Background

ICRP is grateful for the time and effort taken to review and comment on draft publications during their public consultation period. Active public consultations are a valuable part of developing high-quality publications. Comments are welcome from individuals and organisations, and all are considered in revising the draft prior to publication.

To ensure transparency, comments are submitted through the ICRP website and visible by visiting www.icrp.org.

Public Consultation

This draft report was available for public consultation for three months to 3rd August 2018. Responses were received on behalf of twenty-eight organisations and twenty-seven individuals (see annex).

In addition to the responses from public consultation, comments were received from each of the ICRP committees and the Main Commission before and after consultation. The revised report was approved for publication by the Main Commission during its Houston meeting, 3rd – 6th May 2019, with agreement on some final revisions.

Resolution of Comments

The very many constructive comments received during public consultation are gratefully acknowledged and have helped the authors improve the report. It has been revised throughout and in particular:

- The Main Points are substantially shortened and an Executive Summary has been added.
- Sections 2.2 Tissue Reactions and 2.3 Stochastic Effects have been updated.
- Section 2.4 Nominal Risk Coefficients and Detriment has been shortened with reference to the forthcoming TG102 report.
- Section 3.7 brings together discussion of Collective dose.
- Section 3.8 Operational Quantities has been updated with reference to an ICRU/ICRP report approved for publication.
- Section 4.3 Potential Exposures has been added.
• Chapter 5 Medical Exposures has been reordered to distinguish between those applications for which $E$ is applied and those for which measured quantities are preferable.
• Chapter 6 Summary and Conclusions has been replaced with a much shorter 6. Conclusions.

Many of the specific comments made by respondents have been addressed and changes are not itemised here. Opinions on the content of the report and its usefulness ranged from those who considered it to be excellent and very helpful to those who completely disagreed with specific elements of the report. Disagreement centred on two main points made in the report, that: (a) absorbed dose is preferable to equivalent dose to set limits to prevent tissue reactions and ICRP expects to make this change within the next set of general recommendations, and (b) effective dose can be used as an approximate indicator of possible risk.

(a) Use of absorbed dose to set limits to prevent tissue reactions

The report explains that equivalent dose is an intermediate step in the calculation of effective dose, used in the control of risks of stochastic effects. The radiation weighting factors used in the calculation of equivalent dose relate to stochastic effects. It would be more appropriate to use absorbed dose to organs and tissues to set limits to prevent tissue reactions. Radiation weighting relating to tissue reactions could be applied in situations where this is considered necessary. ICRP has not recommended radiation weighting factors for tissue reactions but the need to address this topic is recognised. The proposed changes align with changes to be introduced in the definition of operational quantities, as explained in ICRU report No 95, Operational Quantities for External Radiation Exposure, published jointly with ICRP. The new operational quantities will also be introduced following the publication of new ICRP general recommendations.

Most respondents welcomed the change to the use of absorbed dose to set limits to prevent tissue reactions. Consultation comments on the ICRU/ICRP report were also supportive of corresponding changes to operational quantities. The main reasons given for support were scientific plausibility, and reduced complexity as an aid to communication and teaching. Those respondents who disagreed with the proposed changes argued that the system works very effectively in its current form and changes could be costly in terms of revisions to legislation and the implementation of practical protection, without improving protection. However, since it is proposed that these changes in the protection quantities will be introduced in new general recommendations, together with other changes, once these have been discussed fully with stakeholders over the coming years, this simplification should be readily accommodated and make life easier for those who need to explain dosimetric quantities and their application.

(b) Effective dose as an approximate indicator of possible risk

A central issue in the report is the relationship between effective dose and stochastic risks, principally risks of cancer. It is concluded that effective dose can be used as an “approximate indicator of possible risk”. This wording was chosen to emphasise the uncertainties inherent in the estimation of risk and to acknowledge that the doses under consideration are in many
cases below the levels at which direct epidemiological observations of excess cases of cancer are available. With these caveats, the most straightforward interpretation of the available scientific evidence for the purposes of radiological protection is that a nominal lifetime fatal cancer risk of about $5 \times 10^{-2}$ per Sv applies at low doses or low dose-rates; that is $< 10^{-4}$ per mSv. The evidence also shows differences in risk between males and females and particularly with age at irradiation. Such differences can be taken into account when considering risks to individuals. It is emphasised in the report that situations that require best estimates of risk will be evaluated using best scientific data, including organ / tissue absorbed doses, RBE estimates, and age, sex- and population- specific risk estimates, with consideration of uncertainties.

