Rapporteur – Martin Gledhill, representative of Ministry of Health, New Zealand

Wednesday 28 June

Opening and Welcome

Maria Neira, Director of the Department of Public Health, Environmental and Social Determinants of Health of the World Health Organization (WHO) opened the meeting and welcomed the participants. She spoke of the major changes occurring within WHO, not the least of which is a new Director-General. A key focus of public health is primary prevention, but only 3% of health resources are directed towards this, and only part of that amount goes towards primary prevention. 23% of all global deaths can be attributed to the environment. UV is a significant environmental factor that lends itself to disease prevention, so it is important to combine the efforts of those working in this area from the health and environmental perspectives.

Emilie van Deventer also welcomed meeting participants, including eighteen joining the meeting remotely. Craig Sinclair was elected meeting chair and Leon du Toit as vice-chair. Participants introduced themselves. The agenda was adopted, and the Minutes of the previous meeting adopted with no corrections.

Update on the INTERSUN programme activities (E. van Deventer)

Emilie van Deventer described WHO’s work, role, core functions and governance, and provided the background to the Intersun programme, the partners and stakeholders and the activities to date. The Intersun programme has moved beyond the original focus on solar UV and for several years has also covered artificial sources of UV and their effects on health.

The role of the WHO UV programme Secretariat is to facilitate the work programme and ensure that documents prepared as part of the programme comply with WHO rules. Partnerships with collaborating centres (CCs), NGOs and national authorities are important to contribute towards activities. The recently adopted Framework for Engagement with Non-State Actors (FENSA) may affect how WHO works with them, as WHO works primarily for its Member States. The Intersun work is funded entirely from external contributions, and in the past year only one State has provided funding. Other States and organisations have provided in-kind contributions. CCs have been especially helpful in development of the newly published sunbed brochure.

WHO does not undertake or fund research but helps set research priorities. The latest WHO health risk assessment dates to 1994. There is interest in preparing a research agenda, but this will need to be funded. Several risk management documents have been prepared, and States
should advise if they consider that additional documents are needed. The updated brochure on sunbeds is now available, and is accompanied by related infographics. Information on sunbed regulations is now available in the database of the WHO Global Health Observatory (GHO), but unfortunately only information at the national (rather than sub-national) level can be displayed. The Intersun website has been updated and country UV pages added. The Sun protection listserv has been active. The recent WHO document “Inheriting a sustainable world: Atlas on children’s health and the environment” includes a chapter on UV radiation, indicating the importance of this risk factor for children.

The Intersun programme should develop priorities based on the needs of States, and countries should propose what activities should be undertaken. To that end, a survey will be developed in the next few months.

Review of recent research activities

Update on UV, skin cancers and skin cancer control (A. Green, International Commission on Non-Ionizing Radiation Protection)
The true incidence of non-melanoma skin cancers (now preferably referred to as “Keratinocyte Carcinomas” – KCs) is unknown due to poor registration. Multiple incidences of KCs are often not counted, which also leads to underestimates of the true incidence. Some regional estimates are available.
New Zealand now has the highest incidence of melanoma – most other countries have rising incidence but incidence in Australia is declining. There are large variations in the ratio of age-standardised melanoma incidence to mortality around the world.
In Australia, there has been a focus on primary prevention of melanoma since the mid-1980s, and this appears to be working, especially in young people who have been exposed to Sunsmart messages since they were born.
Screening programmes aim for early detection of melanomas. Population screening results in many false positive detections, so targeted screening of high risk individuals is preferred.
New drugs have increased survival from late melanoma but are expensive.
The following points came up during discussion:
• The reason for big variations between countries in mortality from melanoma could be due to awareness. In Australia there were campaigns to alert people to early detection of melanomas, and two thirds were spotted by patients or their families.
• High risk groups for screening need to be well defined.

