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SOMMAIRE — INHOUD

Annalen van de Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 4, 2009

VOORSTEL VOOR EEN NIEUWE STRUCTUUR VOOR DE REGELGEVING INZAKE DE BESCHERMING VAN DE BEVOLKING EN HET MILIEU TEGEN DE GEVAREN VAN IONISERENDE STRALINGEN

Verslag van de werkgroep regelgeving van de Belgische Vereniging voor Stralingsbescherming

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BVSABR

1 Inleiding: vraag van het FANC

Het Algemeen Reglement voor de Bescherming tegen Ioniserende Stralingen (ARBIS) werd nu meer dan 40 jaar geleden opgesteld. De veelvuldige herzieningen hebben de tekst met de tijd weinig overzichtelijk gemaakt. Ook is er gebrek aan coherentie, meer bepaald artikels die om historische redenen zeer gedetailleerd beschreven worden, anderen die eerder algemeen of abstract blijven. De Wet van 1994 en de laatste grote revisie van het ARBIS in 2001 hebben de toestand niet verbeterd.

Het Federaal Agentschap voor Nucleaire Controle (FANC) wenste daarom werk te maken van een vernieuwde wetgeving voor bescherming tegen ioniserende stralingen. Advies word aan de BVSABR gevraagd over hoe zulk een herziene regelgeving er zou kunnen uitzien. Daarbij zou een vernieuwende aanpak moeten gevolgd worden: nagaan welke de behoeftes zijn aan regelgeving en hierop een nieuwe structuur uitbouwen. De structuur zou de thema's bestrijken die in de regelgeving aan bod moeten komen. Verder werd ook verwacht dat een hiërarchie van de regelgeving zou voorgesteld worden: wat moet in de Wet, wat in Koninklijke/ Ministeriële Besluiten, wat in Aanbevelingen van het FANC.

Gevolggevend op deze vraag en na een inleidende bespreking met het FANC had de werkgroep regelgeving van de BVSABR zich als doelstelling gesteld *een structuur van een vernieuwde regelgeving voor te stellen, die de*

te bestrijken thema's definieert en de mogelijke hiërarchie van het wettelijke kader weergeeft.

De werkgroep omvatte BVSABR-leden werkzaam in de nucleaire industriële sector, in de medische sector en bij de Erkende Instellingen (zie punt 6).

2 Voorbereidend werk

Vooraleer over te gaan tot het definiëren van een nieuwe structuur heeft de werkgroep een reeks 'inleidende' stappen ondernomen teneinde haar inzicht over het onderwerp te verbreden:

- een inventaris werd opgesteld van wat beschouwd kon worden als voordelen en tekortkomingen van de huidige regelgeving;
- de raakvlakken met de Europese Richtlijnen (ER) en de IAEA Conventies werd nagegaan;
- een aantal voorbeelden van analoge regelgevingen in het buitenland werden toegelicht en besproken.

Deze inleidende stappen zullen niet verder in detail besproken worden in dit verslag, vermits ze niet de doelstelling zijn van het te leveren werk. Wel worden hier de belangrijkste aandachtspunten aangehaald die uit deze besprekingen voortvloeiden.

2.1 Inventarisatie voordelen en tekortkomingen van de huidige regelgeving

Een volledige inventaris van de voordelen en tekortkomingen van de huidige regelgeving werd opgesteld. Algemeen kan gesteld worden dat:

Meest beduidende sterke punten van de huidige regelgeving:

(a) De regelgeving, en dan in het bijzonder het ARBIS, is opgesteld als één geheel. Bijkomend is de tekst, voor zover men de bijlagen uitsluit, relatief compact. Een gebruiker hoeft dus zijn weg niet te zoeken in een labyrint van gevarieerde documenten. Er zijn wel een paar uitzonderingen van teksten (K.B.'s) die niet in het ARBIS geïntegreerd zijn.

(b) De administratieve stappen van de vergunningsaanvraag zijn goed gestructureerd. Het principe van indeling in klassen naargelang het risico is eenvoudig en overzichtelijk.

(c) Een belangrijke verantwoordelijkheid is toevertrouwd aan de Dienst voor Fysische Controle, die op zijn beurt gecontroleerd wordt door de Erkende Instelling of door het FANC.

Daarnaast kwamen volgende meest beduidende tekortkomingen naar voor:

(d) Zoals hierboven al aangehaald is het ARBIS historisch gegroeid tot een "patchwork" van bepalingen, niet altijd in logische volgorde en waarbij sommige vereisten sterk gedetailleerd worden, andere algemeen en abstract blijven.

(e) De bepalingen inzake "nucleaire veiligheid" komen slechts in beperkte mate aan bod.

(f) Er is een gebrek aan coherentie met de regelgeving inzake arbeidsveiligheid (CODEX), niet enkel naar de formulering toe maar meer in het bijzonder naar aanpak van het beleid.

(g) De ambiguïteiten over de rol van de Erkende Instellingen en meer bepaald hun rol bij instellingen die niet over een eigen Dienst voor Fysische Controle beschikken.

(h) De uitzonderingen van teksten (K.B.'s) die niet in het ARBIS geïntegreerd zijn.

2.2 Raakvlakken met de Europese Richtlijnen en de IAEA-Conventies

De belangrijkste bron voor verdere evolutie van het ARBIS komt van de Europese Richtlijnen, die wat de bescherming tegen ioniserende stralingen betreft worden opgesteld door de EC, DG TREN. Momenteel wordt aan een revisie van de "Basisrichtlijn" 96/29 Euratom (European Basic Safety Standards) gesleuteld en een revisie zou tegen 2009 kunnen verschijnen. De tendenzen zijn daarbij:

- de integratie van de nieuwe aanpak van de ICRP (met o.a. de nadruk op de beperkingen ("constraints");
- de versterking van de vereisten m.b.t. NORM en vrijgave;
- de consolidatie van de Richtlijn 96/29 met Richtlijnen 97/43 (medische blootstellingen), 90/641 (externe werknemers), 2003/122 (hoog actieve bronnen), 89/618 (informatieplicht);

- de integratie van vereisten inzake nucleaire veiligheid, hoewel dit laatste vermoedelijk eerder een wens is van de Commissie en nog niet in de volgende revisie zal verwerkt zijn.

De Conventies die getekend zijn met IAEA en meer bepaald deze m.b.t. de veiligheid van kerncentrales verdienen ook aandacht. Hoewel België in de praktijk in grote lijnen aan de vereisten voldoet, is dit onafhankelijk van wettelijke bepalingen die heden nagenoeg onbestaande zijn. In een evolutie van het ARBIS zouden minstens enige vereisten kunnen opgenomen worden, en de rol die het FANC en de Erkende Instellingen hierin spelen kunnen verduidelijkt worden.

Raakvlakken met de arbeidsregelgeving, met de milieuregelgeving, met de transportregelgeving, met de medische regelgeving en met de noodplanregelgeving werden in de werkgroep aangekaart maar zullen hier niet verder aangehaald worden.

2.3 Aanpak in buurlanden

De werkgroep heeft ook nagegaan hoe de wetgeving is opgesteld in andere landen. Vermits het onmogelijk was alle Europese regelgevingen individueel “onder de loupe“ te nemen, werd arbitrair gekozen voor de Nederlandse, de Duitse en de Finse wetgeving.

De belangrijkste vaststellingen die hieruit voortvloeien zijn:

- geen ven de drie regelgevingen integreert nucleaire veiligheid en stralingsbescherming, alle drie hebben gescheiden wetteksten die de nucleaire veiligheid behandelen;
- het principe van “richtlijnen” of “aanbevelingen” worden in de drie landen uitvoerig toegepast;
- de Nederlandse en Finse wetgevingen lijken goed gestructureerd; in het bijzonder het Finse model zou voor een aantal aspecten als voorbeeld kunnen gebruikt worden; de Duitse regelgeving geeft daarentegen ook de indruk om historisch uitgegroeid te zijn tot een complex geheel.

3 Voorstel van de werkgroep

3.1 Algemeen

Op basis van de eerdere besprekingen werd door de werkgroep in een eerste stap een hoofdstructuur uitgewerkt, waarbij geopteerd werd voor een drieledige hiërarchie: Wet – K.B. (ARBIS) – Richtlijnen.

Om de hierboven al aangehaalde reden werd geopteerd het ARBIS als één geheel te behouden. De indeling in hoofdstukken volgt de lijn van de Europese Richtlijn 96/29 Euratom.

De invulling van de hoofdstukken moet zoveel mogelijk "gebruikergericht" zijn, d.w.z. dat de bepalingen die betrekking hebben op een bepaalde activiteit zoveel mogelijk geconcentreerd blijven, zo weinig mogelijk verspreid zijn over verscheidene hoofdstukken.

Er werd ook getracht niet alle kaarten van het huidige reglementair model door elkaar te schudden, maar eerder een zachte evolutie tot verbetering van de huidige situatie.

3.2 Voorstel Wet

Het voorstel voor een nieuwe structuur van de Wet werd schematisch, artikel per artikel, opgesteld.

De algemene indeling is nagenoeg ongewijzigd ten aanzien van de Wet van 1994. Er wordt wel voorgesteld nieuwe hoofdstukken toe te voegen m.b.t.:

- de doelstelling van de Wet:
  - een eenvoudig artikel waarin de finaliteit van de Wet wordt toegelicht;
- het vergunningsstelsel:
  - de algemene principes van het vergunningsstelsel worden hier geëxpliciteerd (cf. wat vandaag in ARBIS artikels 5.1-5.3 staat);
  - ook zou hier meer expliciet vermeld worden hoe de federale en de regionale bevoegdheden verdeeld zijn (een meer expliciete verwoording dus van wat vandaag in ARBIS artikel 11, steunend op de uitspraken van het Arbitragehof hieromtrent);
- de organisatie van de controle:
  - het algemene principe van de controle (door de exploitant, door de overheid) wordt hier uiteengezet.

Bijkomend zouden in de Artikels van de Wet opgenomen worden:

- onder hoofdstuk 2, de bevoegde overheid: de verantwoordelijkheden van het FANC m.b.t. het noodplan zou geëxpliciteerd worden, zodat het huidige artikel 72 van het ARBIS overbodig wordt (en de taken van het FANC geconcentreerd worden in de Wet);
- onder hetzelfde hoofdstuk, zou de verantwoordelijkheid inzake dosistoezicht en dosisregistratie (vandaag bij de FOD Tewerkstelling en Arbeid) ook best overgedragen worden aan het FANC, om reden van expertise;
- onder hoofdstuk 5, de bepaling m.b.t. de indemniteiten, vandaag in ARBIS artikel 19.

