter alia*, a basic syllabus that all qualified experts should have received. In response to this, also to meet smaller employers' need for a more transparent system that would help them choose a suitable person and reflecting the conclusions of a qualified experts workshop in 1993, a more structured approach to recognition was taken in the **UK IRR99**, which defined a radiation protection adviser as "... an individual who, or a body which, meets such criteria of competence as may from time to time be specified in writing by the Executive [the regulator]". Criteria, for applicants for certification of competence and for assessing bodies who would consider the applications and issue the certificates, were set out in a statement on radiation protection advisers issued by the regulator.

### **Radiation passbooks**

A daughter directive of the 1980 BSS Directive, adopted in 1990, on the protection of outside workers (employees who work in other employers' controlled areas), was implemented in the United Kingdom by the Ionising Radiations (Outside Workers) Regulations 1993; the provisions were subsequently reviewed, simplified where appropriate and subsumed into the IRR99. The provisions required the use of a radiation passbook (a document approved by the regulator and issued by approved dosimetry services) to carry identifying details of the outside worker and information about the assessed and estimated doses received by that worker. Before an outside worker went to work in another employer's controlled area his employer had to enter, or update, the medical classification and dose assessment information in that worker's radiation passbook. The other employer had to put an estimate of the dose received by the outside worker, while in that other employer's controlled area(s), in the radiation passbook.

## **II.11. SUMMARY OF THE IMPACT OF CHANGES: EURATOM BSS DIRECTIVES 1980 TO 1996 AND UK IRR85 TO IRR99**

It took the United Kingdom ten years and three formal consultative documents to first implement an Euratom BSS Directive, originally aiming to implement the 1976 BSS Directive and finally implementing the 1980 Directive (as amended in 1984), primarily through the Ionising Radiations Regulations 1985 (IRR85). This was a significant development, though existing standards of radiological protection in the United Kingdom were seen as largely consistent with the ICRP's recommendations. The main task had been to integrate the Directive's detailed requirements with those of the existing regulations, licence conditions and non-statutory codes of practice to make regulations that, for the first time in the United Kingdom, covered all work activities involving exposure to ionising radiations including natural radiation sources (principally radon). The UK's consultation process, whereby all interested parties were involved in the development of regulations and guidance, meant that the end products were generally accepted as reasonable and workable (though not necessarily popular).

The most significant issues, in terms of effort and likely costs, were seen as:

- The extension of legislation: to cover all occupational exposure to ionising radiation, though not all the provisions applied to exposure to radon.
- The ALARA investigations: when an employee's whole body dose exceeded 15 mSv for the first time in a calendar year.
- New dose limits: lower than the maximum doses of external radiation permissible under most of the previous legislation (though relatively few employees were thought to receive doses above the new limits).
- Designation of areas: while factories, nuclear licensed sites and research and teaching establishments already worked under similar legal requirements or codes of practice, and for them conversion from the old to the new was seen as relatively straightforward, for those where no comparable provision had been made, such as in hospitals and medical practices, the necessary work was likely to be substantial.
- Radiation protection advisers: use and "recognition". Such appointments were new for factories but not for licensed nuclear

installations nor, in practice, hospitals and universities since they already made equivalent appointments. The value of the services the radiation protection adviser would perform in helping the employer to carry out the various requirements of the regulations was seen as offsetting at least some of any additional costs.

- Classification of workers: fewer employees needed to be classified than under existing regulations and codes, provided that schemes of work were drawn up and operated for those whose exposure was limited, but in practice declassifying workers tended to be perceived as a reduction in protection and the flexibility was not widely used. Costs mainly stemmed from dosimetry, record-keeping and medical surveillance.
- Instruction and training: the initial effort was significant, training staff in the new requirements and making arrangements for compliance, also purchasing copies of the Regulations, Approved Code of Practice and relevant guidance notes.
- Dosimetry and record-keeping: in particular, the different basis for assessing internal dose had cost implications, also the need to use approved dosimetry services.

However, early fears about the effects of the regulations, particularly felt by those who had not previously been subject to any radiation protection legislation, were generally proved to be unfounded. For example, before IRR85 were made the tin mining industry was convinced that they could not comply with the annual dose limit for workers. Even the relevant Inspectorate shared the doubts and a special exemption was prepared to allow an element of averaging over the first few years. In the event compliance was achieved in the first year and the exemption was never issued.

The regulator's mantra for the **change from IRR85 to IRR99** was "evolution not revolution". The main differences were:

- prior authorisation: introduced for certain users of X-ray sets and accelerators;
- risk assessment: building on the existing requirement in other, general management of health and safety, regulations;
- enhanced requirements to keep exposures as low as reasonably practicable;
- lower dose limits: though doses received were generally already below these limits because of interim action taken after the ICRP's 1987 "Como" statement;



- radiation protection advisers: new, explicit, requirements for “recognition”, involving formal certification of an individual’s core competence plus a duty on the employer to consider the individual’s suitability for that employer’s needs, also specification of when a suitable (certificated) radiation protection adviser should be consulted;
- designation of areas: more flexibility for designating controlled or supervised areas and modified requirements for those areas;
- classified persons: modified requirements for designation of classified persons, for assessing and recording their doses and for medical surveillance.

The regulator took great pains to engage stakeholders during the development of IRR99. The efforts included the establishment of 11 topic groups, including internal and external stakeholders, to help develop ideas for the revision of IRR85 and implementation of the 1996 BSS Directive. During the consultation period a series of one-day presentations (including discussion and questions) was held around the country; plus shorter presentations to specific groups including trade union representatives. This helped both sides to understand the true implications of the proposals and gave advance warning of some of the fine-tuning that would be necessary as a result of the consultation to make the final regulations acceptable.

**Table 11. Comparison of protection provisions between IRR85 and IRR99**

<b>Provision</b>	<b>IRR85</b>	<b>IRR99</b>
Application	Work with ionising radiation, including exposure to the short-lived daughters of radon 222.	Practices; work in radon atmospheres at concentrations above a specified level; and work with materials containing naturally occurring radionuclides.
Authorisation	None.	For certain users of x-ray sets and accelerators.
Prior risk assessment	None.	General requirements already existed in other legislation, but specifically no new activity involving work with ionising radiation could begin until a risk assessment had been made.

Table 11. Comparison of protection provisions between IRR85 and IRR99  
(continued)

Provision	IRR85	IRR99
Restriction of exposure	By means of engineering controls and design features; in addition, systems of work and, where appropriate, adequate and suitable personal protective equipment (including respiratory protective equipment); restrictions on handling sources; investigation when employee received 3/10ths of whole body dose limit (15 mSv) for first time in calendar year; [ACOP] restriction on nursing mothers to minimise bodily radioactive contamination.	As IRR85 but enhanced; investigation at 15 mSv or lower dose specified by employer; use dose constraints where appropriate, at planning stage; for pregnant employees, equivalent dose to foetus to be unlikely to exceed 1 mSv during remainder of declared pregnancy; for breastfeeding employee, restrict exposure to prevent significant bodily contamination.
Dose limits	Whole body adult effective dose equivalent: 50 mSv in any calendar year; other limits also, as Directive/ICRP.	Reduced: whole body adult effective dose: 20 mSv in any calendar year; OR where this limit is demonstrably impracticable for an individual, 100 mSv in any period of five consecutive years, max. 50 mSv in any one calendar year, plus conditions; in either case, other limits as per directive/ICRP.
Radiation protection adviser	Appointment needed where: any employee exposed to instantaneous dose rate exceeding 7.5 µSv/h; or controlled area designated which persons entered. Recognition through notification of intention to appoint.	System of recognition of core competence introduced, circumstances where suitable RPA should be consulted specified.
Designation of areas	Controlled and supervised areas defined on prescriptive basis of dose rate or potential contamination levels.	More goal-setting requirements introduced, giving additional flexibility: controlled area – where special procedures needed to restrict significant exposure or prevent or limit probability and magnitude of radiation accidents; supervised area – where necessary to keep conditions under review in case should be controlled area. But alternative simple criteria: controlled area – exposure likely to exceed 6 mSv/y; supervised area – 1 mSv/y.
Classification of persons	Classified workers: aged over 18 years and likely to receive more than 3/10ths of any dose limit.	Classified workers: over 18 and likely to exceed 6 mSv/y or 3/10ths of any dose limit.
Local rules and radiation protection supervisors	Local rules and appointment of one or more radiation protection supervisors required for any work with ionising radiation.	Greater flexibility: local rules only required for work in a controlled area and any other area where appropriate. Duty to appoint radiation protection supervisors restricted to situations where local rules required.

## **PART II.B**

# **REGULATORY IMPLICATIONS**

### **Publication 60 to Publication 103**

An official draft revised BSS directive has not yet been published (as at the time of writing, December 2010) so the implications for regulators of the change from Publication 60 to Publication 103 can only be surmised but, for the United Kingdom, they draw on advice on Application of the 2007 Recommendations of the ICRP to the United Kingdom published by the Health Protection Agency.<sup>8</sup> The European Commission's stated intent is to propose new text only where necessary to address new or significantly revised ICRP recommendations. If this is achieved then much of the finally adopted directive should be unchanged from the 1996 BSS and linked directives and the regulatory impact should be relatively limited. But only time will tell and much can change during negotiations. Publication 103 saw no need for fundamental changes concerning biological risk therefore it seems reasonable to assume that there are no implications for either the revised BSS directive or for national legislation.

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8. The Health Protection Agency (HPA) advises UK bodies with responsibility for protection against radiation on the applicability to the United Kingdom of recommendations issued by the International Commission on Radiological Protection (ICRP). The advice quoted in this report has been reproduced with permission from the Health Protection Agency.