UVR exposure consequences for the eyes and vision in an aging world (S. Mariotti, World Health Organization)
Eye problems related to UV tend to be concentrated in developing countries, especially at high altitudes and in rural areas. There are also greater risks associated with outdoor activities and with some drugs. Several factors are now acting to increase the risks of UV-caused eye diseases, including an aging population, more outdoor activities, new illumination sources, extended periods inside (work, education, and information), lights from multimedia / communication devices and the risk of counterfeit sunglasses which do not provide the protection claimed for them. People do not die of blindness but live with it.

European Commission reports on UV-C lamps and LEDs (T. Samaras, Representative of the European Commission Directorate General of Health DG SANTÉ)
The EC has recently published a report from its Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) entitled “Opinion on Biological effects of UV C radiation relevant to health with particular reference to UV C lamps”. UV-C lamps are widely used, and their use in consumer products is increasing. Even if the lamp is well enclosed there may be risks during maintenance. Most data on health effects comes from accidental exposures to UV-C lamps. There is mechanistic data showing effects, and the mode of action is like UV-B. UV-C has been classified as carcinogenic by IARC (volume 100D). More data is needed on medium- and long-term effects, UV-C dose-response functions, and the degradation of materials used to enclose UV-C lamps.

A preliminary opinion on LEDs should be available soon for consultation. It will cover potential hazards in relation to intensity and wavelength, dose-response functions, and risks in the general population and vulnerable groups.

Reports on UV activities from international organizations and NGOs

International Agency for Research on Cancer (IARC) (U. Schüz)
IARC’s classification of sunbeds as a carcinogenic device continues to have effects, especially amongst cancer prevention organisations. There is a plan to extend the recommendations on UV in the European cancer Code to other regions, and discussions have started with South America.

United Nations Environmental Programme (UNEP) (A. Fenner)
HFCs are greenhouse gases as well as reducing ozone, so the Kigali amendment to the Montreal protocol helps reduce UV exposures. A new video entitled “The Kigali Amendment to the Montreal Protocol - Opportunities and Next Steps” is available on YouTube.

World Meteorological Organization (WMO) (C. Sinclair)
Craig Sinclair now chairs the Science Advisory Group for WMO. This group has agreed to extend the UVI scale above 11. There will be a course on UV measurement and modelling in spring 2018.

International Commission on Illumination (or Commission Internationale de l´Eclairage, CIE) (J. O’Hagan)
The erythema action spectrum and photocarcinogenesis action spectra have been reviewed and reconfirmed. The Standard on the photobiological safety of lamps and lamp systems is under review. There are concerns over the Vitamin-D action spectrum and a review and possible revision should begin soon. The CIE technical report on the use of sunbeds to maintain Vitamin-D levels concludes that they cannot be recommended for this purpose until the appropriate exposure can be assessed. The CIE has published a research strategy, which includes recommendations for work on Healthful lighting and non-visual effects of light.

Euroskin (R. Greinert)
Euroskin has been involved in many of the activities undertaken by IARC and the EU. Recommendations from a Euroskin workshop entitled “From Biomarkers to Molecular Epidemiology” held in November 2016 in Bergen, Norway are on the Euroskin website. There will be a further conference on biomarkers in late 2017 or early 2018, as biomarkers may help
identify people at risk of skin cancer.

**International Commission on Non-Ionizing Radiation Protection (ICNIRP) (A. Green)**

In the coming year ICNIRP will be updating its statements on LEDs and laser pointers. There is a working group on blue light and a project group looking at cosmetic uses of NIR, including those using light and UV.

**International Commission on Occupational Health (ICOH) (F. Gobba)**

ICOH held a training school on occupational skin cancer in September 2016 in Modena, Italy and is participating in a WHO/ILO systematic review for the WHO/ILO joint methodology for estimating work-related burden of disease and injury from UV on cataracts and skin cancers. There will be sessions on effective solar UV protection of workers at an International Conference on “Effects of solar radiation in workers: the need for effective prevention” in Helsinki, Finland in December 2017 and at the ICOH World Congress in Dublin, Ireland in May 2018.

**International Electrotechnical Commission (IEC) (J. Keshvari)**

The IEC has developed several standards covering lasers, UV and optical radiation safety, and is also looking at emerging technologies for projecting images onto the retina. The IEC proposes that the Intersun programme should be extended to cover other optical radiations.