3.3 Voorstel Koninklijk Besluit (ARBIS)

Het voorstel voor een nieuwe indeling van de hoofdstukken en deelhoofdstukken van het ARBIS werd eveneens schematisch, artikel per artikel opgesteld. Buiten de wijzigingen aan de structuur worden ook voorstellen gemaakt om huidige knelpunten of tekortkomingen van de regelgeving op te vangen.

Zoals vermeld wordt voor de indeling in hoofdstukken zoveel mogelijk de structuur van de Europese Richtlijn 96/29 Euratom gevolgd. De indeling tracht ook gebruikersgericht te zijn.

De hoofdstukken 1 en 2 hebben betrekking op de definities en het toepassingsgebied, in omgekeerde volgorde als nu in het ARBIS, maar coherent met de Europese Richtlijn.

Het hoofdstuk 3 heeft betrekking op het vergunningsstelsel, zoals nu in het ARBIS. Het omvat de indeling in klassen, de normale vergunningsprocedures, verder de mogelijke veranderingen aan de vergunning en de ontmanteling- en afvalvergunningen.

Volgt het hoofdstuk 4 dat de algemene vereisten weergeeft, van toepassing op alle vergunde inrichtingen. Het groepeert het algemene beleid, de algemene dosislimieten, de vereisten inzake nucleaire veiligheid en de controle.

De hoofdstukken 5, 6 en 7 geven meer specifieke vereisten naar de klassieke drieledige indeling: de blootstellingen op het werk, de blootstelling van bevolking en milieu en de medische blootstellingen.

In het hoofdstuk 8 worden alle vereisten m.b.t. de natuurlijke stralingsbronnen ondergebracht (inclusief wat vandaag in het ARBIS onder het hoofdstuk 3 te vinden is).

Het hoofdstuk 9 vormt een fusie van de vereisten inzake transport en inzake invoer, doorvoer, uitvoer, vandaag in het ARBIS in twee gescheiden hoofdstukken te vinden.

Het hoofdstuk 10 bundelt alle vereisten m.b.t. abnormale gebeurtenissen en noodsituaties. Er wordt een onderscheid gemaakt tussen gebeurtenissen in vergunde inrichtingen en gebeurtenissen buiten het kader van de vergunde inrichtingen.

Het hoofdstuk 11 behandelt de erkenningen van personen en instellingen. Het hoofdstuk vormt de tegenhanger van het hoofdstuk 3 (ver gunningen van inrichtingen) maar wordt achteraan geplaatst omdat de verschillende functies die aan erkenning moeten onderworpen worden pas in de voorgaande hoofdstukken gedefinieerd is.

De regelgeving eindigt zoals gebruikelijk met een hoofdstuk over slotbepalingen en overgangsbepalingen.

Er valt ook op te merken dat de hoofdstukken 5 t.e.m. 9 telkens ingeleid worden met een artikel dat het toepassingsgebied omschrijft, dit om de gebruiker te begeleiden en misverstanden te vermijden.

3.4 Voorstel richtlijnen FANC

Naar analogie met wat er in andere Europese Lidstaten gebeurt, stelt de werkgroep voor de meer gedetailleerde bepalingen, die niet direct hun plaats hebben in een Koninklijk Besluit, over te hevelen naar Richtlijnen. Deze Richtlijnen worden door het FANC opgesteld en gepubliceerd in het Staatsblad. Ze hebben een bindend karakter.

In de verschillende hoofdstukken van het Koninklijk Besluit wordt vastgelegd wat het FANC in een Richtlijn zal bepalen.

Een voorstel werd uitgewerkt van de op te stellen Richtlijnen. Er wordt daarbij een onderscheid gemaakt tussen 'Administratieve' en 'Technische' Richtlijnen. Administratieve Richtlijnen hebben tot doel een zeker formalisme in te voeren in het voldoen aan reglementaire bepalingen. Technische Richtlijnen geven toelichtingen over de te volgen methode om aan de regelgeving te voldoen.

Hoewel het aantal voorgestelde Richtlijnen (en dus de opdracht voor het FANC) a priori omvangrijk lijkt te zijn, moet opgemerkt worden dat:

- de inhoud van verscheidene Administratieve richtlijnen gelijklopend is, mogelijk kunnen verschillende Richtlijnen in één publicatie gebundeld worden;
- verschillende technische Richtlijnen inhoudelijk uitgewerkt zijn in internationale publicaties, die dus als basis kunnen dienen voor het FANC; ook het voorbeeld van analoge Richtlijnen in andere EU-lidstaten kan als basis gebruikt worden.

4 Besluit

In antwoord op de vraag van het FANC heeft de werkgroep "regelgeving" van de BVSABR een vernieuwde structuur uitgewerkt voor de regelgeving voor de bescherming tegen ioniserende stralingen. In de nieuwe structuur zijn ook een aantal voorstellen verwerkt om tekortkomingen van de huidige regelgeving op te vangen.

Zoals heden berust de regelgeving op een enkele basiswet, met daarop aansluitend een Koninklijk Besluit. Het Koninklijk Besluit dekt ook zoals heden de aspecten betreffende stralingsbescherming en nucleaire veiligheid (of in het K.B. ook de aspecten betreffende de fysische beveiliging moet opgenomen worden wordt opengelaten). Nieuw is dat een hele reeks gedetailleerde administratieve en technische of wetenschappelijke bepalingen uit het K.B. geweerd worden en overgeheveld worden naar bindende Richtlijnen.

De voorgestelde structuur van het Koninklijk Besluit sluit zoveel mogelijk aan bij de indeling van de Europese "Basic Safety Standards", echter geconsolideerd met de andere Europese Richtlijnen die betrekking hebben op stralingsbescherming. De indeling is gebruikersgericht, d.w.z. dat de informatie van toepassing voor één enkel gebruiker zoveel mogelijk

gebundeld wordt, op een samenhangende wijze. Waar van toepassing tracht de regelgeving ook zoveel mogelijk coherent te zijn met de bepalingen van de Codex betreffende welzijn op het werk.

Het resultaat is een toekomstige regelgeving die geen grote kentering betekent ten aanzien van wat vandaag van toepassing is, maar eerder zorgt voor continuïteit, consolidatie waar dit voordelen biedt en meer duidelijkheid en coherentie.

6 Deelnemers aan de werkgroep

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REVISION PROCESS OF THE BSS AND THE DIRECTIVES OF THE EUROPEAN UNION

GOING BEYOND ICRP 103?

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Abstract

In the framework of the currently ongoing discussions concerning the revision of the BSS, as well within the group of scientific experts referred to in Article 31 of the Euratom Treaty as at the level of the Safety Committees of the International Atomic Energy Agency (IAEA), a working group of the Federal Agency for Nuclear Control (working group Radiation and Health) has invited several high level Belgian experts involved in radiation protection for a thorough discussion on the way forward with the new scientific data regarding the effects of ionizing radiation on the human health. The goal of this working group was to perform a "realistic brain storming", meaning that the group should try to find innovative but at the same time realistic and pragmatic ways to take the new scientific data into account. This could later be used as proposals by the Belgian experts in the ongoing international discussions. The following issues were addressed: Cataracts; Circulatory diseases; In utero exposure; Dose and Dose Rate Effectiveness Factor (DDREF); Radon; Individual susceptibilities (age, gender, genetic susceptibilities); Internal exposures. As scientific vigilance, deontology and responsible decision-making, including unavoidable value judgments, are necessary at all levels and as scientific advisors as well as regulators cannot allow themselves to « wait for instructions » from international organisations but have to take their own responsibilities, the answer to the question "*Going beyond ICRP 103?"* is rather clear for the group: *if necessary, yes!*

Basic Safety Standards: main international players and their role

At the EU level, in application of the Euratom Treaty, the Basic Safety Standards (BSS) for radiation protection are fixed by means of Directives, proposed by the European Commission (EC) and approved by the Council (by qualified majority), after having taken the opinion of the European Parliament and of the Economic and Social Committee. The EC proposals are in practice elaborated in collaboration with the so called "Article 31 group of experts" (Art 31 GoE), a group of scientific experts referred to in Article 31 of the Euratom Treaty. This group is officially in charge of advising the European Commission as regards the Basic Safety Standards for the protection of the health of the workers and of the general public against the danger arising from ionizing radiation. In fulfilling their function, the members of the group are independent experts and do not represent Member States or other bodies. Thus, they are supposed to speak on their own behalf and independently of all external pressure. This means they take on, as individuals, high-level responsibilities concerning scientific evaluation and public health. According to their Code of Ethics, the Art 31 experts shall give priority to the protection of public health, to the safety and to the development of the best available operational radiation protection. They may express views on political, economical, financial, and liability matters but the health and safety considerations must always be clearly identifiable in their opinions, proposals, guidance and statements. If the need arises, various options shall be proposed, including options giving priority to health aspects.

In parallel with the EU BSS directives, there are also « International BSS ». These international BSS are part of the numerous Safety Standards of the International Atomic Energy Agency (IAEA), but they are co-sponsored by various other international organisations, namely by the International Labour Organisation (ILO), the Food and Agriculture Organisation (FAO), the Nuclear Energy Agency (NEA), the World Health Organisation (WHO) and the Pan American Heath Organisation (PAHO). Despite this co-sponsorship, the international BSS has to be considered essentially as an IAEA document, due to the fact that the man power and influence of the other organisations are rather limited (particularly as regards ILO and WHO) as compared with the IAEA (and to a lesser extent with the NEA). The International BSS are at the level of a Requirement document, this

meaning that they are obligatory (as opposed to simple Guides), but only for those requesting the aid of the IAEA. Noteworthy they are *not* at all mandatory for the EU, where Member States are required to follow the EU BSS directives. This is important because, besides many common requirements, there are some fundamental differences between the EU and the international BSS. For example, the protection of the embryo and foetus ("child to be born") is much more severe in the EU BSS than in the International BSS, this under pressure of the United States.