## II.12. BASIC DOSIMETRIC QUANTITIES

### Radiation and tissue weighting factors

The revised BSS directive (and thus national legislation) is likely to adopt the ICRP's revised weighting factors, though the quantities can remain unchanged in line with Publication 103. According to advice from the UK Health Protection Agency (HPA), the abandonment of a step function for neutron weighting factor  $W_R$  as a function of energy is a reflection of the fact that in practice only a continuous function was used. The introduction of a  $W_R$  for charged pions is expected to have a small impact on effective dose in the space environment and also around high energy accelerators.

### Collective dose

Collective dose was not mentioned either in the 1996 BSS Directive or in the UK IRR99 (though it was mentioned *en passant* in UK guidance relating to dose constraints: "... a dose constraint should help to filter out options for radiation protection that could lead to unreasonably high levels of individual dose, even though the collective dose for the workforce as a whole is optimised").

Although the UK Health Protection Agency believes that the concept of collective dose remains a useful tool for operational radiological protection, particularly in the planning of complex work involving multiple workers, it seems unlikely that the revised BSS directive or, therefore, the UK legislation will include specific mention. Nevertheless, the HPA recognises that, although the process of optimisation does not explicitly take account of a cost for unit collective dose, there appears to be support in the United Kingdom for the use of a monetary value. The HPA will therefore consider initiating a programme of work on this topic.

### **II.13. PHILOSOPHY OF PROTECTION**

The three types of exposure situation (planned, emergency and existing) now adopted by the ICRP are likely to be reflected in the revised BSS directive and subsequent national legislation. They may indeed be easier concepts to understand and use than were practices and interventions, although “practice” may be retained as a type of activity within a planned exposure situation.

The retention of the three principles of radiological protection (justification, optimisation and dose limits) and the three categories of exposure (occupational, public and medical) is welcome continuity.

## **II.14. OPTIMISATION: DOSE CONSTRAINTS AND REFERENCE LEVELS**

It seems likely that the revised BSS directive will give greater prominence to the use of dose constraints for occupational and public exposure and for medical exposure, as well as reference levels for emergency and existing exposure situations, as tools in optimisation. If it is intended that both employers and competent authorities should be involved in the selection of appropriate values for dose constraints for occupational exposures, then this could have significant implications for both. In the United Kingdom the current guidance on the use of dose constraints, which are seen as merely one of many tools for helping to restrict individual exposures as far as reasonably practicable (ALARP, the UK equivalent to ALARA), leaves such decision-making to the employer. The situation for public exposure is different, in that the competent authority already builds in the concept of constraints in permits for the keeping and use of radioactive materials and the accumulation and disposal of radioactive waste.

It is to be hoped that it will be possible to maintain a proper balance between the use of constraints and the, well established and understood, ALARA concept.

## **II.15. DOSE LIMITS**

The dose limits recommended in Publication 103 are unchanged from those in Publication 60. However, even if the primary dose limit for exposed workers in the revised BSS directive becomes 20 mSv a year, as opposed to 100 mSv in any five-year period (subject to a maximum of 50 mSv in any single year) in the 1996 Directive, it is likely that some flexibility to allow averaging will be retained. This would mean that national legislations could remain unchanged if the Member States so desired.

It is doubtful if the opportunity to average the dose limit for members of the public over five years in special circumstances, currently in the 1996 BSS Directive, will be retained. This might require a change to any national legislation that reflects this flexibility (not the UK IRR99).



## **II.16. EMERGENCY AND EXISTING SITUATIONS (RADON)**

The 1996 BSS Directive included requirements relating to emergency preparedness and the use of appropriate intervention levels, established by the competent authorities, within appropriate intervention plans. As the revised BSS directive will consolidate the 1996 BSS and daughter directives, it is likely that relevant provision from the Public Information and HASS Directives will be incorporated within the requirements for emergency planning and management. The overall requirements may not need to change significantly, apart from reflecting the new terminology (which includes the move to three types of dose: residual, projected and averted), in which case the implications for national legislation may be limited.

The advice from the UK Health Protection Agency on emergency exposure situations is that the 2007 recommendations of the ICRP reflect a refocusing of the underlying philosophy of radiological protection regarding emergencies. Formerly, the ICRP recommended the consideration and optimisation of different protective actions separately. In its new advice, the ICRP also advocates optimisation of the overall response strategy. Furthermore, it recommends that this optimisation of the overall strategy be carried out in the context of optimisation below a reference level of dose. The ICRP has also highlighted the importance of planning for changes in the emergency situation, as the characteristics of the situation evolve.

The HPA judges that the practical implementation of the ICRP extensions to its previous advice does not require substantial or immediate revision of the UK emergency preparedness arrangements. Rather, it considers that the publication of the 2007 recommendations provides an opportunity for considered re-appraisal of the UK arrangements.

### **Radon**

The 1996 BSS Directive began to gently introduce provisions relating to exposure to radon, described in the European Commission's communication on the Directive as:

“... a four-step system to deal with exposures due to natural radiation sources:

- i. the use of surveys or other appropriate means to identify work activities which may lead to a significant increase in the exposure of workers or members of the public;
- ii. the setting-up of appropriate means for monitoring exposures, and the evaluation of the related doses in identified workplaces;
- iii. the implementation, as necessary, of corrective measures to reduce exposure;
- iv. in total or partial application, as necessary, of radiation protection measures for practices...”

The 1996 BSS Directive specifically did not apply to exposure to radon in dwellings.

The section on existing exposure situations in the revised BSS directive is likely to be significantly more explicit in respect of exposure to radon. A radon action plan is likely to be required, covering exposure to radon in dwellings, public buildings and workplaces from all sources (soil, building materials or water) and the European Commission may require sight of such plans and information on identified radon-prone areas.

It is likely that Publication 103’s recommended entry level of 1 000 Bq m<sup>-3</sup> for occupational radiological protection requirements will appear in the revised directive, though Member States may be encouraged to decide their own reference levels for indoor workplace radon concentrations below that maximum value. These requirements would be broadly similar to those in the UK IRR99, although those provisions would have to be extended if measurements were to be required for all workplaces in radon-prone areas. For Member States whose current occupational radiation protection legislation does not include exposure to radon, the implementation implications of any such directive requirements could be considerable.

## **II.17. PROTECTION OF THE ENVIRONMENT**

Unsurprisingly, the 1996 BSS Directive did not contain any requirements relating explicitly to protection of the environment. It is, however, likely that the revised BSS directive will make specific provision for protection of non-human species in the environment. Such requirements should not impact significantly, if at all, on occupational radiation protection, though they will need to be taken into account in the context of permits for radioactive waste disposal. Although the explicit consideration of protecting the environment is new to radiation protection, the topic is not new generally and it is likely that much national legislation already makes provision for this to a greater or lesser extent. In the United Kingdom, the Environment Agency is required to consider the need for assessments of potential radiation doses to flora and fauna when considering applications for permits. Nevertheless, depending on the actual requirements, current national provisions might need to be amended and, particularly, in respect of radioactive effluents, it might be desirable to demonstrate in some fashion that both human and non-human species have been considered in the context of optimisation of protection.

## **II.18. NON-ICRP DEVELOPMENTS**

### **Radiation protection expert and radiation protection officer**

Much work has been done at European level to clarify the nature of the role, the required level in terms of expertise, and the required functions of the BSS directive qualified expert (QE). The First European Platform on Education and Training in Radiation Protection (EUTERP) Workshop, held in May 2007, concluded that a revised definition was needed. It also concluded that a revised BSS directive should include a definition of the Radiation Protection Officer (RPO), a role that is not mentioned in the 1996 BSS Directive although it is defined in the International BSS. Most EU Member States incorporate RPOs into their radiation protection arrangements (for example, the United Kingdom has the radiation protection supervisor [RPS]). The second EUTERP Workshop, in 2008, endorsed this conclusion, agreeing to recommend to the European Commission that the old definition of the qualified expert should be replaced by a new definition for the RPE and that another new definition, for a radiation protection officer, should be added.

## II.19. SUMMARY OF POTENTIAL CHANGES – REGULATORY IMPLICATIONS

The revised BSS directive is likely to adopt most of the changes recommended in Publication 103. Generally, the implications should not be great for those who have implemented the 1996 BSS and linked Directives. In relation to occupational exposure, expanded requirements for dose constraints and exposure to radon are likely to be the most significant.

The revised BSS directive may well contain other changes that will have implications for Member States, but they will not necessarily emanate from the ICRP’s recommendations.

**Table 12. Comparison of protection provisions between the 1996 and possible revised BSS Directives**

Provision	1996 BSS Directive	Possible revised directive
System of protection	As Publication 60 – process-led: practices and interventions.	As Publication 103 – situation-led: planned (within this: occupational, medical and public), emergency and existing exposure situations.
Optimisation – dose constraints	Should be used, where appropriate.	Greater emphasis on use, possible involvement of competent authority in selecting appropriate values.
Dose limits – whole body exposed worker	100 mSv in any five years, max. 50 mSv in any single year, MSs can decide an annual amount.	Possible presentational change to 20 mSv a year, with some flexibility for averaging over five years (max. 50 mSv in any single year).
Designation of areas (where exposure may exceed 1 mSv per year)	1. <i>Controlled area</i> : “an area subject to special rules for the purpose of protection against ionising radiation or of preventing the spread of radioactive contamination and to which access is controlled”. 2. <i>Supervised area</i> : “an area subject to appropriate supervision for the purpose of protection against ionising radiation”.	No change.