**Reports on UV activities from collaborating centres**

**Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) (R. Tinker)**

ARPANSA has a new website and UV section. This provides predictions, measured data and historical data. Over the coming year there will be pop-up UV measurement stations to help raise awareness, including one at the Commonwealth Games. ARPANSA is helping evaluate a UV app with sun protection messages.

**French Association Sécurité Solaire (P. Cesarini)**

By now, about one million school children have followed Sécurité Solaire programmes in schools. The programme is getting into Spanish speaking countries. There is a new project on occupational exposure.

**Bolivia Laboratory for Atmospheric Physics (LFA) (L. Blacutt)**

LFA is now working on climate change, aerosols and greenhouse gases, in addition to UV. The laboratory has received funding to test the performance of sunglasses. Interest in the effects of UV on health has increased, and the city of La Paz has paid to install devices showing UV levels in real time.

**German Federal Office of Radiation Protection (BfS) (C. Baldermann)**

UV has been added to an existing project on climate change, using “structural prevention” to give people the opportunity to escape heat and avoid UV exposure. This could be done by providing shade, adapting work flows to avoid work outdoors when there are high temperatures or UV etc. The work is being done under the auspices of the “UV Prevention Alliance”. Several measures, such as legislative changes, public information programmes and provision of funding, need to be taken to establish fully the project goals. A position paper “Prevention of Adverse Health Effects of the Sun – Structural Prevention in the City and in the
Countryside” has been published on BfS website in April and will be available soon in English. The paper sets out the goals and the measures to be taken to achieve them.

**Australian Cancer Council Victoria (C. Sinclair)**
The Cancer Council Victoria SunSmart app has had 280,000 downloads, and 40% of the users have the sun protection alert times enabled. The app received a favourable review in the Lancet Oncology, and on average users open it 1.7 times per day. The app only covers Australia, but other apps are available for different parts of the world.

Following the sunbed ban some backyard sunbed operators have started operating, and these are being monitored and prosecuted (two prosecutions to date, with more expected).

Some people have raised concerns about the ineffectiveness of sunscreen, and the publicity on social media has required some defence of sunscreen use. The products about which complaints have been raised have met the Standards, but people generally do not use enough and some report allergic reactions.

**UK Public Health England (PHE) (J. O’Hagan)**
UV monitoring continues but the Greenland site is no longer available. Additional instruments are now being used. A project to measure UV exposure of office workers using dosimeters has found that typical daily doses are below 2 SED, and that the highest doses were in autumn.

UV-A exposures of airline pilots have shown some high exposures: flight schedules have the most influence on the dose received.

The Advisory Group on Non-Ionizing Radiation (AGNIR), an independent scientific advisory group, has published in March 2017 a report on “Ultraviolet Radiation, Vitamin D and Health”, which is available for download. There is uncertainty on the amount of UV needed to maintain adequate Vitamin-D.

A campaign has started to get outdoor workers to cover up. This includes taking UV measurement gear to agricultural shows.

A study has found that photodynamic therapy (PDT) can be delivered using daylight. This could increase the uptake of PDT. A conservatory should be used in winter.

**Swiss Federal Office of Public Health (FOPH) (A Schöni)**
FOPH is mainly involved in primary prevention, through publishing UV forecasts, publishing fact sheets and education. A new Federal Bill on Protection Against the Hazards of Non-ionizing Radiation and Sound (LRNIS) has just been published that will enable regulation of NIR devices, including sunbeds (https://www.admin.ch/opc/fr/federal-gazette/2017/3949.pdf, in French).

**Prevention measures**

**Review of the UV index (R Tinker, ARPANSA, Australia)**
A workshop in Melbourne in December 2015 examined whether the UV Index should be modified. Animal studies suggest that there is no UVI threshold for skin cancer, but the importance of sub-erythemal doses for skin cancer in humans is not known. Regular use of sunscreen can prevent skin cancer, and sunglasses protect the eyes.