As well the EU BSS as the international BSS try explicitly to follow as strictly as possible the recommendations of the International Commission on Radiological Protection (ICRP), ICRP (in fact its Main Commission) being considered as the world leader in the field of recommendations for radiation protection. Regarding scientific evaluations, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the committee on Biological Effects of Ionizing Radiation (BEIR) of the United States National Academy of Science (NAS) are currently the world leaders. There is classically a "cascade" (at least in the case of the international BSS), that begins with the UNSCEAR Reports, on which the ICRP bases its recommendations, which are then followed when elaborating the BSS.

Basic safety Standards and Science

Developments in health protection standards in general, including in radiation protection standards, rest on a chain beginning with hard facts and research (some detriment is observed), followed by scientific evaluation (is this observation robust, logical, confirmed, etc?), and then by discussion of the potential regulatory or policy implications (do we have enough elements to take a decision, should we apply the precautionary principle?), the chain making frequently a loop by the request of additional research, to confirm or better specify the initial observation.

Now the issue is the following: as well in the evaluation of the new scientific data as in the evaluation of the potential regulatory or policy implications, there are some unavoidable pitfalls. Three pitfalls are particularly obvious. First of all, each of the actors has a specific mandate to cope with, he is paid by somebody to do or defend something and therefore he is not entirely free (or even entirely not free). It is easy to

understand that there are a lot of potential conflicts of interest (for example, for admitting the existence or the importance of a risk associated with an activity you are paid to promote). Secondly, value judgments are unavoidably present when discussing the policy implications: how much money are we ready to spend for protection, particularly if the number of individuals at risk is small? How far are we going in the precaution? What amount of evidence do we need before acting? Do we need evidence-based results in terms of proved detriment on human beings in large exposed cohorts? Or are we ready to take measures of protection based on animal evidence or on isolated suspect cases (as is routinely done for drugs)? Although frequently denied, value judgments are also often present in scientific evaluations. A frequently seen example is the selection of the bibliographic sources that are the most compatible with the experts' "belief". It is also frequent that scientists make value judgments about the "importance" of a risk. For example, a risk is frequently described as being "negligible": but for *whom* is it negligible? On which *base,* within which framework do we decide that it is negligible?

Finally, a third pitfall in the evaluation of scientific data or policy implications is worth being mentioned: the weight of dominant paradigms. This means that the experts in a specific field, that are often not numerous, are educated and trained in a standardized way, particularly in fields where international harmonization is becoming the rule and the goal. The risk is then important to develop a kind of inbreeding, jeopardizing creativity and favouring the "pensée unique". This is all the more so since the same experts are frequently members of the different organisations active in the field, creating what can be considered as a "pseudo-consensus" or a "club spirit".

A marked illustration of this club spirit (or paradigm) is the meaning of the concept of "scientific cautiousness". For the scientific world (UNSCEAR...) « cautiousness » means that the main concern must be to avoid concluding that a causal relationship exists before it is *firmly proven*. On the contrary, the « cautiousness » expected from groups as the Art 31 GoE or the ICRP is that their main concern should be to protect health; when there is scientific plausibility of the existence of a risk of serious and irreversible harm (*even if there is still uncertainty),* these groups should alert the policy-makers (precaution principle). « Lack of (human health) evidence does not mean evidence of lack of effect ».

As a consequence, we are forced to accept that as well the regulatory BSS as the international recommendations and even the international scientific agreements are unavoidably not based on "pure science". This means that we seriously need to "open" the reflexions, to consult all the stakeholders in the society and to develop a variety of think tanks. This also means that the EU regulators and the national regulators have their own specific ethical responsibilities and that just following an international agreement is not a sufficient justification for a decision.

The RIHSS Seminars

The RIHSS Seminars are scientific seminars organized yearly by a working group of the Art 31 GoE, called Research Implications on the Health and Safety Standards (RIHSS).
During these seminars, leading experts (often coordinators of international research funded by EU) are asked to review the state of the art in a specific field of interest, while other experts specialized in this specific field are invited by the Art 31 experts to act as peer reviewers. The day after the seminar, the Art 31 GoE discuss the potential regulatory implications for Europe.
The RIHSS Seminars can be considered as a bridge between research and regulators.
The RIHSS Seminars topics cover Radon (1997), Thyroid diseases and lessons from Chernobyl (1998), Genetic susceptibility (1999), Cancer risks at low dose (2000), In utero exposure in early phases of pregnancy (2001), Ionizing radiation and breast cancer (2002), Medical overexposures (2003), a Critical review the ICRP draft 2005 recommendations (2004), Alpha-emitters: assessment of risk (2005), New insights in radiation risk and BSS (2006), Tritium and low energy beta emitters (2007), Radiation induced circulatory diseases (2008) and Childhood leukaemia's (2009).
The Proceedings are published in the EC Radiation Protection Serie and are available on the web site of the EC:

http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm

The RIHSS Seminars and the last ICRP Recommendations

Before publishing its last recommendations (Publication 103), the ICRP had carried out a long and wide consultation. Various successive drafts have been submitted to international open consultations. Three RIHSS Seminars have been organized in 2004, 2006 and 2008 to discuss the relevant ICRP drafts or associated issues.

A lot of scientific and regulatory concerns have been expressed during the 2004 Seminar. Some of these concerns have been adequately addressed by the ICRP in subsequent drafts.

The 2006 RIHSS Seminar was devoted to New insights in radiation risk and BSS and covered a wide variety of new results having potential implications for radiation protection, including new epidemiological data (nuclear workers, Techa River, large scale indoor radon studies), biological aspects in relation to age/gender sensitivities, new biological data in relation with low dose risk, new data on genetic risk and, last but not least, new challenging evidence regarding radiation-induced cataracts.

Finally, new challenging evidence regarding radiation induced circulatory diseases has been presented and discussed during the 2008 RIHSS Seminar.

Globally, although the ICRP has made a real effort to consult largely the international community and to take comments into account, the final recommendations recently issued (Publication 103) are disappointing on many points. Some recurrent concerns, expressed as well during the RIHSS Seminars as by various stakeholders, including the Belgian Association for Radiation Protection and the Belgian Federal Agency for Nuclear Control, are still not adequately addressed in the final recommendations. Probably the most important among these recurrent concerns is the *lack of precautionary approach by ICRP in relation with new scientific data.*
The main concerns expressed can be summarized in this way:

- Regarding radiation-induction of **cataract**, new data challenging the current dose threshold are available (see farther). ICRP has still not revisited the relationship between the dose to the lens and the occurrence of cataracts for adapting the protection system.
- Regarding radiation-induced **circulatory diseases**, there are new data available pointing to the possible induction by radiation of these diseases at much lower doses than currently assumed (see farther). While no

definite answer can be given regarding the shape of the dose-response at low dose and regarding the numerical values of possible threshold doses, that situation is to a certain extent comparable with the situation ICRP faced in the past regarding cancer induction. ICRP should have taken these data explicitly into account in its judgements and recommendations, particularly in the relatively high dose situations that can occur in medical applications and in prolonged exposures.

- Regarding **pregnancy**, the new data, the large residual uncertainties and the ethical aspects in the evaluation of the effects of in utero exposures are insufficiently taken into account in ICRP documents. There is a risk that the figure of 100 mGy to the embryo/foetus could be understood as a kind of "limit of concern" in medical exposures and prolonged exposure situations.
- Regarding cancer risk estimation, the main issue is the value of the **DDREF**: as a lot of recent epidemiological data seem to point consistently to a DDREF lower than 2, the ICRP choice for a DDREF of 2 is difficult to justify. From a radiation protection point of view, *strong evidence* is needed for assuming a lower risk per unit dose at low or protracted exposures than for high acute doses.
- Regarding exposures to **radon indoors,** the recent European pooled analysis showed that the increase in lung cancer risk for residential exposures to radon is statistically significant even at concentrations lower than 200 Bq/m^3, challenging therefore the ICRP reference levels (with success, given that ICRP made recently a statement recommending a decrease of these reference levels).
- Regarding the issue of the **inter-individual differences**, as the radiation-induced cancer risk is significantly different for women (v/men) and for children (v/adults), particularly for certain tissues (breast cancer in women, thyroid cancer in children ...), it seems more appropriate, based on equity considerations, to promote **age** and **gender** specific protection measures, such as specific w_T or specific organ dose constraints/limits. Similarly, it seems to be appropriate to proactively take into account differences in **genetic susceptibilities** to radiation-induced effects, particularly in high dose situations (some medical exposures, rescue workers …). The ICRP decided to keep an "average" prospective approach, neglecting these aspects.

- Regarding genetic risk, based on the current evidence, one can still doubt if the radiation-induced genetic risk is really practically limited to **2 generations,** as implied by the risk factor chosen by the ICRP. Taking the numerous uncertainties into account, we should not neglect the possibility of significant long term risks. The genetic consequences of **continuous** exposure of many consecutive generations (as may be the case after a major accident or increased use of medical ionizing radiation) is insufficiently taken into account.

FANC Radiation and Health Group: new insights in radiation risk and BSS

Within the Federal Agency for Nuclear Control, there are several "communities of practice" where interested experts or individuals from all services or departments can exchange their views and knowledge about common concerns, including new scientific evidence and policy implications. The oldest of these communities of practice is the group Radiation and Health, whose scope, clearly indicated by its name, is the follow up of new evidence regarding the effects of ionizing radiation on the health.

In the framework of the currently ongoing discussions concerning the revision of the BSS, as well within the Art 31 GoE as at the level of the Safety Committees of the IAEA (RASSC, WASSC, …), the group Radiation and Health has invited several high level Belgian experts involved in radiation protection for a thorough discussion on the way forward with the new scientific data. The goal of this "enlarged" Radiation and Health working group (R&H WG) was to perform a "realistic brain storming", meaning that the group should try to find innovative but at the same time realistic and pragmatic ways to take the new scientific data into account. This could later be used as proposals by the Belgian experts in the ongoing international discussions. The following issues were addressed: Cataracts; Circulatory diseases; In utero exposure; Dose and Dose Rate Effectiveness Factor (DDREF); Radon; Individual susceptibilities (age, gender, genetic susceptibilities); Internal exposures. The genetic risk issue has not been addressed.