Table 12. Comparison of protection provisions between the 1996 and possible revised BSS directives (*continued*)

Provision	1996 BSS Directive	Possible revised directive
Classification of people	<p>1. <i>Category A</i>: “those exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose...”</p> <p>2. <i>Category B</i>: “those exposed workers who are not classified as exposed category A workers”.</p>	No change.
Radon	Identify work activities which may be of concern; set up appropriate means for monitoring exposure and evaluating doses; as necessary, implement corrective measures to reduce exposure; and apply total or partial radiation protection measures for practices.	Expanded requirements: may include a national radon action plan for dwellings, public buildings and workplaces and reflection of ICRP recommended entry level of 1 000 Bq m <sup>-3</sup> (or lower reference levels decided by MSs) for occupational radiation protection requirements.
Education, training and information	Information: health risks of the work, particularly for pregnant and breastfeeding women. Relevant radiation protection training.	Probably enhanced provisions, perhaps requiring establishment of legislative and administrative framework for RP education, training and information and appropriate refresher and updating action.

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RADIATION PROTECTION

Giovanni Silini

BOLOGNA, Settembre 1992



**ASSOCIAZIONE ITALIANA DI PROTEZIONE  
CONTRO LE RADIAZIONI (A.I.R.P.)**

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## PRESENTAZIONE

Il premio Sievert dell'IRPA per il 1992 è stato attribuito al prof. Giovanni Silini, socio onorario della nostra Associazione.

Ciò costituisce motivo di orgoglio e di gratificazione per la radioprotezione italiana che ancora una volta ha ottenuto indirettamente un riconoscimento di prestigio a livello internazionale.

Certamente il merito maggiore va riconosciuto al vincitore del premio prof. G.Silini per il forte impegno e la qualificata professionalità dedicati alla disciplina della radioprotezione. Ritengo, comunque, che lo stesso Giovanni Silini concordi nel riconoscere che al premio ricevuto, abbia contribuito l'impegno più che trentennale dei radioprotezionisti italiani.

La nostra Associazione ha ritenuto doveroso pubblicare il testo della Sievert Lecture e di inviarlo a tutti i propri Soci, anche in virtù del suo contenuto che certamente servirà a fornire elementi chiarificatori sull'approccio generale ai problemi della radioprotezione.

Il Presidente AIRP  
G.Busuoli



## Il Sievert Award

A partire dal 1973, ciascun congresso IRPA è stato aperto dalla Sievert Lecture presentata dal vincitore del Sievert Award, premio in onore di Rolf M. SIEVERT, pioniere della fisica delle radiazioni e della radioprotezione.

Chi riceve il premio deve avere fornito notevoli e qualificati contributi nel campo della radioprotezione e presenta la Sievert Lecture all'apertura del Congresso Internazionale dell'IRPA.

Le Associazioni affiliate all'IRPA propongono le nomine per il Sievert Award ed un Comitato dell'IRPA, sotto la presidenza del vice-presidente dell'Associazione Internazionale seleziona due candidati. La decisione finale a chi attribuire il premio è del Consiglio Direttivo dell'IRPA.

I vincitori del Sievert Award sino al Congresso di Montreal sono stati:

1973: Prof. Bo Lindell (Svezia)  
1977: Prof. W.V.Meyneord (U.K.)  
1980: Dr. Lauriston S. Taylor (USA)  
1984: Sir Edward Pochin (U.K.)  
1988: Prof. Dr. Wolfgang Jacobi (FRG)  
1992: Prof. Giovanni Silini (Italia)

Il prof. Giovanni Silini ha avuto una brillante carriera nel campo della radiobiologia ed ha occupato posti di responsabilità nel settore specifico. E' stato segretario del Comitato Scientifico delle Nazioni Unite sugli Effetti delle Radiazioni Atomiche (UNSCEAR) dal 1980 al 1988.

Dal 1988 è impegnato in attività di consulenza nel campo della radiobiologia e radioprotezione sia a livello nazionale (ENEA) che a livello internazionale (UNSCEAR). E' membro della "main Commission" dell'ICRP.





# 1992 SIEVERT LECTURE

## ETHICAL ISSUES

IN

## RADIATION PROTECTION

Giovanni Silini  
Via S. Maurizio, 22 24065 LOVERE (Bergamo) Italy

### PREFACE

Contrary to those who preceded me in this series of lectures, I never knew Professor Rolf M. Sievert because when he died in 1966 I was just starting my work in animal radiation biology and only later did I become acquainted with the subject and problems of radiation protection. However, judging from what I have come to know about Sievert through his work and conversations with friends who were associated with him, this large congress of people would not have been possible without his pioneering work. In him, scientific excellence was paralleled by penetrating intuition. In a 1947 lecture in honour of Sylvanus Thompson, commenting on the fact that a new epoch, that of atomic energy, was about to come, he had the following to say: "We cannot as yet estimate what risks of injury by radiation this epoch can bring. We have, however, reason to expect that the problem of protection against injuries by ionizing radiation will be of an entirely other magnitude than hitherto, and it is probable that it will become a general social problem of prime importance". Clearly, a remarkable foresight about a discipline that has gradually flourished internationally to its present state.

The honour that IRPA has bestowed upon me by asking to deliver this lecture is in sharp contrast with the little I have achieved in radiation protection. Others, with better credentials and authority, might have done a better job. But since this burden has fallen upon me, I can only hope that what I am about to say will not be too unworthy of the person we remember and of those who paid tribute to his memory in past lectures.

## INTRODUCTION

My intention today is not that of delivering a sermon. It is simply to bring you to consider some of the ideas that underlie the principles and the numbers that we are confronted with every day in our professional life. It is to discuss the fundamental values that are implicit in our practical activities, and to verify that we have not lost touch with the principles of human respect and compassion that must inspire our work as members of a scientific community.

Radiation protection is not a fundamental science, a free intellectual re-construction of the why's and how's of nature, that may be regarded as intrinsically good, in so far as it only tends to enlarge the boundaries of human knowledge. Radiation protection is an applied discipline. Its purpose is to define the limits within which some human activities with potentially harmful consequences may safely be carried out. This requires discussion of the principles on which protection of the individuals and of the species should be based, and necessarily involves ethical considerations.

As some of you may know, ethical principles are of two kinds: there are the very general first-order ones, that is the values that should ultimately guide all choices for any action; and the more limited second-order principles, dealing mainly with the meaning and the applicability of the ethical language and the analysis of ethical concepts (Mackie 1977). Of the first set of principles, only one, perhaps, is required by radiation protection: the principle that to improve health and living conditions and thus to minimize the suffering of human beings is a good aim in itself, and therefore an objective that we ought to work for.

It is characteristic of ethical principles to be universalized, in the sense that when a principle is seen as ethically right, those who adopt the principle are committed to follow it under all relevant circumstances, irrespective of any qualitative differences of those stating, or affected by, the principle in question. A further stage in this process of universalization is to apply the principle irrespective of how individuals might vary in respect to their physical and mental qualities, resources or social status, including those individuals who will only be born in the future (Mackie 1977). Usually, radiation protection does not demand adoption of a third and more advanced stage of universalization, that of applying a principle irrespective of preferences, tastes, values or ideas.

So, except for one very general first-order principle, radiation protection does not require any other major ethical statement. In this context, therefore, morality is understood in the restricted sense of a methodology to set special constraints of conduct in the interest of those exposed to radiation to develop guidelines to restrain the selfish inclination by some agent or agents to act against such interest. This more limited function is however important in promoting the development of universally acceptable ethical behaviours.

Since radiation protection principles are meant to apply to all persons and societies, they should be sufficiently flexible to be adopted in countries with a wide spectrum of religious, political, social and economic conditions. They should also be sufficiently comprehensive to apply reasonably to all activities involving radiation exposure, even those for which exposure has a low

probability of occurrence. Finally, they should cover both present and foreseeable exposure situations.

Owing to all these requirements, it is obvious that such principles could not be derived from sets of values belonging to the cultural heritage of any particular group, but should be built on universally-shared secular values. These are, for example, the equality of rights for all human beings; the need to reasonably balance the interests of any individual against those of all others; the requirement to protect our species by preserving the material conditions for its continuation; and, finally, the right for each person to try to achieve freedom from one common heritage of the human condition, which is suffering and sorrow.

The main question I should like to discuss is: to what extent do we cover all these requirements in our particular field?

Present radiation protection doctrine (ICRP 1990) is based on a body of scientific knowledge, one underlying assumption and three general principles. My objective is to discuss first the adequacy of the existing scientific information for the purpose of setting safety standards; then to consider the foundation of the underlying assumption; and finally, to discuss a few aspects of the three general principles. All this, of course, in the light of ethical considerations.

### THE BASIC SCIENTIFIC DATA

Let me start with the scientific bases on which the system is built (Silini 1991). As you all know, we classify radiation effects into a few major groups, according to their nature and mode of expression at different dose levels. For some effects, our knowledge derives from direct experience in man, gained in many cases in an attempt to cure disease; sometimes as a result of accidents in the course of industrial activities; and in a few cases as a consequence of deliberate acts of warfare or the development of weapons.

Broadly speaking, we identify at high dose deterministic effects on cells, tissues or the whole body. These may be clinically dramatic, but are usually not too difficult to avoid, except in the course of accidents. Experience of these effects in man is large. Therefore, their prediction as a function of dose, time and radiation quality is rather well founded (UNSCEAR 1982, 1988).

At low or very low doses and dose rates effects of a different nature are seen. They are called late somatic (or stochastic) and consist in the appearance of an excess of cancer and leukaemia above the natural rate. Their existence is proven, but precise assessment of their rate of induction per unit dose is difficult in man. To this end, primary data obtained from human epidemiology must be adapted for general use to account for various dependencies on dose, dose rate, organs, age, time of induction and other variables of radiobiological interest. Recently, our understanding of all these risk-related variables has considerably increased. As a result, one feels that current estimates are more realistic than in the past and, perhaps, less likely to increase further, barring drastic changes in the projected trend of the primary data or new and unexpected findings. Of course, our knowledge of these effects is only descriptive. We still lack the understanding of the mechanisms through which cancer (and radiation-induced cancer in

particular) is brought about.