The UV Index is a useful risk communication tool. Good human evidence would be needed as the basis for any revision. In the meantime, it can continue to be adapted to suit local conditions. UVI of 3 is still of public health significance.

A publication on the workshop is being reviewed by Health Physics.

The following points came up during discussion:
• A research agenda could be prepared, but time and funding are required for this.
• While there is evidence that exposure to UVI below 3 could cause cancer, this is animal data and there is no good epidemiological evidence on people. At low UV doses there are effective repair mechanisms.

**Population-based studies of sunscreens (A Green, QIMR Berghofer Medical Research Institute, Australia)**

Snapshot studies of sunscreen use around the world show large variations between countries. Most people do not apply enough to obtain the full protection. Predictors of use include gender, age, education, previous experience of sunburn and sunbed use. Less than 1% of the population is truly allergic to (rather than suffering irritation from) sunscreen. Sunscreen users experience few side effects after long term use and are not Vitamin-D deficient.

The one randomised trial on sunscreen use which has been carried out found that there was a reduction in melanoma and SCC, but no effect on BCC.

During discussion, it was mentioned that a study in Germany on transplant patients had found that sunscreen was very effective in suppressing DNA damage and immune depression.

**Embedding shade in social/health policy (G. Kapelos, Ryerson University, Canada)**

As part of its 2001 action plan to prevent cancer, the city of Toronto included measures to develop and implement a sun safety programme. This included provision of shade and protection measures for all city employees working outdoors. A UV working group was established with a big mix of expertise. As the programme developed the city established procedures for conducting a shade audit, and then a shade policy which required provision of shade (either natural or constructed) when planning and constructing new outdoor facilities or refurbishing existing ones. Shade Guidelines were published in 2010, followed by design Standards.

The process showed the need for supportive urban policies and adequate resourcing, and the need to insinuate the need for shade into policies so that consideration of shade became part of standard procedures when developing facilities. There should be engagement with a wide range of stakeholders and exploration of synergies with other policy areas and agendas.

**Webinar on Artificial tanning devices**

(*This section of the meeting was open to the public*)


**Health effects of sunbeds: Summary of the 2016 EC SCHEER Opinion (JF Doré, R. Greinert)**

The EC's SCHEER Opinion on the biological effects of UV relevant to health, with particular reference to sunbeds, was published in November 2016. UV is a complete carcinogen, both initiating and promoting tumours. Skin cancer induction is a stochastic process, which means that there is no safe dose. 1 MED gives rise to 10,000 to 100,000 pre-mutagenic lesions in every exposed cell. While the action spectrum for Vitamin-D production is like that for skin cancer, Vitamin-D synthesis plateaus at doses well below 1 MED.

There have been four meta-analyses examining skin cancer and sunbed use. Almost all Case-Control studies show an association between increased risk of melanoma and ever use of a sunbed. This is independent of sun behaviour and individual susceptibility. There is also
Evidence for an association with NMSC. Overall there is an increased risk, especially for first use of a sunbed before the age of 35. A recent study by Ghiasvand shows that sunbed use is also associated with early onset melanoma.

Economic burden of melanoma associated with sunbed use (M. Krensel, Hamburg Institute for Health Services Research in Dermatology and Nursing)

Economic costs of melanoma arise from both the cost of treatment, and the indirect costs from lost work days and early death. There are few studies on the cost of melanoma in Europe, and six were useful for the analysis. Studies on the costs of other diseases, however, could be used as a model for this work.

It was estimated that 3483 cases of melanoma in 18 European countries could be caused by sunbed use. The costs of the disease varied widely between countries, and direct costs accounted for about 60–80% of the total. After further adjustments of the model the costs of melanoma per patient varied from €1751 to €12611, depending on the country.

This work has been submitted for publication.

The WHO brochure on public health interventions to manage sunbeds (E. van Deventer, WHO)

WHO first published a guidance on sunbeds in 2003. Since then, IARC classified tanning beds as a carcinogen (vol. 100D). The new WHO brochure complements the recent SCHEER Opinion. A set of two related infographics have been developed and are available in 4 languages.