The issue of radiation induced cataracts

In the current BSS, dose limits for the lens of the eye (150 mSv/y for the exposed workers and 15 mSv/y for members of the public) are based on ICRP recommendations in Publication 60 (1991). These recommendations were based on postulated threshold doses of **5 Sv** (equivalent dose) for detectable opacities and **8 Sv** for visual impairment (cataract) in conditions of highly fractionated or **protracted exposure** (adult population) (ICRP 60, annexe B, p 103, table B-1). Corresponding figures for single acute exposures were 0.5-2 and 5 Sv. Note that these ICRP 60 figures are the same as those from ICRP Publication 41 (1984) (ICRP 41, p 28, table 6), based themselves on radiotherapy studies. The dose limit for the lens of the eye for members of the public are based on "an arbitrary reduction factor of 10" (ICRP 60, p 46, 194).

During the EU Scientific Seminar held in Luxembourg on 17 October 2006 about "New Insights in Radiation Risk and Basic Safety Standards", Norman J. Kleiman, Director of the Eye Radiation and Environmental Research Laboratory in the Columbia University reviewed the new available evidence regarding radiation-induced cataracts. In various exposed populations, including those undergoing CT scans (Klein, 1993), radiotherapy (Wilde, 1997; Hall, 1999), the astronaut pool (Cucinotta, 2001; Rastegar, 2002), atomic bomb survivors (Minamoto, 2004; Nakashima, 2006), residents of contaminated buildings (Chen, 2001) and the Chernobyl accident "liquidators" (Worgul, 2003, 2007), dose-related lens opacification at exposures significantly lower than 2 Gy was reported. Kleiman noted that the evidence to date points to a dose threshold **no greater than 700 mGy**, which challenges the current ICRP guidelines.

Moreover, Kleiman reported new observations that are even consistent with the absence of a dose threshold**.** Although the mechanism of radiation induced cataracts is not known precisely, genomic damage resulting in altered cell division, transcription and/or abnormal lens fibre cell differentiation is now considered to be the salient injury, rather than cell killing. For this reason, the classification of cataracts as a deterministic effect must be called into question. Several lines of evidence from experimental and epidemiologic studies suggest a **stochastic** basis for radiation cataracts. Animal studies have shown that individuals that are haplo-insufficient for genes involved in DNA damage repair and/or cell

cycle checkpoint control may be more susceptible to the cataractogenic effects of ionizing radiation than wild-types. Atm, Brca1 and Rad9 heterozygotes demonstrate enhanced sensitivity to radiation-induced cataract formation. Heterozygosity of the *Atm* gene is estimated to occur in 0.5-1% of the Western population. The roles of Atm, Rad9 and Brca1 in the cell cycle and during DNA repair are consistent with a genotoxic basis for radiation cataractogenesis. These findings may have important implications for radiosensitive subsets of the human population and for the astronaut core.

Kleiman concluded that, given that all national and international risk standards for ocular exposure are predicated on a relatively high threshold, current risk guidelines for ocular radiation safety require reassessment.

Since the 2006 EU Seminar, a lot of new evidence was published that confirmed these conclusions. A review of these new results has been made in November 2009 by the Art 31 RIHSS Working Party and is described hereafter.

In 2007, Chumak *et al* investigated the lens dosimetry in the above-mentioned (Worgul, 2007) study of a cohort of exposed clean-up workers (liquidators) at the Chernobyl Nuclear Power Plant and concluded that the current dosimetric methodology provides reasonable estimates of individual γ-ray and ß-particle doses to the lens of the eye that are *sufficiently accurate* to have utility in this kind of epidemiological/clinical study.

Also in 2007, Kleiman *et al)* investigated the impact of *dual heterozygosity* for *Mrad9* and *Atm* (genes regulating multiple cellular responses to DNA damage) on radiation-induced cataractogenesis in mice. Posterior subcapsular cataracts, characteristic of radiation exposure, developed earlier (and were more severe) in X-irradiated (50 cGy) double heterozygotes than in single heterozygotes, which were more prone to cataractogenesis than wild-type controls.

There was also a new study regarding Atomic Bomb Survivors published in 2007. Neriishi *et al.* (Radiation Effects Research Foundation) investigated the radiation dose response in postoperative cataract cases among atomic bomb survivors. Because many in the radiation protection community have believed that, while relatively low doses of radiation may cause small, clinically insignificant opacities, a large dose threshold (in the

order of 5 Gy) exists for large, vision-impairing cataracts, this study was designed to evaluate evidence regarding *clinically significant* cataracts, namely, those that were removed surgically. The prevalence of postoperative cataracts in A-bomb survivors increased significantly with A-bomb radiation dose. The estimate (0.1 Gy) and upper bound (0.8 Gy) of the dose threshold for operative cataract prevalence was much lower than the threshold usually assumed by the radiation protection community and was statistically compatible with no threshold at all.

In 2008, Chodick *et al*. presented the results of a 20-Year prospective cohort study among more than 35,000 US radiologic technologists, aiming to determine the risk of cataract with respect to occupational and non occupational exposures to ionizing radiation and to personal characteristics. For workers in the highest category (mean, 60 mGy) versus lowest category (mean, 5 mGy) of occupational dose to the lens of the eye, the adjusted hazard ratio of cataract was 1.18 (95% confidence interval: 0.99, 1.40). Although based on questionnaires and self-reports, this study supports the hypothesis that the lowest cataractogenic dose in humans is substantially less than previously thought.

The results of a NASA study of cataracts in astronauts (Chylack *et al.,* 2009) also suggest increased cataract risks at smaller radiation doses than have been reported previously.

Vano *et al.* investigated in 2008 radiation doses to the eye lens of the interventionalist from medical procedures performed with and without use of radiation protection measures. With typical reported workloads, radiation doses to eye lenses may exceed the ICRP threshold for deterministic effects (ie, lens opacities or cataracts) after several years of work if radiation protection tools are not used.

An international study called RELID (Retrospective Evaluation of Lens Injuries and Dose) was initiated by the IAEA in 2008. A number of eye testing exercises have been held and show that large proportions (sometimes going to 40 %) of interventional cardiologists and even technicians or nurses had posterior subcapsular opacities. The majority did not use leaded protective lenses nor suspended leaded screens.

In a recent review performed by a team including HPA experts, E.A. Ainsbury *et al* concluded that recent studies indicate that "the threshold for

cataract development is certainly less than was previously estimated, **of the order of 0.5 Gy**, or that radiation cataractogenesis may in fact be more accurately described by a linear, no-threshold model".

On 14 May 2009, the German Commission on Radiological Protection (SSK) also reviewed the available data and adopted new recommendations regarding radiation-induced cataracts.
The SSK considered that recent epidemiological studies have not demonstrated any threshold value below which damage to the lens of the eye from ionising radiation can be ruled out with certainty and that there is a **strong probability that the threshold dose is < 0.8 Gy**.
In various studies, an increase in the cataract rate was indeed observed after radiation exposure of around 0.5 Gy. As comparable effects were observed after short-term exposure and after exposure over longer periods, the SSK stressed the importance of looking to the lifetime dose, instead of only to the annual dose. The current dose limit for the lens i.e. 0.15 Gy, would amount to a cumulative dose of 3 Gy over a 20-year exposure period. This dose is higher, by a factor of almost 6, than the dose at which additional cataracts have been observed, and according to current knowledge, would more than double the risk of spontaneous cataract. The SSK recommends that the German regulatory provisions "be brought into line with the latest scientific findings" and that, for activities which are known to be associated with possible significant lens exposure, appropriate protection measures must be foreseen, as well measurement of the lens dose and occupational medical examination of the lens.

In the latest recommendations (Publication 103), ICRP kept the same dose limits for the lens of the eye, while warning that this limit is "currently being reviewed by an ICRP Task Group". At this date, the report of this Task Group is not yet available and we are still waiting for the recommendation of the main Commission.

Cataracts: Radiation and Health proposals

As many other experts, the members of the enlarged Radiation and Health Working Group (R&H WG) consider that, while the possible future ICRP recommendations on this issue should be taken into account, it would certainly not be acceptable, based on the current scientific knowledge, to keep the old dose limits for the lens of the eye.

The R&H WG makes the following proposals:

1. The dose limits for the lens of the eye should be decreased by a factor of 3 to 5
2. ALARA procedures and lens dose constraints, including lifetime constraints, should be applied in risk situations
3. Risk analysis and Action plans (monitoring of lens dose, use of protection tools, periodical ophthalmic examination …) should be mandatory in risk situations.

Emerging evidence for radiation-induced circulatory diseases

In recent years, radiation-induced blood circulatory system diseases has become a growing concern, particularly in the field of radiotherapy, after irradiation of the heart or of large arteries. There is currently a lot of research in the field, including within the European Research Framework Programmes. Some new challenging data have recently been published or are in the process of being published. Although evidence for radiation-induced circulatory disease was reviewed some years ago by the United Nations Scientific Committee on the Effects of Atomic Radiations (UNSCEAR) and published recently in Volume 1 of the UNSCEAR 2006 Report (annex B: Epidemiological evaluation of cardiovascular disease and other non-cancer diseases following radiation exposure), some of these new data were not available at that time for evaluation by UNSCEAR. This is why the issue of radiation induced circulatory diseases has been presented and discussed thoroughly during the 2008 RIHSS Seminar.

Last evidence for a radiation-associated excess risk of diseases of the blood circulatory system among the Japanese survivors of the atomic bombings has been reviewed. About 87 000 survivors belong to the Life Span Study (LSS) cohort. This study, investigating mortality and cancer incidence, started in 1950 and is still underway. The Adult Health Study (AHS) is a subset of the LSS that started in 1958 and consists of a cohort of about 20 000 persons followed by biennial health examinations, allowing disease *morbidity* to be investigated for a range of diseases, including circulatory disease. On the basis of current evidence, it was concluded that increased risks of circulatory diseases are apparent even below doses of 2 Gy, the data being consistent with a linear no-threshold dose-response relationship but also with a threshold dose of around 0.5 Gy. Under the assumption of

an underlying linear no-threshold dose-response relationship, the radiation-associated circulatory disease deaths represent a significant proportion of all radiation-associated deaths, although bias and confounding (which may be negative) cannot yet be reliably discounted as explanations for the association.