For both classes of somatic effects - the deterministic and the stochastic - there is enough experience in man, so that models of induction in animals may simply be used to fill the gaps and to generalize dose-time relationships and trends with radiation quality. This is good, because the species-specificity of many of these effects is so pronounced that it would simply be impossible to project rates of induction across species. It is acceptable, however, to use animal data in order to project general trends with dose and time or to validate mechanisms.

Unfortunately, for a third class of effects, the stochastic hereditary ones, we are still to a large extent dependent on data from experimental animals. The existence of clinically relevant hereditary effects brought about by alteration of germinal cells in man has never been demonstrated, but the absence of such evidence is not in itself a cause for reassurance nor concern. Since radiation may definitely cause such effects in many other living species and we know of no special reason why the human genome should be an exception, we must assume that the human species may also be susceptible. The best we can do, under these circumstances, is to take the estimates of hereditary effects in species that are phylogenetically near to man and try to adapt these estimates for our species, on the basis of present knowledge of human genetics. Scientifically this procedure is unsatisfactory. Ethically it is justified out of necessity, as the only possible course of action.

An important ethical issue deals with the assessment of those hereditary effects that may appear in man in the very far future. A significant step forward - at variance with previous (ICRP 1977) practice - has been taken recently by ascribing all genetic damage to the person exposed. This implies that all hereditary harm, be it the early-appearing dominant or the very long-term recessive damage, is treated in exactly the same way and given exactly the same weight. Provisionally, and until our capacity to qualify hereditary radiation effects will improve, this seems the most reasonable decision to make.

Equally unsatisfactory is our inability to account for the type of genetic disorders which are most relevant in man, the non-mendelian multi-factorial disorders. Thus, we must take note - with some disappointment - that the slight apparent reduction of radiation-induced hereditary risk estimates observed over the years is due both to a decrease in our confidence to quantify part of this damage, and to a real decrease of the overall estimates. Future progress as to the relative contribution of these two components is expected to depend critically on advancements in fundamental human genetics, rather than in radiation genetics (UNSCEAR 1986).

## THE MAIN GENERAL ASSUMPTION

The main general assumption on which radiation protection rests is that, at sufficiently small doses and dose rates, there is a non-threshold linear relationship between the dose and the probability of induction of late somatic and genetic effects. I am purposely using the word assumption because this statement cannot be scientifically demonstrated at the low doses that would be required. In fact, the relatively low incidence (per unit dose) of radiation-induced cancer and hereditary diseases is masked by a very

incidence (per unit dose) of radiation-induced cancer and hereditary diseases is masked by a very high background of other neoplastic and genetic conditions, that are unrelated with radiation exposure in excess of the natural level. This happens for two reasons. One is biological, because we have no means as yet of recognizing radiation-induced conditions from those that are caused by other agents. The second reason is statistical, because it is impossible, at the low doses and with the small populations usually available, to demonstrate the significance of a small number of supposedly radiation-induced health effects over a large number of effects of the same kind of uncertain etiology.

The implications of the non-threshold linearity assumption are clear. It postulates, in essence, that each dose of radiation, however small, has a finite probability of producing effects of the stochastic type; and that each dose increment, however minute, will increase this probability in a manner which is directly proportional to the increment. The two aspects need separate discussion.

The first aspect has to do with the absence of the threshold. Radiation protection is among the very few health-protection disciplines to postulate absence of threshold in the dose relationship for stochastic effects. In other fields of toxicology one usually identifies a level of dose that carries positive evidence of harm, and then sets the "safe" limit well below that level. Such a procedure implicitly assumes that the dose-effect relationship has some threshold below which the toxic agent is considered harmless. By excluding a threshold, radiation protection not only adheres to a probabilistic approach to risk assessment, but also implicitly refuses to consider small risks as irrelevant. In fact, even if they are sufficiently low to be of no relevance for the individual, they might not be quite so irrelevant as source-related collective risks. This is the reason why both the individual and the collective aspects of the risk must be considered in any assessment.

**Going now to the ethical implications of the linear relationship between dose and probability of effect, there are justifications of a scientific nature for, and practical advantages in, this assumption.**

Scientifically, we know that radiation energy is transferred to living matter along the tracks of ionizing particles. It seems reasonable to believe that, when the number of tracks per cell is on the average well below one (which happens at low doses and dose rates), single-track mechanisms giving rise to linear dose-effect relationships must be eventually the only ones operating, while double-track mechanisms (giving rise to quadratic relationships) must vanish. No matter to what extent linear relationships may be modified by various processes of repair of the initial damage, the kinetics will continue to be linear as long as the repair mechanisms will not themselves become dose-dependent, which only happens at very high doses and dose rates.

There are also practical considerations. On the one hand, in the presence of a high background level of radiation, linearity of risk due to a small dose increment is not an unacceptable proposition. On the other hand, postulating any non-linear relationships would imply the need of keeping track of the radiation history of each person, in order to calculate the attendant risk for each dose increment. Since radiation protection cannot clearly be tailored to each individual, the problem of assessing risks would have to be solved on the basis of large averages for and

between individuals, which would be equivalent to assuming linearity from the start. Finally, dose-related assessments and restrictions would be difficult, because the impact of each source would also depend on the exposure from other sources.

The question is then: if linearity between dose and the probability of stochastic effects is a scientific certainty or an inescapable practical necessity, where lies its ethical quality? It lies in the value assigned to the slope of the dose-linearity relationship, that is in the number we choose as the "nominal probability coefficient" for planning of radiation protection. Obviously, this value should not be too low, otherwise the resulting radiation protection requirements would not be stringent enough. Nor should it be made artificially low by applying correction factors (for dose and dose rate, for example) under conditions where dose and dose-rate effects are not operating: such an approach would equally result in less stringent standards of protection.

It is less obvious that the nominal probability coefficient should not be too conservative, particularly in the face of the inherent uncertainties. However, excessive conservatism would unduly penalize practices involving radiation: comparative exercises against other practices carrying health risks. Excessive conservatism may also result in an uneven - and therefore inefficient - distribution of resources available for protection against different sources of health risk. A realistic assessment of the coefficient is therefore to be advocated, in spite of the scientific and practical difficulties involved in such assessments. And the best way to achieve this goal is through reasonably frequent reviews of the scientific evidence and adjustment of the values as needed.

There are many ethical problems that could be discussed in connection with the assumption of non-threshold linearity. I will briefly touch on two.

The first problem concerns the existence of a variability in the appearance of stochastic damage among members of a population and the question for whom radiation protection standards should be developed. It is well established that susceptibility to cancer is not uniform, as shown by families with high predisposition to develop some tumour types. We also know that individuals homozygous for some genes are particularly sensitive to the immediate effects of radiation; and that cells *in vitro* that are homo- or hetero-zygous for these genes are also more radiosensitive than cells from normal individuals. What we ignore is whether people susceptible with respect to "natural" tumour induction may also be more prone to develop radiation-induced tumours; and we have as yet no easy way to identify people with abnormally high sensitivity to radiation; consequently, individual radiosusceptibility to cancer induction, and its distribution in the population, is an unexplored field.

Under these conditions, should radiation protection be planned with respect to the most sensitive or to the average member of the population? The answer is that probability coefficients for cancer induction are normally derived from people with all degrees of sensitivity. Thus, by using real epidemiological data as our reference point, we derive average values of population susceptibility, which include the most sensitive individuals. Such a procedure should be sufficient for planning of protection, provided that the distribution of genes linked with hypersensitivity could be dealt with individually in the context of occupational medicine.

The hypothesis of non-threshold linearity, among its many advantages, allows doses and probabilities of stochastic effects to be summed up in space and time. Integration in space I will consider later; here I am concerned (and this is my second question) with assessment of radiation effects in time, i.e., with the potential damage to future generations and how should protection be planned for exposures taking place late (and sometimes very late) into the future.

The question has many facets. There is first a general problem arising from the need of taking actions (of allowing actions to be taken) in the presence of uncertainties of different kind about the long-term future. To cite just a few, think of the uncertainties inherent to the inadequacy of the human mind to foresee long-term phenomena; or the uncertainties about the behaviour of any human group and the need to monitor the group's actions by independent evaluators. Other uncertainties arise in predicting the future of human societies and their degree of stability in the face of changing ethical values, political organizations, social structure, economic trends. And, finally, how can we reliably forecast the future of our environment and the modifications caused upon it by present and future human behaviour (Ethical Aspects on Nuclear Waste 1988)?

Then there is the question of our responsibilities to future generations and how to compare and value short-term effects with the very long-term damage resulting from present practices? Science is unable to suggest any answer to this kind of problem. Life is evolutionary by definition and the balance between species is unstable over long periods of time. There are no obvious ethical concepts to be derived from evolution and its mechanisms. Solutions to these problems must therefore be sought at a different level. If it is true that all human beings are equal regardless of ethnic, religious and national characteristics and that this right to equality could not be exercised without a right to a liveable environment, then there must be a principle of intergenerational equity by which we ought to respect the right of future generations by refraining from practices that may compromise their opportunities in the future. There is, in other words, an implicit social contract by which, since we derive from our ancestors our life and living means, we owe to our followers the same heritage we receive. We cannot obviously decide and plan for them, but we can at least avoid pre-empting their future decisions by giving them the same opportunities we received (Shrader-Frechette 1981).

These statements are clearly too general to provide practical guidance. To translate principles into practice, radiation protection charges to the account of present practices the commitment of any future somatic harm. It also attributes to the account of any exposed person all the hereditary damage - dominant and recessive, monogenic and polygenic - estimated on the basis of doses received by that person. By doing so, it gives exactly the same weight to all types of harm caused by an exposure received, now or in the future, irrespective of the time at which such damage will become manifest.