Many respondents welcomed the clarity of the discussion of this topic and the conclusions drawn. However, others expressed strong objections. The strongest objections came from those who consider that it is unsafe to assume that there are risks at doses below which there is direct epidemiological evidence of excess cancers in populations. The available evidence does indicate that for some organs/tissues and cancer types, there are dose thresholds below which radiation does not increase the risk of cancer. However, ICRP and other international organisations interpret the available scientific evidence from epidemiological and experimental studies to indicate that the most biologically plausible interpretation for practical protection purposes is a linear non-threshold relationship between dose and all stochastic effects taken together. This LNT relationship applies to absorbed and equivalent doses to organs / tissues as well as effective dose.

Other respondents expressed the view that cancer risks should not be estimated using effective dose and population-averaged risk coefficients, but using organs doses and age-, sex-, and population-specific risk coefficients. The report makes this clear and emphasises that best scientific data should be used in risk estimation where such calculations are warranted. But effective dose, calculated for protection purposes and the control of exposures, can give some indication of possible risk, as a detriment-weighted average of organ equivalent doses.

It has been argued that ICRP has not intended to specify a relationship between effective dose and stochastic risks. This is clearly not true as reference back to the 1977 Publications 26 and 27 will show (for example, paragraphs 104 -109 of Publication 26). Discussion of potential exposures as in Publication 103 (now included in the current report) provides a good example of a direct linking of effective dose and risk. The probability of death from an occurrence is taken as the product of the probability of the occurrence and the fatal cancer risk associated with the effective dose incurred.

Concerns were expressed about the use of collective effective dose and the calculations of numbers of deaths. Accepting a relationship between doses ($D$, $H$ or $E$) and risks, the corollary is that numbers of cancers and deaths can be estimated. It is true that collective dose has been misused to make alarmist predictions of numbers of deaths. To deny the possibility of risk at low doses is not the answer – rather the informed consideration of the data presented in relation to background rates of morbidity / mortality. Radiation protection professionals have a duty to communicate risks – differentiating between what we know from direct evidence and what we judge to be appropriate without direct evidence.
The greatest concerns were expressed in relation to medical exposures and risks to patients. There appears to be some reluctance to accept that there may be risks associated with low doses because this may lead to inappropriate decisions on treatment that do not consider benefit as well as risk. The possibility of very small risks associated with low levels of radiation (estimated as $D$, $H$ or $E$) should be acknowledged in the justification of procedures for which the benefit will be substantially greater in the vast majority of cases.

Annex: Consultation respondents

Responses were received on behalf of the following organisations: American Association of Physicists in Medicine (AAPM), Ben Gurion University, Israel, Canadian Nuclear Safety Commission (CNSC), Cancer Research Institute of the Electric Power Industry, Japan (CRIEPI), Duke University, USA, Dutch Authority for Nuclear Safety and Radiation Protection (ANVS), Dutch National Institute for Public Health and the Environment (RIVM), European Federation of Organisations for Medical Physics (EFOMP), European Nuclear Installations Safety Standards (ENISS), European Society of Radiology (ESR), Federation of Electric Power Companies of Japan (FEPC RMC), German Radiological Protection Commission (SSK), German-Swiss Association for Radiation Protection, Image Gently Alliance, Integrated Radiological Services, Ltd, UK, International Organisation of Medical Physics (IOMP), International Radiation Protection Association (IRPA), International Society of Radiographers and Technologists (ISRRT), Japan Health Physics Society, Netherlands Commission on Radiation Dosimetry (NCS), Nuclear Energy Agency, Committee on Radiological Protection and Public Health (NEA, CRPPH), NV5 Dade Mueller, USA, Public Health England (PHE), Society for Medical Physics of the Netherlands, Swedish Radiation Safety Authority (SSM), UK Society for Radiological Protection (SRP), United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the World Nuclear Association (WNA). Individuals who responded were: Yann Billarand, Caridad Borrás, Michel Bourguignon, Joachim Breckow, Sneha Chandrasekhar, Florence Cua, Darrel R Fisher, Anna Friedl, Jolyon Hendry, Hou Jie, Chris J Huskens, Tuvia Kravchik, Jeffrey Mahn, Thomas McKenna, Mark Miller, Shinichiro Miyazaki, Elizabeth Pitcher, RB Rakesh, Denis Remedios, Sandra Sarmento, Yoshiyuki Segawa, Graham Smith, Luigi Spiazzi, Jun Chiro Tada, Tetsuo Tanabe, Stefan Thierfeldt, and Brant Ulsh.