More challenging are the (still unpublished) results of the Southern Urals Radiation Risk Research (SOUL) project, supported by the European Commission's 6th Framework Programme (Euratom) and the Federal Medical Biological Agency (Russian Federation). In this study risks of morbidity and mortality from circulatory diseases were estimated up to the end of 2000 in the cohort of workers (about 12 000 workers, among which about 3500 women) first employed at the main facilities of Mayak PA in 1948-1958 in relation to external and internal radiation, whilst allowing for age, gender and non-radiation risk factors. The Mayak Production Association (PA) was the first Russian nuclear facility and is located 10 km from the city of Ozyorsk in the Southern Urals. Mayak PA started operation in June 1948 and included all the plants necessary to produce weapon-grade plutonium: reactors, radiochemical plant, plutonium plant and auxiliary plants.

The SOUL study is characterized by a large database on dosimetry and regular medical examinations. In addition, there is very good information on confounding factors (including smoking and alcohol) and quality control checks were conducted on a regular basis. The effects studied were ischemic heart diseases (IHD) and cerebrovascular diseases (CVD).

Individual monitoring of exposures to external gamma doses was conducted from the beginning of operations at Mayak. The average total external gamma dose for the whole employment period was 0.91 Gy (range 0-5.92 Gy) for males and 0.65 Gy (range 0-5.70 Gy) for females. Plutonium body burden was measured (and estimates of internal doses were subsequently derived) only for 30% of workers who were in contact with transuranium radionuclides. Therefore analyses of internal exposures were restricted to monitored workers. The absorbed dose to liver was used in analyses of internal exposure as surrogate for dose to blood vessels/heart; although these doses would differ, they were considered to be highly correlated. The average absorbed liver dose from internal alpha exposure was 0.40 range 0-17.90 Gy) for males and 0.81 Gy (range 0-127.82 Gy) for females.

The risk of morbidity was statistically significantly increased for workers with a total dose from chronic external gamma ray exposure above 1 Gy for IHD, and above 0.5 Gy for CVD, (when compared with doses less than 0.5 Gy). There was a statistically significant increasing trend in IHD and CVD morbidity with increasing total external dose. The risk for IHD morbidity is higher for women than for men (ERR/Gy: 0.71 vs 0.39).

When looking at internal exposures, risks of both mortality and morbidity from IHD and CVD were raised among workers with total absorbed doses to the liver from internal alpha exposure above 0.1 Gy, when compared with workers monitored for such exposures who had lower doses. There were statistically significant increasing trends with increasing total internal alpha dose to the liver in IHD mortality and in CVD morbidity. There was less evidence for a trend with internal dose in IHD mortality after adjusting for external dose, whereas this adjustment had little impact on the findings for CVD morbidity.

Globally, the risk estimates are compatible with those from other large occupational studies and from the A-bomb survivors. In particular, the data are consistent with a linear dose-response relationship from doses as low as 0.5 Gy, but with much fewer limitations in this study regarding statistical power and confounding factors. In addition, this study confirms the acute exposure findings from the LSS data in the context of protracted doses.

The general flavour of the presentations and of the discussions was that the currently available scientific data are *solid enough* for imposing us to take this problem seriously into account not only in radiotherapy, but also in the field of radiological protection in general.

Finally there was a broad consensus within the Article 31 Group of experts on the following conclusions:

- Although a lot of confounding factors have to be taken into account, epidemiological evidence is accumulating in favour of an increased risk of circulatory disease for doses higher than 0.5 Gy, including after protracted exposures.

- The radiation-associated circulatory diseases could represent a significant proportion of the radiation-associated mortality, making of this topic a

public health pertinent issue at high doses (i.e. radiotherapy, accidental exposures, …).

- The problem of irradiation of the blood vessels and the heart is currently a growing concern in radiotherapy. One of the key problems is to know which anatomical structures are important for the risk (critical targets).
- The possible biological mechanisms are still unknown. Active R&D is ongoing (projects NOTE and CARDIORISK in Europe). A major limitation is however the fact that good animal models are lacking.
- The currently available scientific data are solid enough for imposing us to take this problem seriously into account. Policy and regulatory implications should be further discussed. Suggestions included the explicit introduction in the BSS of the concept of optimisation and dose constraints for the heart and for the other organs, information of public health authorities and of the medical community (not only in radiotherapy, as for example repetitive CT scans in radiology may lead to cumulative exposures that are far from being negligible), development and diffusion of radiotherapeutic strategies to minimize unnecessary heart doses (in particular for the treatment of breast cancers) and stimulation of R&D (including in the field of effects of internal exposures).

Radiation-induced circulatory diseases: Radiation and Health proposals

The R&H WG makes the following proposals:

1. ALARA procedures and **organ** dose constraints, including lifetime constraints, should be applied in risk situations
2. Risk analysis and Action plans should be mandatory in risk situations.

The issue of early in utero exposures: new evidence and uncertainties

As regards protection during pregnancy, the EU Basic Safety Standards Directive states that the protection of the child to be born shall be comparable with that provided to for members of the public, with work conditions for the mother making unlikely that the dose to the child to be born will exceed 1 mSv during “at least the remainder of the pregnancy” (i.e. from the day the pregnant woman has informed the undertaking of her condition).

To limit the dose to the embryo during the first days of his existence, the former BSS Directive stated that the dose to the abdomen of women of reproductive capacity shall not exceed 13 mSv in a quarter. This kind of provision has now disappeared.
In practice thus, the "child to be born" has now the same dose limit as the members of the public (at least from the declaration of the pregnancy).

As it is the case for the approach of the genetic risk, the risk from in utero irradiation is currently regarded with more optimism, and threshold figures, like the emblematic 100 mSv numerical value, are frequently presented as the break-point criterion in situations like emergency planning, post-accidental relocations or medical accidental irradiations. This evolution is noteworthy in the last ICRP Recommendations and related documents.

In the same time period, a lot of new radiobiological and epidemiological data became available.
After irradiation during the pre-implantation period, generally considered as safe with regard to the radiation-induced risks, non lethal congenital malformations *have* been induced in animals, particularly (but not only) in those with a genetic predisposition to specific congenital malformations or with genetic disorders in the pathways of DNA-repair.
Moreover, during the zygote-stage (about 1 day), there could be no threshold dose for the radiation-induction of congenital malformations in genetically predisposed animal strains.
After irradiation during the organogenesis, more congenital malformations have also been induced in animals with genetic disorders. There are similarities with the effects of chemical agents.
In these cases, the cause of the congenital malformations may not be an increased loss of cells (classic deterministic effect) but rather the persistence of un-repaired or mis-repaired DNA-damaged cells ("teratogenically damaged cells").

Now, in humans, similar genetic susceptibilities probably exist: there are indeed families showing clusters of spontaneous congenital malformation. There are also in humans many genes implicated in the DNA-damage response and involved in the genetic susceptibility to cancer induction by irradiation; if the mechanisms are similar (persistence of mis-repaired DNA-damaged cells), it is plausible that human genotypes leading to cancer-proneness are also associated with a genetic susceptibility to the

radiation-induction of congenital abnormalities (or more subtle tissue dysfunctions).

Due to genetic susceptibilities, there could then be for some individuals a higher risk of radiation-induced malformations (or dysfunctions) or lower thresholds (or even no threshold at day 1?) and this risk could also exist during the "safe" periods of pre- and early post-implantation (when women are not aware of being pregnant). Although frequently assumed to be low, the frequency of these individuals is not known.

This raises doubts about the "definite" and generalized character of the 100 mSv threshold dose for lethal, developmental or detrimental effects (other than cancer) after irradiation during the first trimester of pregnancy, currently applied by many as a practical criterion: this could be an unjustified simplification.

On the basis of the precautionary principle, this does require cautiousness in the medical field, particularly for high dose examinations, including those performed during the pre/post implantation stage, in women not aware of being pregnant. The application of the ten-day rule (planning the non-urgent examination within the ten days following the beginning of the menstruation), whenever the abdominal dose could be significant, would largely reduce these problems.

When looking at the potential implications of these new data, a basic question is how much scientific evidence is needed before the scientific community feels it is necessary to apply the precautionary principle. A related question is to know if the various stakeholders (besides the experts) would need the same amount of evidence before recommending precautionary action.

First stages of pregnancy: Radiation and Health proposals

The R&H WG makes the following proposals:

1. The role of the occupational physician in information/prevention should be enhanced
2. The women should have a real possibility to protect themselves when trying to get pregnant (in nuclear medicine for example)
3. Financial protection of women should be guaranteed if early preventive measures are taken by the occupational physician.

The DDREF issue

DDREF means Dose and Dose Rate Effectiveness Factor. DDREF is currently used to correct (reduce) risk coefficients observed at high dose and dose rate when the exposure occurs at low dose and dose rate. For radiation induced cancers, a DDREF of 2 has been proposed by ICRP and is at the basis of the current radiation protection standards. In its last recommendations, ICRP still keeps this factor of 2, although a lot of recent epidemiological data seem to point consistently to a DDREF lower than 2 (including the LSS incidence data showing a quasi-linear dose-response for solid cancers, in other words a DDREF of 1).

Recently, the US National Academy of Sciences BEIR VII Committee conducted a critical review of the epidemiologic and experimental evidence concerning low doses of low-LET radiation. It concluded that the risk would continue in a linear fashion at lower doses without a threshold and that (although there is uncertainty in the exact magnitude of the effect) the smallest dose has the potential to cause a small increase in risk to humans. Risk models were developed by BEIR VII for estimation of the effects of low doses and low dose-rates, such as those related to natural background radiation. The models use a DDREF of 1.5, with a credibility interval ranging from 1.1 to 2.3, to extrapolate solid cancer risk estimates derived from studies atomic bomb survivors.

The DDREF issue: Radiation and Health proposals

The R&H WG makes the following proposals, all of them aiming at reinforcing the implementation of the ALARA principle:

1. ALARA procedures should be made mandatory
2. The use of dose constraints should be more actively promoted
3. Optimisation should be explicitly requested even under the reference levels
4. Where necessary, lifetime dose limits and/or constraints should be applied.

The radon issue: new data

As clearly shown during the 2006 RIHSS seminar, new epidemiological data, coming from large scale indoor radon studies (7 000 cases of lung cancers; 14 000 controls), show a clear linear dose response relationship

between radon in houses and lung cancer risk (RR = 1.08 for 100 Bq m^{-3}; CI 95% = 1,03 – 1,16). The same studies show statistically significant effects even at radon concentrations lower than 200 Bq m^{-3}. A significant increase also exists in the non-smokers population.