### THE THREE GENERAL PRINCIPLES

Going now to the main principles of the ICRP system of dose limitation, I would like to preface the discussion by pointing out that the system is to be taken in its entirety and no one part (especially individual dose limitation) should be applied in isolation. One should also add what might appear redundant but, as the latin sentence goes, "repetita iuvant": just as it is necessary



that the scientific data leading to practical recommendations be assessed in a fair manner, it is also imperative that implementation of the system be undertaken in good faith. Periodic evaluations of its effectiveness should help to improve performance and to achieve, together with a gradual lowering of the overall doses, a more even distribution of them in space and time.

### **JUSTIFICATION OF A PRACTICE**

In its most recent enunciation by the ICRP, the first general principle of radiation protection, that of justification of a practice, states that "No practice involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes". At first sight, the principle appears utterly obvious: only a fool, in fact, could consider to undertake actions which are more harmful than beneficial. However, when closely examined, the statement appears very complex. Two concepts, benefit and detriment, are difficult to define and to apply to the other two terms, individuals and society.

The ethical problems posed by the interplay of these four terms are numerous. They turn, first of all, on how to define benefits in a comparable and consistent way and, above all, in a way which is fair to both individuals and groups. Secondly, who is to do this balancing operation and when? Thirdly, how should one compare radiation-related benefits and detriments with benefits and detriments induced by other practices?

Before discussing ethics, let us first be clear on some points: there is no wish on the part of radiation protection experts to take any of these decisions. In democratic societies, the role of balancing quantities and values of different nature, which are incommensurable by any rational standard, is left to people elected to exercise political authority. In stating this principle, radiation protection simply intends to put forward some requests: firstly, that the radiation-induced health detriment should specifically be considered as one element in the decision process; secondly, that the role of radiation protection specialists should not be that of choosing between a range of viable options, but that of advising about the viability of an option involving the use of radiation; and, fourthly, that judgements should not be taken once and forever, because options considered viable in a given context at a given time, may not continue to be so with changing conditions or the passage of time.

In general, estimates of all the consequences of a decision, beyond the most immediate ones, are extremely complex because they interplay with the primary or secondary results of other decisions, taken independently by other agents. In practice, therefore, one simply assesses the ethical quality of the most immediate consequences of a proposed decision, leaving aside the obscure chain of second- and third-order events and their possible interplay.

Similar arguments apply to the complexities of the socio-economic situations to be faced when making such decisions. Each individual belongs to different circles (family, group, work-force, nation, etc.) with different dimensions, aims and requirements. Circles of different order may cooperate or conflict with each other at any given time, and their interests may also change with time. Given such a high degree of complexity, how could one possibly trace what may be satisfactory or detrimental for each actor in the game of life? An open mind, reasonableness and

a balanced judgement are pre-requisites for fair decisions and these appear under such circumstances the most valuable ethical requirements.

One often regards the principle of justification as a very extensive one, involving decisions at the national or international level in respect to large programs of action: these are certainly the most striking cases to which the principle applies. However, justification of generalized medical practices involving exposure to radiation is a process of the same nature; actually, the principle of justification should apply to any single medical practice. It is true that any doctor carries out this process almost implicitly. It is also true that in medical practice benefits and risks accrue to the same patient, and this makes decisions somewhat easier. Furthermore, the risks of not

undertaking an examination are often more relevant than its potentially harmful consequences, i.e., medical practices are often heavily justified. But all these are simply secondary connotations of one and the same process of justification.

As a final note, it seems fair to ask that whoever has the responsibility of justifying a practice (from a clinician prescribing an x-ray examination, to a political body deciding upon a nuclear programme) should be well informed of the values at issue and the responsibilities at stake for all active and passive subjects of that practice. Personally, I am not satisfied that this is always so, and I am sure that many of you have often felt the same way. This is exactly why there is a need for the apparently obvious principle of justification.

### **OPTIMIZATION OF PROTECTION**

I will now turn to the second basic principle, the optimization of protection. In its newest formulation this principle reads: "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 exposure (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements." The complications introduced into the new text are due to the deepening of the concept since the time it was first stated, to a novel attempt to enlarge it to include the so-called potential exposures, and to a desire to minimise the inequities in the resulting distribution of doses. All these, however important, are secondary technical specifications superimposed upon a general principle.

This stipulates that when attempting to minimize the doses received by individuals and groups, one comes to a point where further investments (of financial resources, staff, services, etc.) are grossly out of proportion with the doses saved. And, since optimization is not performed in a vacuum but in a world with limited resources, at that point it is no longer advantageous to invest for increasingly small returns. I should hasten to state that this process of balancing doses and resources takes place under a ceiling of doses that should not be exceeded deliberately under normal circumstances: these are the individual dose limits that must be met irrespective of cost.

The optimization principle is obviously modelled on utilitarianism, a philosophical theory that takes human general well being to be the foundation of morality. In its most extreme form, utilitarianism assumes that right actions are those that cause the greatest happiness to the greatest number of people, happiness being defined as the balance of pleasure over pain. It further assumes that it is possible to measure and to algebraically sum up pleasure and pain, and to take as the right action that which produces the least negative or the greatest positive balance (Engelhardt 1991).

To philosophers, the main merits of utilitarianism are its coherence and unselfishness, that provide a unitary procedure for morally correct decisions. But there are also objections: for example, it is really possible to quantify all the values to be balanced? Is the greatest total happiness the goal to be pursued or is the distribution of happiness also an important factor? For these and other reasons, utilitarianism is not universally accepted as a true ethical system (Mackie 1977).

To be sure, radiation protection adopts and recommends the concepts of the theory in a restricted sense, starting from the main premises; for example, human well being is given the more limited meaning of absence of effects on health. Radiation protection borrows the ideas of the theory simply as a device to counteract selfish interests on the part of individuals and groups against other individuals and groups. In other words, it uses its main principles as a methodology to help setting boundaries to the pursuit of narrow egoistic tendencies.

It is interesting to point out that the utilitarian theory, which is based on a purely aggregative principle, does not itself provide any precise answer regarding boundaries. The main criticism about the theory is actually that it is open to the possibility that the happiness of some may be reached through the misery of others. To avoid such a danger, a distributive principle must be added to the aggregative rule of the theory, to limit the unfairness (or at least

the most extreme unfairness) in the sacrifice of some for the sake of others. So much for the ethical foundations of utilitarianism.

Discussions on optimization must start from its objective, which is that of limiting exposure and thus decreasing the associated health detriment. If disease and suffering have the same value, irrespective of their etiological agent, it appears intuitively preferable to make the most out of the resources available. There is no apparent reason why, for the same amount of human detriment avoided, one should invest more resources to reduce radiation damage, while, for example, neglecting the prophylaxis of some infectious disease through vaccination, or the reduction of transportation accidents by an efficient communication system, or the cure of cardiovascular emergencies by increasing the number of intensive care units over the territory. All these are aspects of a well integrated system of health planning and should be looked at and cared for in a uniform manner to achieve a distribution of resources that avoids a maximum of detriment and suffering.

To help achieve optimization, a variety of formal decision-making techniques may be used. One of these, cost-benefit analysis, requires that the two quantities to be weighted against each other should be expressed in the same units, usually monetary units (ICRP 1983). This need has often

given rise to the misunderstanding that expressing a health risk in terms of money is equivalent to assigning a value to human health, which is definitely a highly un-ethical and therefore unacceptable procedure. It is easy to rebut such criticism on a number of accounts. Semantic reasons, first: the amount of money conventionally attributed to life is not the cost of life, but the resources needed to save that life. Secondly, conceptual reasons: cost-benefit analysis is simply a technique used in order to save the maximum amount of life and suffering. Thirdly, procedural reasons: optimization is carried out on a statistical basis for the sole purpose of programming the least possible exposure. A procedure of analysis *a priori* is quite different from situations encountered in medical practice, where no efforts should reasonably be spared to take the best possible care of a disease which has actually occurred. Thus, I have personally no difficulty in accepting the principle of optimization as morally sound.

Formal methods of optimization have many advantages. To cite the principal ones, they make comparisons systematic and quantitative and require decisions to be taken in a sequence of steps that anybody at any time could trace and check. The main disadvantage is that it may be difficult - perhaps impossible - to assign meaningful quantitative weight to some "intangible" values that could, as a result, be neglected (Reich 1978).

However, no decision process is entirely free from value judgements. How is one to unambiguously separate facts and opinions, descriptions and evaluations, when the appraisal of those who perform an analysis may to some extent determine its outcome? This difficulty may become crucial in assessing the uncertainties on the results of the analysis. Some, for example, will take a very low probability of risk as evidence that no injury will in fact be seen; on the contrary, the logical impossibility to prove absence of injury will strengthen in others the belief that injury will eventually result.

To my mind, the advantages of formalized techniques of optimization by far overcome the criticism that can be raised against them. In most of the examples that I know of, the results appear unambiguous. And in cases of doubt the old hippocratic rule "primum non nocere" should take priority over an uncertain benefit.

Yet, many have difficulties in accepting and applying optimization. They prefer to rely on compliance with limits, thus adopting a view of protection that falls short of its real spirit. Some managers eager to increase their economic returns; some regulatory agencies inclined to assert their authority rather than to educate the users to a correct culture of safety; some inspectors keen to set rules against which to define statutory offenses. All these tend to encourage such erroneous concepts and behaviours.

We should remember instead that there is no definite boundary between safe and dangerous doses; that working at the limit for a long time produces a risk which is definitely bordering on unacceptability; that below the limits there is a wide region of doses that can be kept as low as reasonably achievable. In the recognition and implementation of these principles lies exactly our professional responsibility. To verify compliance with limits does not require any great ability; it is infinitely more challenging and rewarding to improve on existing exposure situations.

Which leads me to a further ethical point to which little attention is paid: the concept and practice of optimization confers a dynamic character to the objectives of our profession which is totally at variance with the static concept associated with limit compliance. Needless to say, the former is much more valuable, since it leads to an ever-increasing standard of performance.