The key part of the brochure covers policy options. Education through public health campaigns is important but needs to be maintained over time otherwise people forget. Specific legislation may be required if tanning beds are considered as consumer products rather than medical devices. Two separate industries are involved: the manufacture of sunbeds, and the provision of sunbed services, and both should be considered in controls.

Policies that have been developed by Member States include a complete ban on all provision of sunbed services (e.g. Australia) and sunbed sales for domestic use (e.g. Brazil), restrictions on use (such as minimum ages, prohibition of unsupervised use), management of sunbeds (e.g. licensing, restriction of doses, operator training), and the provision of information (e.g. information to consumers about health risks, mandatory warning signs, prohibition of promoting health benefits). Surveys in many countries, however, often show poor compliance with regulations or voluntary codes of practice.

Country experiences

Argentina (C. Caspani, Ministry of Health, Province of Santa Fe)

The Province of Santa Fe initially adopted regulations based on those used in Spain, limiting the irradiance. Very few beds complied, and tanning facilities were banned. There was a large uproar, resulting in withdrawal of the regulations. Sunbeds are considered as consumer devices and, as such, only electrical safety is considered now. A project has started to catalogue all the sunbeds used in Santa Fe, and their characteristics, but this work is making slow progress. Experience to date suggests that the best way to proceed is to make agreements with municipalities, and with organisations that regulate and control the sunbed operators.

Australia (R. Tinker, ARPANSA)

Australia proceeded rapidly from voluntary Standards in 2002, to Regulations in 2008 and a complete ban in 2015. The ban was mainly motivated by the death of Clare Oliver, who
attributed her melanoma to sunbed use. A cost-benefit analysis showed net benefits from a ban, and all Australian States worked together to achieve it. Operators were given a two-year transition period, and some States offered a buy-back programme. There is still some private ownership of sunbeds.

There is now a focus on enforcement, and agencies are working with social media to reduce support for illegal operators. Some States want to ban the import of sunbeds.

**Belgium (B. Boonen, Belgian Cancer Foundation)**

A recent report from the Superior Health Council of Belgium recommends that sunbeds be banned. In the interim, there should be information provided to the public about the risks of UV and the rationale for a ban. It is estimated that a ban would prevent nearly 6,000 melanoma deaths in Belgium over a 50-year period and save €238M in healthcare costs.

Use of sunbeds is controlled by the Ministry of the Economy, which has proposed warning signs, requirement for a skin type certificate from a GP, a ban on promoting benefits of sunbeds and ID cards for users. The Ministry is concerned about the possible emergence of a “grey” industry and increased private use. These proposals have led to widespread discussion on freedom of choice. Several MPs support a ban. The sunbed industry says that they are already compliant, and sunbeds are a controlled environment. Compliance surveys, however, find that 94% of operators are non-compliant.

**Germany (A. Pütz, B. Keller, Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety)**

Under-18s have been banned from commercial sunbeds in Germany since 2009, and a 2012 Ordinance mandated the EN-60335-2-27 Standard and imposed other requirements such as the presence of qualified staff, warning signs and the provision of information to users. Implementation and enforcement varies widely, depending on the availability of manpower. In some areas under-18s are still using sunbeds. There has also been discussion about the “nanny-state”. The number of operators is decreasing.

**New Zealand (M. Gledhill, representing the Ministry of Health)**

Since 2012, public health staff has been visiting commercial sunbed operators every six months to try and improve compliance with a voluntary operating Standard. Once a year there is a systematic assessment of compliance, which shows that compliance has slowly improved over time. Compliance in the Auckland area improved markedly after introduction of a bylaw regulating sunbed operators. The New Zealand sunbed industry is not very large, and shrinking, and most operators say they want to do a good job.

**Norway (Lill Tove Norvang Nilsen, Norwegian Radiation Protection Authority)**

Norwegian Regulations require compliance with EN 60335-2-27, set an age restriction (18), require warning information be provided to clients, trained staff and eye protection. Operators must be registered with NRPA.