From a public health perspective, taking actions for radon concentrations as low as 100 Bq m^{-3} for dwelling might then be justified, depending on national situations. This challenged the ICRP reference levels. Fortunately ICRP has made recently a statement recommending a reduction of the reference levels.

The radon issue: Radiation and Health proposals

The R&H WG makes the following proposals:

1. A collective approach (collective dose) should complement the peak approach, that was focusing on high level radon concentrations
2. The planning value should be 100 Bq m^{-3}
3. The Reference Level for existing houses, schools, … should be 200 Bq m^{-3}
4. Worker doses should be registered if higher than 200 Bq m^{-3}

The issue of Individual susceptibilities

Our "protective" genes (DNA-repair genes, cell-cycle regulations genes) are affected in a series of human genetic disorders**.** The so-called high penetrance disorders are characterized by a strong expression: the (rare) affected individuals show radiosensitivity after acute exposure (radiotherapy) and cancer-proneness (in general and after irradiation). The effects of the (frequent) low penetrance disorders (with generally subtle mutations or polymorphisms) are still poorly known: they *could* have the same potential risks, at some degree. Less than 1 % of the population has strongly expressing genetic disorders associated with a very high probability of cancer, accounting for 5 to 10 % of all occurring cancers. Age of onset of malignancies in that subpopulation is strikingly low. Similar estimates concerning weakly expressing genes are not available.

Screening tests for some genes related to cancer susceptibility (« DNA-chip » methods) are now becoming available for genetic testing. Their predictive value is currently low. Nevertheless the future availability of such tests, together with new scientific developments (ongoing research

with rodent models) could lead to an ethical and legal challenge in the future.
Anyway, in high dose situations (radiotherapy, high dose medical exposures, rescue workers …), it seems to be appropriate to proactively take into account such genetic susceptibilities to radiation-induced effects.

Besides these genetic susceptibilities, there is also the fact that radiation-induced cancer risks are significantly different for women (v/men) and for children (v/adults), particularly for certain tissues (breast cancer in women, thyroid cancer in children ...). Based on equity considerations, the question raises of the need to promote age and gender specific protection measures, such as specific w_T or specific organ dose constraints/limits. The use of gender specific Wt is proposed by some, disputed by others. One the questions is whether such a decision should be made by ICRP or by the regulators (societal judgement).

Individual susceptibilities: Radiation and Health proposals

Based on equity considerations, the R&H WG considers that specific protection measures are appropriate and makes the following proposals:

1. The role and the means of action of the occupational physicians should be enhanced, particularly in information and prevention but also via the setting up of dose constraints (for individuals or groups of individuals)
2. Appropriate organ dose constraints should be used.

Internal exposures

This issue has been thoroughly discussed during the EU 2004 RIHSS seminar, coming at the time of the publication of the CERRIE Report. The CERRIE (Committee Examining Radiation Risks from Internal Emitters) was a UK Committee appointed by the Minister for the Environment to "consider risk models for radiation and health that apply to exposure to radiation from internal radionuclides in the light of recent studies and to identify any further research that may be needed." The conclusions of the CERRIE report were presented and discussed during the RIHSS seminar. The CERRIE Committee considered uncertainties in dose estimates (both radiation-weighted and effective dose) at considerable length, reaching the conclusion that assessment of uncertainties in dose and risk estimates

should be an important component of the dose estimation process. Only in cases where prospective calculations suggested that doses were "well below" regulatory dose constraints (or limits) would omission of specific consideration of uncertainties be justified. The Committee concluded also that non-trivial uncertainties arise at all stages in the dose assessment process, and that overall uncertainty in estimates of effective dose would almost always cover a wide range, encompassed by a multiplying factor of 2-3 both above and below the estimated central value of dose. In some cases, this factor might be up to or exceed an order of magnitude, again in either direction.

Internal exposures: Radiation and Health proposals

The issue of internal exposure has not yet been thoroughly discussed in the group.

Nevertheless, the R&H WG makes the following first proposals:

1. A security margin should be applied when there are large uncertainties
2. A general warning for uncertainty should be highlighted.

Conclusions

The risks arising from the exposure of the population to ionizing radiations are making part of the current societal concerns, together with issues like GMO, dioxin or global warming.

All these issues are dealt with in an international context where economical and political interests are at stake and present large uncertainties regarding their consequences that require considering the possible application of the precautionary approach.

Now, as regards radiological protection, there is a paradoxical evolution: although the uncertainties on health effects are still present and are even growing, the application of the precautionary principle seems to be decreasing in the international organizations coping with this matter.

There is clearly a need for scientific modesty and for the further application of the precautionary principle. Scientific vigilance, deontology and responsible decision-making, including unavoidable value judgments, are necessary at all levels and scientific advisors and regulators cannot allow

themselves to « wait for instructions » from international organisations but have to take their own responsibilities.

Then *Going beyond ICRP 103?* The answer is: *if necessary, yes!*

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Association belge de Radioprotection, Vol.34, n°4, 2009
Belgische Vereniging voor Stralingsbescherming, Vol.34, nr 4, 2009

YOUNG SCIENTISTS AWARD – PRESENTATION

Gilbert Eggermont
President BVS-ABR

In 2009, IRPA Europe suggested to organize a « Young Scientists Award » competition to identify valuable outstanding work in the field of Radiation Protection of Young professsionals as well at master as at PhD level.

A selection committee examined the abstracts proposed to be presented at the Helsinki meeting of IRPA Europe and selected two candidates for presentation of their work at the general assembly of BVS-ABR in December 2009.

The first selected candidate, Dr Damien Braekers, will be designated to present his work in Helsinki in June. His presentation " Reduction of radioxenon emissions from radiopharmaceutical facilities – A pilot study" will be published in a forthcoming number or the "Annales de l'Association belge de Radioprotection-Annalen van de Belgische Vereniging voor Stralingsbescherming", after the Helsinki meeting.

The second young awardee, is Vanessa Cauwels. She will get this year the Master diploma at the XIOS Hogeschool Limburg. Her contribution "Accident dosimetry using chipcards : the Belgian case" is published hereafter.

BVS-ABR will offer the two winners, a financial support for their scientific activity as well as a free membership.

BVS-ABR congratulate them with the start of a successful professional career in Radiological Protection.

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De Belgische Vereniging voor Stralingsbescherming heeft aansluitend bij een oproep van de Europese IRPA in 2009 een "Young Scientists Award" wedstrijd georganiseerd waarbij zowel startende als gevorderde jongeren in

opleiding stralingsbescherming werden aangezocht om hun recent werk voor te stellen.

Een selectiecomité onderzocht de kandidaturen op basis van de ingediende abstracts voor de IRPA conferentie in Helsinki. Twee laureaten werden weerhouden en uitgenodigd hun werk voor te stellen op de algemene vergadering van BVS in december 2009.

Een Belgische postdoc, dr Damien Braekers, werd geselecteerd en ook voorgedragen voor de Europese Young Scientists Award die zal toegekend worden in juni in Helsinki. Zijn bijdrage "Reduction of radioxenon emissions from radiopharmaceutical facilities – A pilot study" zal in een later nummer verschijnen na die conferentie.

Een tweede pas afstuderende jonge laureate werd geselecteerd, Vanessa Cauwels. Ze zal dit jaar afstuderen aan het XIOS Hogeschool Limburg. Haar bijdrage "Accident dosimetry using chipcards : the Belgian case" is in dit nummer opgenomen.

Beide laureaten ontvingen de BVS-ABR een geldelijke bijdrage ter ondersteuning van hun wetenschappelijke activiteit en een gratis lidmaatschap van de vereniging.

BVS-ABR wenst hen een succesvolle loopbaan in de stralingsbescherming.

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En réponse à une invitation de l'IRPA Europe en 2009, pour organiser un concours "Young Scientists Award" pour permettre à des jeunes professionnels, tant du niveau du "Master" que du "PhD" de présenter leur récent travail en radioprotection.

Un comité de sélection a examiné les candidatures sur base d'abstracts proposés pour la conférence IRPA Europe d'Helsinki. Deux lauréats ont été retenus et invités à présenter leur travail à l'assemblée générale de BVS-ABR en décembre 2009.

Un premier candidat belge, le Dr Damien Braekers, a été sélectionné et proposé pour le "Young Scientists Award" européen qui sera désigné en juin 2010 à Helsinki. Sa présentation

“Reduction of radioxenon emissions from radiopharmaceutical facilities – A pilot study” sera publiée dans un prochain numéro des “Annales de l’Association belge de Radioprotection”, après cette conférence.

La seconde jeune lauréate belge est Vanessa Cauwels. Elle sera diplômée cette année de la XIOS Hogeschool Limburg. Sa contribution “Accident dosimetry using chipcards : the Belgian case” est publiée ci-après.

Les deux lauréats ont reçu de BVS-ABR une participation financière de soutien pour leur activité scientifique et une inscription gratuite à notre association.

L’Association belge de Radioprotection les congratule tous deux et leur souhaite un parcours professionnel fructueux en Radioprotection.

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ACCIDENT DOSIMETRY USING CHIP CARDS: THE BELGIAN CASE

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Introduction

Accident dosimetry aims to determine the absorbed dose in case of a nuclear or radiological accident. The dosimetric results are useful to ensure the proper medical treatment of exposed individuals, to provide correct information to the public and are useful in epidemiological studies [1].

For the purpose of accident dosimetry objects can be used that are found within the accident area or that are worn close to the body of exposed individuals and possess a certain radiation sensitivity. Objects that meet such requirements, are e.g. ceramic materials and semiconductor devices. Previous studies have shown sensitivity for optical stimulation (OSL) and thermal stimulation (TL) of quartz in bricks [2]. Also personal objects, such as cell phone components and USB flash drive components, were investigated recently using TL and OSL [3, 4]. These devices can be regarded as personal dosemeters, since they are worn close to the body.

This study will be focusing on the pertinent OSL properties of various chip cards, in order to expand the list of personal objects useful in accident dosimetry. The great advantage of chip cards is that nowadays everyone possesses at least one, in the form of bankcards, SIM cards, etc. The exact properties of chip cards as an accident dosemeter are investigated using OSL as a sequel to earlier research [5, 6, 7] in order to determine whether the results of that research can be adopted for 'Belgian' cards.