### INDIVIDUAL DOSE LIMITATION

The principles of justification and optimization may to a large extent be viewed as logical steps in the strategy of decisions applicable to many human activities (ICRP 1989). With the third principle, that of individual dose limitation, we enter a field which is very specific to radiation protection and could not be implemented without detailed notions of radiation effects and risks.

When discussing the intrinsic limitations of utilitarianism, I have already mentioned that, in order to be implemented, the theory requires that, to the aggregative principle on which it rests, a distributive principle be added to avoid major inequities. Recognizing such a need, the new recommendations of ICRP suggest the use of source-related restrictions to individual doses, called dose constraints. They are meant to avoid a very uneven distribution of doses in the process of optimization. But these constraints apply usually well below the individual-related primary limits of exposure, that I would like to discuss now. I shall do so by tracing the logic in their derivation.

Regarding the exposure of workers, the ICRP had adopted in the past the policy that it would not wish to see radiation risks to run higher than the risk of accidental deaths in other safe industries (ICRP 1977). The risk of death was taken at that time as a yardstick for comparison on the ground that death from cancer (or any comparable hereditary effect) was the worst possible consequence of radiation exposure: if radiation could be shown to be safe on this ground, other comparisons based on non-lethal consequences would be even safer.

Recently, however, new considerations have been pointed out. Firstly, the safety of industrial operations is found to be at different levels in countries with differing conditions of socio-economic development. Secondly, in any one country, the rate of accidental death in various industries tends to decrease with time, due to a ever-increasing demand for safety. Thirdly, the risk of death in industrial activities is calculated by averaging over groups of workers, while radiation dose limits are meant to apply to individuals. Fourthly, non-fatal harm should be added to the risk of death for the purpose of setting limits. And, finally, in deriving previous limits, assumptions had been made regarding their implementation, while, in principle, limits should be set independently of any assumption about their eventual compliance.

New scientific evidence has also shown that age at irradiation and time since exposure are very important features in the induction and expression of radiation-induced death due to cancer or hereditary damage. The preamble to old wills in my country used to say that "nothing is as sure as death and nothing is less sure that the time of its occurrence". In other words, after a few centuries, we have also come to realize that, since the probability of death is one hundred per cent for all of us, it is hardly a good means of comparison. On the contrary, it is the age at which death occurs (together with the quality of life afforded by the non-lethal conditions, I

should add now) that is the variable that matters.

At the same time, it has been pointed out that probably the most correct way to project the occurrence of radiation-induced cancer into the future from present epidemiological data is through a multiplicative model in which the natural rate of induction and the radiation dose together determine the final outcome of a given exposure (an additive model had been used until now).

All these considerations and facts prompted the ICRP to adopt a different course of action in the selection of the limits. The Commission proposes now to enlarge the perspective of the exercise and to consider a wide range of attributes associated with radiation-induced effects (neoplastic lethal and non-lethal and severe hereditary conditions). These attributes are: the probability of death from effects over the entire life; the life time lost when radiation-induced death occurs; the combination of both these parameters, that is the reduction of life expectancy; and the increase in the probability of dying in each one year at any age, conditional upon having reached that age. Then the Commission calculates the value of the attributes at doses of between 10 and 50 mSv/year (corresponding approximately to 0.5-2.5 Sv in a working life time) and selects as the limit the annual dose that it considers just short of unacceptable.

There is obviously a degree of subjectivity in selecting such a value, but hopefully not a great amount of arbitrariness. It is important to spend one minute to illustrate the main points of the reasoning.

First of all, why set the limit at the level which is just unacceptable and not at one which is clearly acceptable? Because under the assumption of linearity without threshold the only dose acceptable without question is zero. This alternative would, therefore, reject all doses from man-made radiation and would also be meaningless in view of the high level of unavoidable natural radiation. On the other hand, setting the limit at a dose just short of unacceptable carries the corollary that to keep a worker continuously at the limit implies a risk which is definitely too high.

Secondly, new scientific evidence and its re-interpretation had shown that the nominal risk coefficient for tumours and genetic effects combined had increased since 1977. On the basis of the previous limit and of the new nominal risk coefficients, a worker continuously exposed at the limit would see his life expectancy reduced by about one year with an attributable probability of death of about 9%: these figures would universally have been regarded as unacceptable and the limit should have been decreased. The question is: how much?

To use the words of the Commission, the new limit should be such "that the total effective dose received in a full working life would be prevented from exceeding about 1 Sv received moderately uniformly year by year and that the application of its system of radiological protection should be such that this figure would only rarely be approached". On this basis "the Commission now recommends a limit on effective dose of 20 mSv per year, averaged over 5 years (100 mSv in 5 years), with the further provision that the effective dose should not exceed 50 mSv in any single year".

I would be lying to you if I should claim that this decision was an easy one to make. It was a compromise just short of unacceptable to any of those who had to take it and came to be judged as tolerable for the Commission as whole, with various shades of dissatisfaction. But this is inevitable: as I said before, when deciding on these matters each person carries his own human, cultural and professional sensitivities which add to the logical line of thought (and I specifically mean adding in the sense of enriching). My own tendency would have been more restrictive, and therefore I have to remind myself all the time that limits are recommended for universal use and should cut across the needs of various groups and societies. They are suggested values, that individual countries may accept or reject, hopefully to adopt lower limits. Actually, the system itself recommends various ways to reduce the risk implied by the primary limits.

As to the limit of dose for the public, the ICRP proceeds in analogy with that for workers. It still aims at a dose level just short of unacceptable for continuous exposure and it still assesses the limit by comparing various attributes of lethal, non-lethal and hereditary harm. It comes eventually to a recommended level of 1 mSv per year. An alternative procedure, that of selecting a fraction of the natural background to be the limit would have been unacceptable in principle, because the fact that we are exposed to doses from natural radiation sources (even with ample fluctuations in space and time) cannot in principle justify the addition of any dose, however small, from man-made sources. Comparisons with background are useful *a posteriori*, but would be unwarranted *a priori* for the purpose of selecting limits.

The choice for the public of a limit which is considerably smaller than for the workers (about a factor of 20, at present) is ethically justified on the grounds that this limit applies to a much larger population, that exposure is for the whole life (and not only for the working life); and that the public at large includes here also the most susceptible young ages. Also, members of the public are only protected by source control and not by individual monitoring. All these considerations make sense from a general point of view. What is more perplexing to me is why workers should in theory be allowed (as they in practice do) to receive higher doses than other members of the public of the same age. Explanations usually given are that workers are paid to do a given job, but my objection is that this implies acceptance of the concept that a potential risk to human health and life may be traded for money. It is also said that workers undergo the relevant risks voluntarily as a matter of free choice. But is this true under conditions of high unemployment? And, in any case, is it fair to ask anybody to choose between no work and work under high risk?

The fact does remain that limits for professional exposure are normally higher than for public exposure for many human activities. I have no argument to oppose the wide public acceptance of this state of affairs. It could be an excess of scruples on my part, and it could be utopian and unrealistic even to contemplate such an idea: but I would eventually like to see a system in which each person is protected as a human being, irrespective of any working condition. And I believe that on this point there is room for further improvements.

## CONCLUSIONS

At the end of this presentation, I should try to answer the question that has long been in my mind and perhaps in your mind too, since I started the present talk. Is the present system of radiation protection founded on sound ethical grounds? Overall, I believe that the answer should be yes, because the ethical propositions on which it is founded are good; the methodologies to develop the basic principles into a set of recommendations are morally acceptable; and the system appears reasonably coherent, flexible, stringent enough to keep the risks low, but not zero, which would be an impossible target to achieve, as long as there are benefits to be gained from the use of radiation.

Naturally, as is true of all human endeavour, the system could still be improved. Some improvements will come about in due course as new experience is gained. This applies, for example to the updating of risk estimates based on new scientific evidence. From it, as in the past, revision of the present recommendations will probably derive.

Other improvements will presumably require original research and development in order, for example, to further clarify the meaning of the principle of justification, or to include environmental, in addition to human, protection.

To meet further and more advanced requests, revolutionary, rather than evolutionary, approaches of the present system might be necessary. I am referring here to my suggestion to protect individuals as human beings and not as workers and public; or to the further universalization of the basic ethical principles to take into account non-objective health detriment and other preferences, desires or ideals.

Such further developments would almost certainly make the system more stringent. As it become so, some people may find it more acceptable but others may look upon it as too obtrusive. We certainly should ask ourselves whether we have taken the present system as far as it could go in order to preserve coherence, which is undoubtedly its main merit. On the other hand, we must see that protection against radiation is not pushed too much, because it may fall out of perspective and be unfairly penalized in comparison with protection against other health hazards.

My personal feeling at present, from a global perspective, is that adoption of the system, imperfect though it may be, by all countries would be likely to save more doses than might be saved by further marginal improvements in countries where the system is already well in operation. If this feeling is correct, then we should continue working, as we have done in the past, in order to develop the system rationally, while trying all the time to behave reasonably.

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GIULIO ORAZIO BRAVI

## *Giovanni Silini (1931 - 2011), storico*

1. Giovanni Silini ha iniziato a dedicarsi agli studi storici, proseguiti poi con fedele continuità e rigorosa sistematicità, a partire dal 1981, quando pubblicò nella collana “Monumenta Brixiae Historica: Fontes”, edita dall’Ateneo di Scienze Lettere e Arti di Brescia, *I nuovi Statuti veneti di Lovere del 1605*.

L’avvio, a cinquant’anni, di questa nuova esperienza intellettuale nel campo della ricerca storica, dedicata inizialmente alla conoscenza della sua città natale, Lovere, coincise, forse non del tutto a caso, con il suo arrivo a Vienna come responsabile del Segretariato per lo studio degli effetti della Radiazione Atomica al Dipartimento delle Nazioni Unite, incarico che coprì sino al 1988, e che segnò il coronamento di una brillante carriera scientifica. Il venir meno dell’assillante bisogno professionale di produrre testi scientifici, liberò tempo ed energie per dedicarsi, finalmente, agli amati studi storici.