Enforcement and inspection is delegated to local authorities. NRPA trains the enforcement staff and provides UV measurement equipment and offers training courses for operators. Information is available to the public on the NRPA website, and there is active use of the media to raise awareness.

This work has been going on for many years, with dedicated personnel and resources, and cooperation with local authorities. Forthcoming inspections and surveys will show the degree of success that has been achieved.
USA (S. Miller, Food and Drug Administration)
The USA delegate was unable to make her presentation due to technical reasons, but it was circulated to participants. She wished to highlight the following additional information:

- A 10% tax on sunbed services was introduced in 2010, following which the number of operators dropped by 50% (although this may have been confounded by a downturn in the economy, and greater public awareness of the risks).
- There has been a drop in the numbers of high school girls using sunbeds, from 15.6% to 7.3%.
- The US is still awaiting guidance on the introduction of Regulations.

During discussion the following points came up:

- Most regulatory options for controlling sunbeds have been tried and are outlined in the new WHO booklet.
- Greece expects to publish legislation in the next few months. It will contain most elements on restriction and management of exposures.
- It would be good to have a way to share Regulatory Impact Statements prepared for sunbed controls.
- Arguments about unemployment and other economic costs are sometimes raised against banning sunbeds.
- There is no data on whether people in Asia, where sunbed use is less prevalent than in the USA and Europe, are more or less susceptible to skin cancer from sunbeds.

Thursday 29 June

Reporting non-melanoma skin cancers

Update on international discussions (GBD, ICD-11, ILO) (S M John, University of Osnabruck, Germany)
Outdoor workers have increased risks of SCC and BCC compared with the general population. This mostly affects males, and it is found that they often have difficulty understanding medical information. Recent German studies show a doubling dose of around 7,000 SED. In countries like Germany, where SCC and BCC are recognised as occupational diseases, there are much higher registrations than in countries where they are not recognised. In Germany, skin diseases comprise 40% of all occupational disease. The European Commission funded “StanDerm” COST Action has provided a blueprint of standards for the prevention, diagnosis and treatment of occupational skin diseases. A long-term goal is to get SCC and BCC on the list of occupational diseases in Europe and have a Directive on solar UV exposure. The WHO and ILO have prioritised systematic reviews of the risks of cataracts and skin cancer as a function of occupational exposure to UV. At the moment cancer registries do not report NMSCs (KCs), but they cost around €500M per year. Skin cancer can easily be prevented with good health education and use of sun shields, clothing and sunscreen (in that order).
Blue light can be used to show pre-cancers on the skin, and whether sunscreen has been properly applied. UV induced skin cancer should be included in the list of occupational diseases. The European Council is currently updating the law on carcinogens but does not include UV.

Points arising from discussion include:
- Teachers in kindergartens receive about 100 SEDs per year. Doses to school teachers will be investigated next year. Children are probably getting a similar or higher dose. There is a lot of work to be done to raise awareness of UV in German schools.
- There is no information on outdoor workers and skin cancer in developing countries, but Mark Wittlich would like to establish partnerships to gather such data.

**Non-melanoma Skin Cancer (NMSC) as a reportable occupational disease (C. Wright, South African Medical Research Council)**

South Africa receives 5-6 SED per day in the highest exposure month. There is little information on skin cancer in black Africans. Overall, skin cancer in white South Africans is higher than in other races. Melanoma rates in whites have doubled in the past decade. South Africa is well behind in the prevention, education, early detection, treatment, and compensation for skin cancer. There is no data on the prevalence of occupational skin cancers. There are many challenges facing any efforts to improve this. Using a Canadian model, it is estimated that about 8.7% of South Africa’s working population are outdoor workers exposed to UV. These people are mostly engaged in farming, mining and personal/protective services. While there is no data on occupational skin cancers in South Africa one positive sign is that the military has a Sunsmart skin cancer awareness month.

**Way forward**

**Future work plan**

Emilie van Deventer noted that it is important to have feedback about the Intersun meetings. There are now many attendants, and it is important to know their needs and interests.