After a rough selection of various kinds of chip cards, based on the overall radiation sensitivity, a detailed investigation of the relevant OSL properties

was focused on one specific card type, i.e. the SIM card. The first part of the project was intended to determine the most promising part of the OSL curve for dose determination (integration window). The shape of the OSL curve was considered, in function of the sample number, the dose and inherent OSL fading. The lowest detectable dose in function of the integration window and the uncertainty on the result as a function of the integration window were taken into account as well.

In the second part of the project, properties such as fading, dose response and sensitivity changes were investigated using the proposed integration window. Finally, the dose recovery potential using a single aliquot regenerative dose method (SAR protocol) was investigated, with promising results.

Materials and methods

Several kinds of chip cards, SIM cards, SIS cards and bank cards - were investigated enabling identification of a specific wide spread type with good OSL properties. Sample preparation was done by extracting the chips from the cards using an industrial punch prior to irradiation. No chemical treatments were used. To avoid loss of information, the samples were irradiated in the absence of daylight.

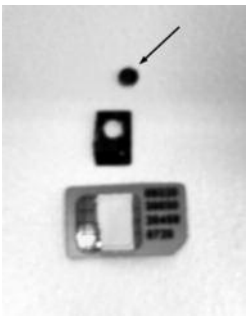

Figure 1: Sample preparations was done by extracting the chip module from the card. Samples were taken using an industrial punch.

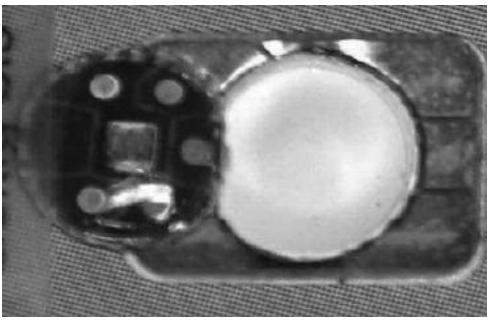

Figure 2: The chip is surrounded by an epoxy encapsulant, responsible for the OSL signal [8].

OSL measurements of chip cards were executed with the Risø TL/OSL Luminescence Reader (model TL/OSL-DA-20). Continuous wave optical stimulation was performed using a cluster of blue LED's, emitting light

with a wavelength of 470 nm. The LED's are equipped with a green long pass filter (GG-420) to prevent blue light from reaching the PMT [9]. A power of 45 mW/cm^2 was delivered to the samples. The stimulation time was 120 s and no thermal preheating was used. The luminescence emission was recorded using a Hoya U-340 filter in front of the photomultiplier tube (bialkali PMT, type EMI 9235Q), enabling detection in the UV-range [8]. The OSL curve was plotted using 400 datapoints. Stimulation with blue light was used, since the epoxy encapsulant, surrounding the chip (figure 2) and responsible for the OSL signal, contains SiO_2which should respond well to blue LED optical stimulation.

The samples were irradiated using a $^{90}Sr/^{90}Y$ beta-source with an activity of 1,48 GBq, mounted in the Risø TL/OSL Luminescence Reader, at a dose rate of about 114 mGy/s. The gamma-equivalent dose rate was determined from Co-60 irradiated chip cards measured immediately after administration of the gamma dose. Gamma irradiations were performed with a Co-60 source delivering a dose rate of about 2 Gy/h (air kerma).

The obtained OSL curves were analyzed using the Risø Analyst software and Origin 8.0.

Results

Integration window

From the investigated chip cards, SIM cards, which are found in cell phones, turned out to be the most wide spread card with excellent radiation sensitivity. An analysis of the obtained OSL curves, following irradiation with the built in $^{90}Sr/^{90}Y$-betasource (1140 mGy), revealed that three OSL components are responsible for the emitted luminescence after irradiation and optical stimulation. Normalised OSL curves were fitted with a 3rd order exponential decay:

$$y = y_0 + A_1 e^{\frac{-x}{\tau_1}} + A_2 e^{\frac{-x}{\tau_2}} + A_3 e^{\frac{-x}{\tau_3}} \qquad \text{(Eq. 1)}$$

The results in figure 3 indicate that every OSL curve can be decomposed into three OSL components with distinct fitting parameters A and τ, as can be seen from the three clusters. The clusters confirm the identical shape of all obtained OSL curves. This could mean a single protocol can be used to make an estimation of the absorbed dose, if other properties, such as fading

properties and dose response properties, are identical as well for all samples. These properties are discussed in detail later in this paper.

Figure 3 shows that every OSL curve contains a so-called 'fast', 'medium' and 'slow' component. About 60% of the OSL signal is delivered by the fast component.

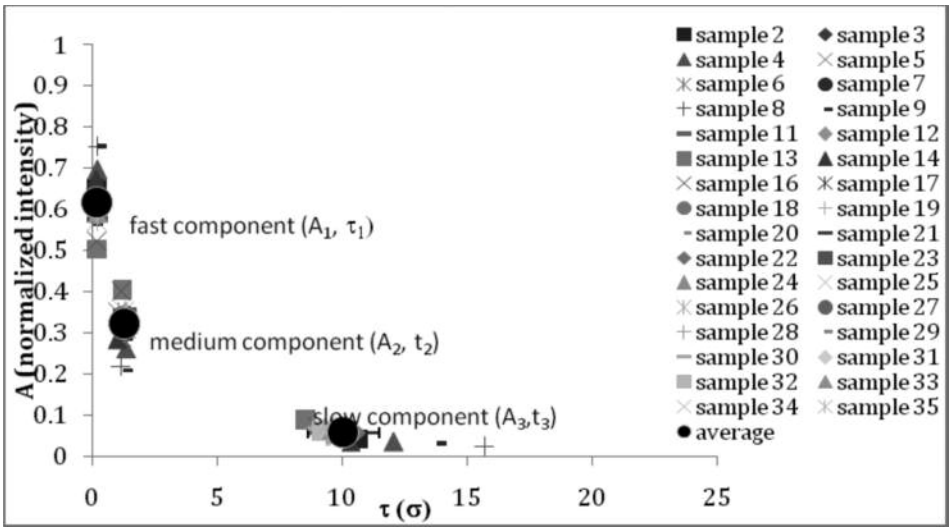

Figure 3: OSL curves from several SIM cards were fitted using a 3rd order exponential decay. The parameter pairs (A_1, τ_1), (A_2, τ_2) and (A_3, τ_3) are consistent for all investigated cards, allowing to identify three components in the OSL signal.

The properties of the slow component, with a mean value of τ_3 of (10,08 ± 1,46)s indicate that a stimulation time of 120s would be sufficient to obtain the whole OSL signal. Exposure to different doses did not change the properties of the OSL curves. A stimulation time of 120s can thus be used in every situation, independent of the absorbed dose.

To obtain information on the stability of the components, 10 samples were subjected to a fading test. The optical stimulation was performed after varying delay times following irradiation (0, 10, 30, 100, 300, 1000, 3000, 10000 and 30000 minutes). Analyses of the obtained OSL curves showed that all components fade simultaneously, as pointed out in figure 4. This might suggest that all observed OSL components equally suffer from thermal and athermal instability.

In order to make a proper choice for the integration window, the relative uncertainty as well as the lowest detectable dose (LDD) as a function of the integration window was determined for a set of 6 samples. A good integration window means that both the uncertainty and the LDD should be as low as possible.

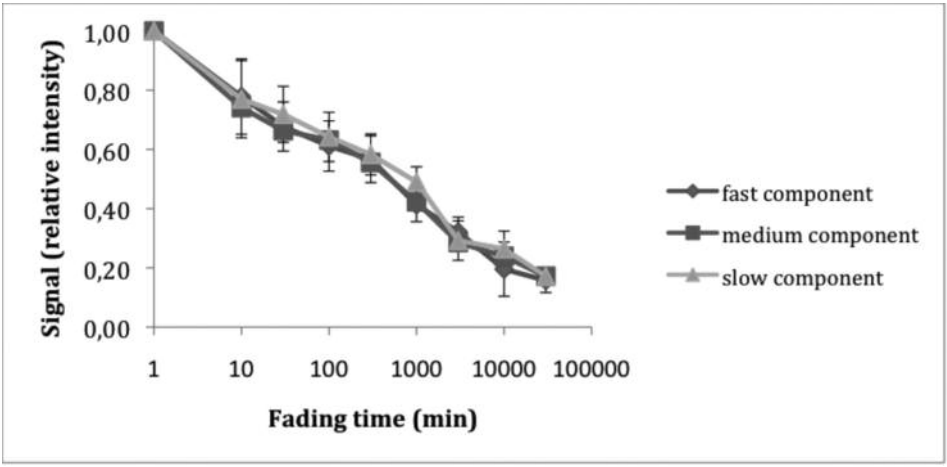

Figure 4: Averaged fading results for the fast, medium and slow component. It can be seen that the three components have similar fading rates.

The uncertainty on the results is determined using the following formula [10]:

$$\hat{\sigma}_S = \sqrt{Y_0 - B + \left(1 + \frac{1}{k}\right)\hat{\sigma}_B^2} \qquad \text{(Eq. 2)}$$

$\hat{\sigma}_S$ being the absolute uncertainty on the calculated signal *S,* Y_O the value of the entire signal including background signal and *B* the value of the background signal.*k* is equal to the ratio of the amount of channels used to determine the background signal and the amount of channels used to determine Y_O.

$\hat{\sigma}_B$ is equal to the standard deviation of the background signal.

The lowest detectable dose (LDD) was estimated using the dose response curve of several samples. As can be seen in figure 5, the dose response appears to be linear. The LDD was determined as the intersection point between the extrapolated dose response curve and the average background

signal increased with three times the standard deviation of this background signal. The average background signal and the standard deviation on this background signal were determined by 10 zero dose measurements performed on every considered sample.