Laureatosi in medicina a Pavia nel 1956, dove era stato studente dell’Almo Collegio Borromeo, specializzatosi poi in anestesologia, Silini fu ricercatore prima a Londra, poi a Stanford negli Stati Uniti, per continuare, dal 1963, al Centro Nucleare della Casaccia di Roma dove, dal 1974 al 1979, fu Direttore della Divisione per la Ricerca sulla Protezione dalle Radiazioni. Come scienziato di radiobiologia ha tenuto corsi di specializzazione presso università italiane e straniere, è stato membro di commissioni internazionali per la protezione dalle radiazioni, ha organizzato meeting in Italia e all’estero sugli effetti delle radiazioni, ha curato numerose pubblicazioni.

La sua intelligente passione per la storia, che a partire dal 1988, quando si congeda dall’incarico viennese, diventerà esclusiva e alla quale dedicherà tutte le sue notevoli capacità, ha prodotto un buon numero di pubblicazioni alla cui ideazione, preparazione e redazione Silini ha riservato, pur nel radicale mutamento del campo d’indagine, lo stesso rigore metodologico dei precedenti studi scientifici. Ravvisiamo tale rigore: a) nella scelta di tematiche storiografiche circoscritte nell’oggetto e nella cronologia, riconducibili alle condizioni economiche, demografiche e politico-istituzionali di Lovere e del territorio bergamasco tra XV e XVIII secolo; b) nella costante ricerca dell’imprescindibile supporto delle fonti archivistiche, assunte e considerate nella loro specifica natura seriale, al fine di conseguire risultati quantitativi e statistici di lungo periodo (Silini aborrisce dall’aneddoto, dalla notizia ‘gustosa’, ‘singolare’, di cui al contrario vanno ghiotti molti storici locali); c) nel confronto che stabiliva, sulla scorta della più aggiornata bibliografia, tra i risultati conseguiti con le sue ricerche locali (Lovere, territorio bergamasco) con quelli di altri ricercatori, relativi ad altre, più vaste realtà territoriali.

2. Sul fascicolo n. 2, maggio 1982, della rivista “Archivio storico bergamasco”, l’allora direttore dell’Archivio di Stato di Bergamo, Mario De Grazia, aveva recensito, alle pp. 165-167, l’edizione degli *Statuti di Lovere del 1605*. Il recensore aveva messo giustamente in evidenza il lavoro filologico compiuto dall’autore nel collazionare cinque testimoni degli *Statuti*, la meticolosa indagine condotta sui documenti di approvazione degli *Statuti* da parte delle autorità veneziane e bergamasche, la pertinente e ricca annotazione storica del testo, la cura di un utile glossario dei termini giuridici e degli antichi istituti amministrativi. Silini rimarrà sempre fedele a questi preziosi e validissimi criteri nella cura di molte altre edizioni statutarie, di Comunità di valle e di singoli Comuni dell’Alta Valle Seriana e della Valle di Scalve, che appronterà negli anni Novanta e nel primo decennio di questo secolo, giovandosi della collaborazione, in molti casi, di Antonio Previtali.

La rivista “Archivio storico bergamasco”, sulla quale era uscita la recensione, era stata fondata l’anno prima, 1981, da un gruppo di giovani studiosi, di cui anch’io facevo parte, che avevano dato vita al Centro studi e ricerche Archivio Bergamasco. La neonata associazione di studi intendeva caratterizzare la sua attività di indagine con l’adozione di una aggiornata metodologia per la quale era fondamentale l’uso critico delle fonti, l’assunzione problematica di ipotesi di ricerca, il necessario confronto tra realtà locale e contesto nazionale, l’apertura a tematiche nuove di argomento sociale ed economico rimaste sempre ai margini della storiografia bergamasca. L’incontro del gruppo di Archivio Bergamasco con Giovanni Silini venne a cadere in un momento nel quale sia lo storico di Lovere sia i giovani ricercatori intendevano perseguire comuni obiettivi, per cui ne sortirono un proficuo sodalizio e una vicendevole stima.

Avvenne infatti che nell’autunno dell’anno 1982, Silini, forse perché lusingato dalla bella recensione apparsa sulla nostra rivista, più probabilmente perché ne condivideva l’indirizzo editoriale, mi propose, nella mia veste di direttore, un saggio dal titolo *Caratteristiche, prezzi e rendita della proprietà immobiliare a Lovere e dintorni tra i secoli XV e XVI*, un lavoro tutto condotto sugli atti notarili dell’Archivio di Stato di Bergamo. Paolo Berlanda, che del comitato redazionale era l’esperto di economia (oggi è Direttore generale della Polis Fondi Immobiliari), letto il testo espresse un giudizio molto positivo: il saggio rappresentava a suo parere una novità assoluta nel panorama degli studi storici locali bergamaschi. Quel saggio, apparso sul n. 4 del 1983, fu il primo di una serie di saggi di notevole qualità, che toccarono argomenti di demografia storica, economia, condizioni sociali del Loverese: saggi che il lettore può oggi leggere sul sito <http://www.archiviobergamasco.it/pubblicazioni/rivista/default.htm> dove tutti i fascicoli di “Archivio storico bergamasco” sono pubblicati on-line.

Nella lettera del 7 agosto 1984, inviata da Vienna, con la quale accompagnava un nuovo articolo propostomi per la pubblicazione, dal titolo *Nascere, vivere e morire a Lovere nei secoli XVII e XVIII (Indagine demografica)*, Silini scriveva: «Passerò nella prima metà di settembre per sentire i suoi commenti dopo che lo avrà letto perché, come si accorgerà, il mio è un modo un poco eterodosso di fare la storia e potrebbe anche non piacerle». Silini era cosciente che, al contrario di molti saggi di impianto narrativo e di taglio più tradizionale che comparivano sulla rivista, i suoi lavori si caratterizzavano per una prosa sobria, estremamente tecnica, intervallata da non poche tabelle nelle quali erano elencati i dati quantitativi desunti dall'analisi di centinaia di atti notarili: donde il suo timore che simili lavori potessero «non piacere», in particolare a lettori di storia abituati ad una prosa più coinvolgente. Devo onestamente confessare che anch'io mi trovavo tra questi lettori. Silini lo capiva quando mi veniva spontaneo dirgli alla consegna da parte sua di un nuovo lavoro – Ma ancora tabelle? –. Oggi, dopo tanti anni, posso dire con certezza che i suoi studi (con le loro tabelle), mai generici, mai retorici, pieni di cose, di dati certi, di ipotesi fondate sempre e solo su documenti criticamente vagliati, continuano a mantenere intatta la loro validità, originalità e utilità. Con quegli studi egli innovò profondamente il modo di affrontare la storia locale di una comunità, di una terra: non una sequela di vicende, per lo più acriticamente rabberciate, che dalla preistoria andavano ai Caduti della Prima Guerra mondiale, ma l'analisi, per archi temporali ben determinati, dell'andamento della popolazione, dei principali fattori demografici di crescita e di decadenza, delle condizioni di vita materiale, delle strategie di sopravvivenza e di sviluppo messe in atto da una comunità in particolari momenti storici.

La collaborazione di Silini con Archivio Bergamasco durò sino al 1992 quando venne pubblicato il volume *E viva a sancto Marcho! Lovere al tempo delle guerre d'Italia*, uscito come numero monografico doppio, 22-23, della rivista "Archivio storico bergamasco", che dal 1985 era edita da Pierluigi Lubrina. Già dal 1983 Silini aveva cominciato a lavorare a questa pubblicazione, che rimase la sua unica pubblicazione monografica, mentre per il resto si limitò sempre a saggi o alla edizione commentata di fonti documentarie. Ne aveva parlato con me e con l'editore Lubrina per la prima volta nel maggio 1986. Paolo Corsini, docente di Storia moderna all'Università di Parma (sarà Sindaco di Brescia dal 1998 al 2008), aveva dato del lavoro un giudizio positivo; un giudizio altrettanto lusinghiero aveva espresso il prof. Giorgio Chittolini. La ricerca, condotta sul *Registro delle Parti* del Comune di Lovere conservato nella Biblioteca Civica di Bergamo, compreso tra gli anni 1493 e 1517, ricostruiva le vicende politico-istituzionali di Lovere nel contesto storico dei territori di Bergamo e Brescia durante un periodo di grande interesse per i cambiamenti politici e gli eventi bellici che si erano accavallati in rapida successione in quei decenni. Il prof. Corsini nel 1983 aveva proposto a Silini di pubblicare il testo presso la Fondazione Micheletti di Brescia, cosa che poi non avvenne, anche perché l'autore avvertiva che il lavoro aveva bisogno di ulteriori approfondimenti e aggiustamenti. Andrea Zonca e Claudio Calzana, membri del comitato di redazione di "Archivio storico bergamasco", ai quali avevo sottoposto per un loro giudizio il dattiloscritto di Silini, avevano suggerito in una relazione consegnatami il 24 maggio 1989 di sftlire l'apparato delle note, di ridurre la parte riservata alle vicende "italiane" per dare maggiore spazio alla realtà locale di Lovere. Silini fece tesoro di queste osservazioni, stabilendo un nuovo equilibrio nell'elaborazione del testo tra fatti generali e realtà territoriale. La pubblicazione vide la luce nel 1992 e conobbe un buon successo. Ma mi pare di poter dire che l'autore, nella lunga gestazione di quel volume, che si protrasse dal 1983 al 1992, maturò la consapevolezza che il meglio di sé lo dava non in un volume ma nella brevità e specificità del saggio specialistico oppure nel commento articolato e preciso di un documento statutario. In realtà dopo il 1992 non si impegnò più in un lungo lavoro monografico.