Suggestions included:
- If there is an interest in well-being, should the meeting scope be extended to include visible light? For example, in indoor environments with less light there is evidence to suggest that this affects well-being and quality of life. There was support for this idea.
- The meeting could cover screens and LED street lighting – there is a need for credible WHO information on this.
- The agenda should not be overloaded.
- Annual meetings are good.
- There is a lot of measurement data, but protection measures are often poor. There are many good examples of protection around the world, perhaps WHO could bring these together and publish them.
- A database of structural prevention measures from around the world (for example, traffic lights in Colombia that show the UV Index), that anyone could contribute to, would be good. The UN Environment representative said that they would support this.

There was discussion about a UV research agenda and how this could be progressed. An
agenda would need support from member states. The likely process would be to survey relevant experts to help list topics from a public health point of view. The resulting list would be reviewed by an expert group, which would develop rationales and key research questions. This would require about twelve experts from around the world, covering different regions. If their time were an “in kind” contribution, the total cost would be at least $20k to bring them together. Skin cancer in developing countries was suggested as one topic.

**Upcoming meetings**

The 4th International Conference on UV and skin cancer prevention will be held in Toronto in May 2018. This will be publicised on the Sun protection list server.

**Wrap up**

The meeting acknowledged the efforts of Emilie van Deventer in bringing the meeting together with very limited resources at her disposal.

**Opening of the session common to UV and EMF topics**

**Medical and cosmetic uses of Non-Ionizing Radiation (NIR) devices**

**WHO programme on medical devices (A. Velázquez)**

The WHO definition of health technologies covers a very wide range of products and devices, and includes some cosmetic devices. There are around 10,000 types of medical devices. The [WHO Health Technology Resolution (WHA 67.20)](https://www.who.int/healthinfo/IHDP/resolution/wha2017_04_12_067_20/en/) supports establishing and strengthening regional networks of regulatory authorities. There is a new Model Regulatory Framework for medical Devices (2017) which sets out four levels of risk and recommends a regulatory regime depending on the risk. The framework outlines controls and enforcement procedures for the pre-market, placing on market, and post market phases of device introduction.

Only 58% of countries currently have medical device regulations. The EU has a new Medical Device Regulations (April 2017) which includes devices that emit high intensity electromagnetic radiation. Benefits from the use of such devices should outweigh the risks. WHO needs more resources for this work and should work with Member States on NIR devices. WHO is working with other organisations, such as the IEC, on safety Standards. To date there has been no work looking at counterfeit medical devices.

**Diagnostic devices using NIR: Regulations and potential health risks (ICNIRP) (A. Green)**

Adele Green described the 2017 [ICNIRP statement on diagnostic devices using NIR](https://www.icnirp.org). The aim was to review the range of devices being used in clinical settings, document policies and regulations governing their use and the protection of patients and healthcare workers. ICNIRP also looked at potential risks for patients/operators, to determine whether there was hazardous equipment not covered by regulations. The review found that there are gaps in the evidence including, for example, some optical exposures, and the use of contrast media with ultrasound. Discussion raised the comment that there needs to be greater awareness on the part of clinicians about possible risks of fetal MRI.

**French report on health risks related to the use of devices intended for the performance of aesthetic procedures (ANSES) (O. Merckel)**
In France there is a growing demand for cosmetic procedures, commercial operators have varying amounts of training, and some devices on sale are intended for home use. Some serious complications have been reported. ANSES reviewed non-invasive hair removal and lipolysis devices and techniques.

Non-invasive hair removal literature generally showed mild, localised reactions such as inflammation and pigmentation disorders. Case reports, however, showed some deep skin and eye burns due to poor practice. The efficacy of lipolysis, except for cold “therapy” is questionable, and there were reports of severe inflammation and pain. There is no information about possible long-term effects, and assessments of “tolerance” to the treatments are poor. There are disputes between physicians and beauticians about the illegal practice of medicine.

The ANSES appraisal recommended that these devices should be regulated, and that cosmetic devices should be subject to the same requirements as medical devices. User qualifications should be specified, and information provided on potential adverse effects. There is also a need for studies on long term effects, and a system to report adverse incidents.