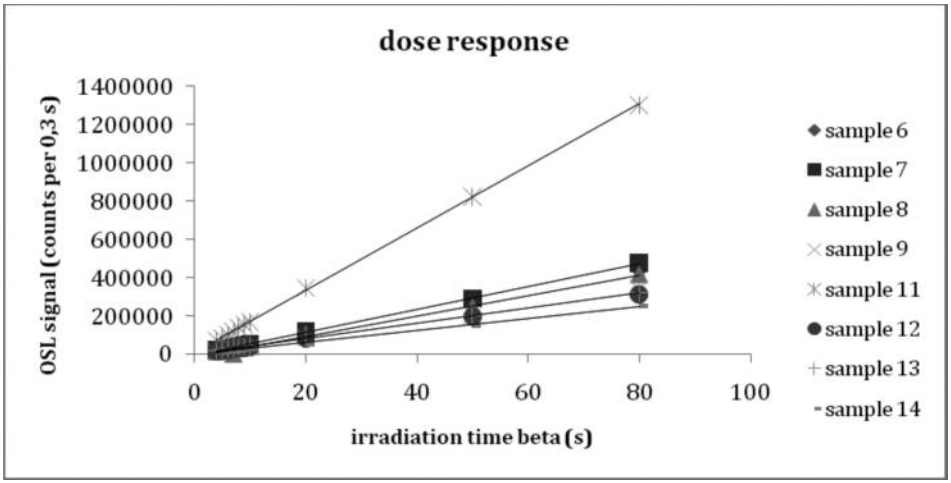

Figure 5: the dose response of several samples appears to be linear.

The multiplication of the LDD and the relative uncertainty as a function of the integration window was used as a proxy to determine the optimal integration window. The results show that multiplication minima are located within the first 2,10 s of the OSL curve. This means the fast component, responsible for about 60% of the OSL signal, is the most interesting part of the OSL curve.

The integration windows are therefore set at 0s to 2,1s to estimate the value of Y_O, and 105s to 120s to estimate the value of B. The LDD calculated with these integration windows is approximately equal to 2 mGy, depending on the sample.

Protocol for the estimation of the absorbed dose

Using the integration window as determined in the previous section, the fading rate, the dose response and sensitivity changes caused by repeated irradiation-OSL readout cycles were investigated.

Fading occurs simultaneously in all investigated samples as illustrated by figure 4. This offers the opportunity a universal fading factor. The latter

was determined by fitting the composite fading curve of figure 6 using a 3rd order exponential decay.

$$f = 0{,}198 + 0{,}27e^{\frac{-t}{11{,}7}} + 0{,}319e^{\frac{-t}{0{,}110}} + 0{,}206e^{\frac{-t}{104}} \quad \text{(Eq. 3)}$$

with f being the percentage of the signal still available at time t (hours) following irradiation.

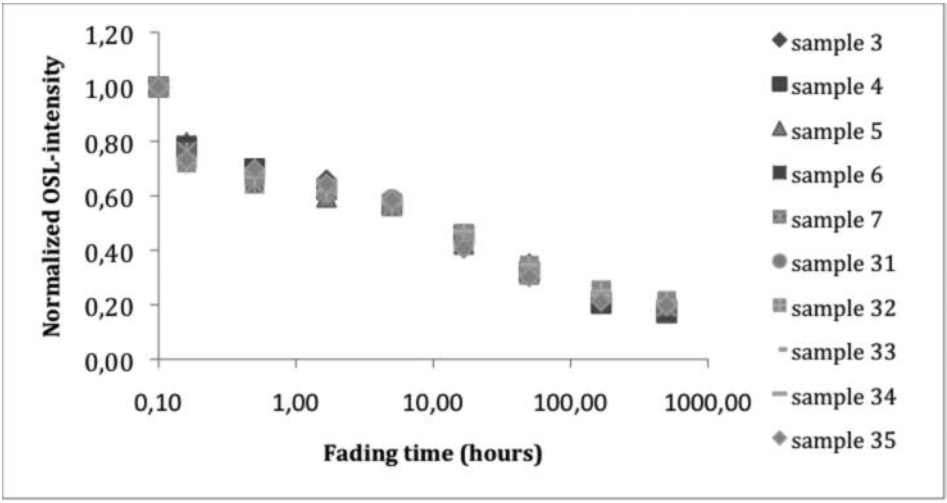

Figure 6: Fading occurs simultaneously in every sample.

The dose response turned out to be linear with the absorbed dose for all investigated samples. Nevertheless because of repetitive irradiations and optical stimulations sensitivity changes may occur. In principle, sensitivity changes can be detected using the SAR protocol (single aliquot regeneration protocol), by comparing the OSL output to the OSL output obtained after successive irradiations. The first OSL output gives a value for L_n, thus a value for the unknown dose D. Next, an irradiation with a known test dose is performed, which after OSL delivers a value for T_n. A known dose D_r is then delivered to the sample, giving a value for L_r after irradiation. Again the known test dose is delivered to the sample, so a value for T_r is obtained. The known doses can be delivered by the built in beta source. The unknown dose can now be calculated taking sensitivity changes into account:

$$D = \frac{L_n}{L_r}\frac{T_r}{T_n}D_r \quad \text{(Eq. 4)}$$

If no sensitivity changes occur, the values of T_n and T_r are equal, and the ratio is equal to 1, making correction for sensitivity changes unnecessary.

The Risø TL/OSL Luminescence Reader makes it very easy to perform measurements and calculations based on this protocol using the Risø Analyst software. 10 samples were irradiated with the betasource during 10s and a SAR protocol was applied. The test dose response was investigated to check for sensitivity changes. The dose recovery test revealed that the given betadose of 10s could be recovered within error limits. The results of this test are shown in figure 5, with the horizontal line being 10s betadose delivered to the samples. Moreover no sensitivity changes were found as illustrated in figure 6, which means no sensitivity changes occur and no correction should be made. This, together with the linearity of the dose response and the uniform fading behaviour, opens the possibility to perform fast dose measurements using only one calibration point.

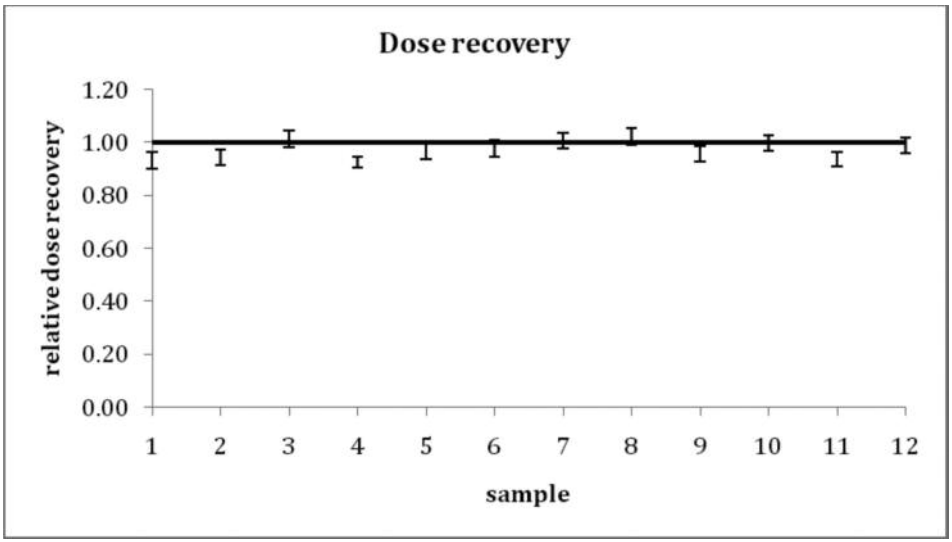

Figure 7: Dose recovery potential of the SAR protocol using the chip module from SIM cards. The given beta dose can be recovered within error limits.

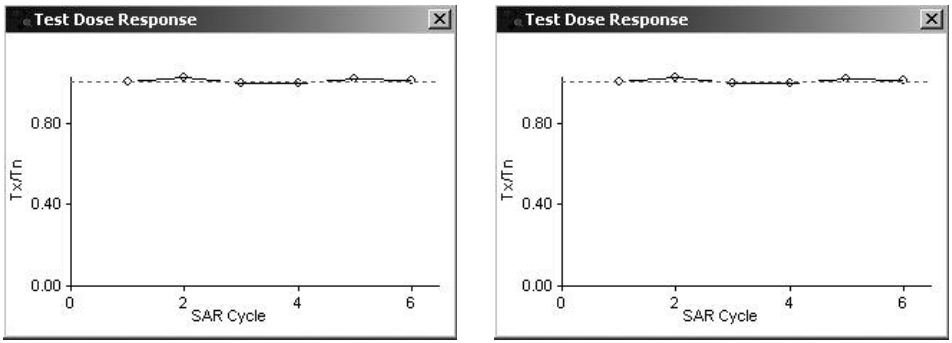

Figure 8: Normalized test dose response of sample 13 and 16 monitored over several SAR cycles.

If the estimation of the dose is made several hours or days after the irradiation event, which is mostly the case in accident dosimetry, a correction for fading should be made. The results obtained after running the SAR protocol and processing with Risø Analyst software need modification in the following way:

- The result is given in the form $y = a + bx$, with

  $y = \frac{L_n}{T_n}$

  and x the irradiation time in s.

  L_n is equal to $Y_{o,x}$ - B_x = S_x, the signal caused by the accident dose. T_n is equal to $Y_{o,n}$ - B_n = S_n, the signal caused by the first test dose applied according to the SAR protocol. The meaning of the symbols are explained with equation 2.

- L should be corrected for fading, using the formula in Eq. 3 in order to obtain L_{n_corr} . L_{n_corr} is equal to $\frac{L_n}{f}$

- By filling in this value in the equation $y = a + bx$ an irradiation time in s is obtained. By multiplying this value with the dose rate of the built in beta source the accident dose is obtained.
- The uncertainty on this value should be obtained by taking the uncertainty on $\frac{L_n}{T_n}$ into account based on the considerations in Duller and Bo Li [10] and [11] as well as the uncertainty on f, a, b and the dose rate. The overall uncertainty is approximately equal to 8 %.

Conclusions

The results of this study seem to confirm the potential of chip cards in accident dosimetry. Especially SIM cards seem to be the most promising given their good sensitivity to irradiation and optical stimulation using blue LED's. The lowest detectable dose is extremely low in comparison to other techniques used in accident dosimetry, but is dependent on the chip card.

Individual chip cards show differences in radiation sensitivity necessitating individual calibration for dose assessment. Fading is ubiquitous but the rate seems to be similar for all investigated samples, enabling the use of a universal fading correction factor. In order to make an estimation of the absorbed dose, the SAR protocol seems to be a very useful tool. Corrections for fading can easily be performed on the obtained results.

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