La pubblicazione del volume *E viva a sancto Marcho! Lovere al tempo delle guerre d'Italia* segnò anche la momentanea interruzione delle pubblicazioni di "Archivio storico bergamasco", a seguito del fallimento della casa editrice Pierluigi Lubrina. La rivista riprenderà le pubblicazioni nel 1994 con una nuova veste grafica presso le Edizioni Junior di Bergamo. Della nuova serie usciranno tre numeri, negli anni 1994-1995. Silini, che non fece mai mistero di quanto non gli piacesse la nuova veste grafica della rivista, non vi pubblicò alcun saggio.

3. Nel 1996 io diventavo direttore della Biblioteca Civica di Bergamo e, in tale ruolo, assumevo anche il compito di direttore della rivista "Bergomum", organo ufficiale della Biblioteca. Dati i nostri ottimi rapporti personali, la vicendevole stima, l'amore che Silini aveva per la Biblioteca, di cui era assiduo frequentatore, dal 1996 ha inizio la sua collaborazione alla rivista "Bergomum", con la pubblicazione del saggio *L'estimo generale di Bergamasca del 1547*. Se le indagini apparse su "Archivio storico bergamasco" erano state prevalentemente di natura economica, sociale e demografica, e tutte avevano riguardato Lovere, i saggi pubblicati su "Bergomum" saranno prevalentemente di natura politico-istituzionale e riguarderanno tutto il territorio bergamasco, pur restando l'autore saldamente ancorato al periodo dell'età veneta.

Data a partire dal 1997, con la pubblicazione presso l'editore Ferrari degli *Statuti ed ordini del Comune di Clusone (1460-1524)*, la notevole serie di edizioni statutarie che, accanto ai lavori di carattere economico e demografico degli anni Ottanta e primi anni Novanta, rappresenta il secondo, grande interesse storiografico coltivato da Silini. Dico 'secondo' per numero di pubblicazioni e perché cronologicamente queste si concentrano nella seconda metà degli anni Novanta e nel primo decennio di questo secolo: in realtà l'esordio di Silini sul terreno storiografico nel 1981 era avvenuto con la pubblicazione, come abbiamo ricordato, degli *Statuti di Lovere* del 1605. E anche la sua ultima fatica riguarda ancora un'edizione statutaria: *Ordinamenti viciniali e di contrada della Valle di Scalve*, uscita nel 2011. Nel condurre queste ricerche Silini ha avuto il merito di recuperare agli studi, aggiornando il catalogo di Maria Rosa Cortesi del 1983 (*Statuti rurali e statuti di Valle. La provincia di Bergamo nei secoli XIII-XVIII*, Bergamo, Novecento Grafico, 1983, Fonti per lo studio del territorio bergamasco, III), nuovi testimoni, ritrovati presso biblioteche italiane e straniere,

e sui quali siamo informati grazie al saggio di Antonio Previtali, *Edizioni di statuti comunali e di valle d'antico regime (1980-2010)*, in "Quaderni di Archivio Bergamasco", n. 4, 2010, pp. 39-48.

Merita infine di ricordare che due ampie e complesse ricerche di natura politico-istituzionale condotte da Silini su documenti conservati nell'Archivio storico del Comune di Bergamo, depositato nella Biblioteca Civica, sono consultabili in rete sul sito della Biblioteca (<http://www.bibliotecamai.org/frame.asp?page=editoria/editoria.html>): *Bergamo 1512. Narrazione degli avvenimenti politici e militari di un anno drammatico*, pubblicato in rete nel 2001; *I giurisdicenti del territorio bergamasco nel periodo della dominazione veneta*, pubblicato in rete nel 2005.

4. Nel 1989, l'allora assessore alla cultura del Comune di Bergamo, Carlo Passerini Tosi, incaricò Archivio Bergamasco di organizzare un ciclo di conferenze avente per tema *Bergamo, Terra di San Marco*. Per illustrare l'economia bergamasca del periodo veneto chiesi a Silini un suo intervento. Considerate le finalità divulgative del ciclo, proposi al conferenziere di concludere la sua relazione con alcune considerazioni di metodo, che sarebbero state utili per il pubblico di ascoltatori, molti dei quali erano giovani studenti universitari. Silini non era del tutto convinto della mia proposta, non amando per nulla parlare di sé, ma alla fine accondiscese. Gli opuscoli allora pubblicati con i testi delle conferenze sono esauriti da tempo e pressoché introvabili. Penso di fare un servizio gradito ai lettori riproponendo qui le belle, sagge e ancora attuali parole che Silini pronunciò a conclusione della sua relazione, come ci eravamo accordati (*Venezia e la Terraferma. Economia e società*, Bergamo, Comune di Bergamo: Assessorato alla Cultura, 1989, pp. 107-109):

«Mi è stato chiesto di aggiungere qualche commento riguardo alla possibilità di condurre ricerche più approfondite di storia economica sul territorio di Bergamo, a beneficio di quei ricercatori che intendessero imbarcarsi in questo genere di indagini. Per quello che valgono, cercherò quindi di esporre brevemente le conclusioni che posso trarre dalla mia limitata esperienza di dilettante e manovale della ricerca storica: ma qui devo abbandonare il terreno sicuro dei dati ed affrontare quello incerto dei consigli che lasciano spesso il tempo che trovano. Essendo stato per tutta la vita prima un ricercatore, poi un direttore di ricerca, e da ultimo un valutatore delle ricerche altrui, so per esperienza che, alla fine, è l'interesse personale di chi conduce il lavoro che determina le scelte e che i tentativi di coordinamento in questo campo sono sempre difficili e spesso si rivelano inutili.

In ogni caso, ho già detto in precedenza quale può essere il tipo di informazioni che tali ricerche potrebbero generare e dove si possano ritrovare le fonti più abbondanti per alcuni filoni di indagini, senza naturalmente escluderne numerosi altri. È appena il caso di ricordare che bisogna esaminare queste fonti molto criticamente per rendersi conto di eventuali errori di rilevamento, occasionali o sistematici; che conviene sempre dare la preferenza ai dati primari, piuttosto che a quelli derivati; e che la storia economica si fa su serie di dati, perché le informazioni isolate non sono in genere di molto aiuto.

Una delle difficoltà maggiori nella quantificazione dei fenomeni è quella di reperire dati globali, laddove quelli parziali sono spesso abbondanti ma di difficile integrazione. Un altro aspetto importante riguarda la possibilità di mettere i dati su scale comparabili e comuni, il che implica una conversione delle unità monetarie e di misura che non è sempre immediata. Considerazione speciale va data al fatto che deve esistere la necessaria proporzione tra qualità e quantità dei dati di base ed il metodo statistico o il modello d'analisi ad essi applicato. È intuitivo che nessuna metodologia, per quanto raffinata riuscirà mai a correggere informazioni originariamente viziate o false. Da questo punto di vista, si richiede particolare cautela con certi dati economici, per esempio quelli di natura fiscale, daziaria o di estimo; o con certi dati demografici, per esempio quelli sulla mortalità perinatale o neonatale.

E' necessario ricordare che è difficile fare della teoria economica a livello locale, soprattutto quando le variabili che giocano sui fenomeni in esame non siano tutte sotto controllo. Quando si esaminano fenomeni cristallizzati nel tempo vi è da parte del ricercatore la tendenza a semplificare l'interpretazione degli andamenti osservati, dimenticandosi di molte variabili di carattere, per esempio, sociale e politico che, in quanto non note o difficilmente quantificabili, vengono quasi invariabilmente ignorate. Non si deve pensare che i sistemi economici del passato fossero meno complessi di quanto non siano quelli attuali; anzi, bisogna aver sempre a mente che le realtà descritte sono parziali e raramente generalizzabili. Si richiede quindi grande cautela nelle interpretazioni generali: e tuttavia queste sono necessarie, almeno per settori significativi della vita economica, perché in caso contrario i fenomeni descritti rimangono al livello della preziosità inutile.

Operativamente, è sempre necessario formulare preliminarmente ed esplicitamente il problema che si vuole affrontare e discuterne le difficoltà di soluzione ed i possibili risultati. Ciò non toglie che nella fase di esecuzione la ricerca prenda poi strade diverse ed inattese che si possano rivelare interessanti. Poiché il tempo ha un suo valore (e la vita del ricercatore una durata finita) è essenziale operare scelte strategiche ragionevoli su settori economici rappresentativi, per non disperdersi in vie tortuose, impercorribili e, alla fine, non paganti. Bisognerà anche confrontare i dati relativi ai diversi settori dell'economia e non stancarsi di inquadrare gli andamenti osservati in ambiti più vasti, per precisare omologie e scostamenti. Tralascio naturalmente i problemi di finanziamento, ma desidero far notare che, contrariamente a quanto si crede, questi studi possono raggiungere costi abbastanza elevati, soprattutto costi di personale: d'altra parte (e questo vale per chi desideri finanziare tali ricerche) la condizione essenziale per mantenere il controllo di un programma è quella di compensare gli esecutori.

Nella mia opinione, lo spazio aperto per questo genere di studi è illimitato, ma proprio per questo vi è la necessità di focalizzare oculatamente le scelte per non disperdere le forze. Il materiale da analizzare è ingentissimo: quel che manca sono le persone motivate ad intraprendere un lavoro di raccolta, di analisi e di confronto che è difficile, tedioso e,

per definizione, limitato. Un lavoro che certamente sconsiglierei a chi avesse ambizioni da premio Nobel, ma che può dare soddisfazioni intellettuali non piccole a chi ha curiosità, fantasia e voglia di divertirsi lavorando lontano dalle luci della ribalta. Di recente, questo mi pare un tipo di attività forse un poco in disuso, ma ad esso sarà pur necessario tornare se vorremo, come possiamo e dovremmo, mantenere in questi campi un posto preminente sulla scena internazionale: che è, in definitiva il livello al quale si fanno i confronti significativi».

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