Swedish report on aesthetic ultrasound devices (SSM) (J. Estenberg)
The 2013 report SSM 2013:31 surveyed ultrasound devices available in Sweden used for cosmetic/aesthetic purposes (body contouring and fat reduction). These used kHz frequencies, and some also used RF and/or lasers. A further report looking at cosmetic devices using any form of NIR is now being prepared.

Infrasound and Ultrasound-Why do we even talk about this here? (WFUMB) (J. Abramowicz)
In the USA, the FDA includes infrasound and ultrasound within its definition of radiation. Regarding infrasound, there are various natural and artificial sources of infrasound, and only limited evidence of any biological or health effects. Some organisations have recommended infrasound limits, but only one country has mandated limits.
Regarding ultrasound, it is widely used in medicine, and in some industrial processes. There are two broad types of effect: thermal (absorption of acoustic energy in tissue) and mechanical (such as radiation pressure, cavitation). Since 1992, as a condition for allowing higher ultrasound output from diagnostic equipment, the FDA required the display of a Thermal Index (TI) and Mechanical index (MI), which predict the potential magnitude of these effects. There is poor understanding amongst users, however, of what these signify. There have been concerns about possible effects of ultrasound use in early pregnancy, but the only outcome with some evidence is on non-right handedness. Exposure minimisation is recommended. Professional bodies involved with ultrasound have published guidelines for its use. Ultrasound is also used for various therapeutic purposes, and in cosmetic applications.

The new NIR law in Switzerland (D. Storch)
Switzerland has just published a law and ordinances for protection against NIR and sound, and products which produce them. It is based on product safety legislation but allows additional controls on the uses of NIR devices. It will permit, for example, specifying that IPL cannot be used for tattoo removal, controls on sunbeds, and training requirements for people that use NIR devices. Implementation is expected in 2019.

International standards for Non-Ionizing Radiation (NIR) Protection
Update on recent activities (E. van Deventer)
International Standards (IS) for NIR have been proposed using the example of the IR-BSS. The
target audience for such voluntary Standards would be policy-makers, radiation regulators and relevant employers. Following the IR paradigm, with UNSCEAR reviewing effects and providing the scientific basis, ICRP making recommendations and the IAEA publishing Standards, for NIR the scientific basis is provided by the Environmental Health Criteria monographs, organisations like ICNIRP, the CIE and ICES make recommendations and WHO (and possibly other relevant organizations) would then provide IS for NIR.

Along the same lines as the IAEA Fundamental Safety Principles (FSP), there would also be FSP for NIR which provide a common safety philosophy across all NIR.

A lot of feedback was received in the draft FSP-NIR circulated in 2016. The main comments were:

- The draft was too closely aligned with IR and did not explicitly consider the differences between IR and NIR;
- The approach was too broad to manage the different risks from each NIR modality;
- The scope could be too broad (e.g. including ultrasound and military applications);
- The IR terminology used is not always appropriate and does not have the same meaning, so could cause confusion;
- Existing international regulations cover some areas (e.g. occupational/public exposure, product safety) and should be considered as there are many NIR products on the market.

For now, the priority will be to develop the IS-NIR. Some of the background work for this is already complete (e.g. EHC monographs). The proposed structure is to have an introduction, general recommendations, then Standards for public, occupational and medical exposures for each NIR modality. There are three main steps: reviewing existing regulations and guidance, identifying regulatory gaps and needs, and establishing main recommendations. The first two are complete, and the third is in progress. Existing regulations catalogued include ILO practical guides, recommendations and Directives from the EU, recommendations from Member States, e.g. the US ACGIH, and FDA Guidance documents, as well as reports from bodies such as ANSES, SSM and AGNIR. Gaps include regulation beyond product safety Standards, cosmetic applications and sun protection.

General recommendations are the establishment of a legal framework, specifying the responsibilities of regulatory bodies and allocating responsibilities for public, occupational and medical safety. There are also possible specific recommendations for public, occupational and medical exposures, such as monitoring compliance and provision of information, education and training.

It is envisaged that a draft table of contents will be ready next year.