

# **WHO Standards Harmonization for the African Region**

## **Cape Town, South Africa**

### **6 December 2001**

ICNIRP - 10 years on

Alastair McKinlay, ICNIRP Chairman

IRPA/INIRC was formed in 1974 after ICRP decided not to expand into NIR. Received Charter under German law as not for profit organisation in 1992 and ICNIRP was formed. The Commission has 12 members, Chairman and Vice-Chairman but no one from industry and receives no money direct from industry.

All of the Commission is up for re-appointment in 2004. Some members will be tenure-expired at that time. Current phase of expanding expertise and structural development. Now have four standing committees (epidemiology, biology, physics and engineering, and optical radiation) and consulting members.

Standing committee members review the literature in their field. They then prepare specialist reports as requested by main Commission. Advise on preparation of exposure guidelines where a multidisciplinary input is required. When ICNIRP needs more up-to-date technical knowledge, then appoints consulting members. This allows a wider scientific input and broadens consultation. Prospective consulting members are proposed by Standing Committee Chairmen and appointed by main Commission.

Partners in NIR protection

Proposals are circulated to IRPA for onward distribution to their member societies and members. Links with WHO through the International EMF Project also on the UV question as some UV is class 2A carcinogen. WMO also have an interest in this. CIE links are also important.

ILO contract ICNIRP to produce occupational exposure guides.

EC FP 5 report on RFID interference with implanted medical devices.

ICOH and IEC are other partner groups.

Publications:

- Environmental Health Perspectives publication next month on ELF Epidemiology.
- Two other reports on ELF from Physics and Biology Standing Committees.
- RF reports start preparation next year.
- General protection statement is going to press in Health Physics.
- Sunbed statement and ultrasound are also near to publication.

### **Guidelines**

These are living documents and subject to review, need to be seen as advice based upon science. They form frameworks for developing practical radiation protection policies. They are summaries of the science without providing a detailed review of all literature. Provide limits and then measurable fields levels as reference levels for hazard assessment. These are only one input into policy development.

These are not the last word and are not defensive mechanisms and are not mandatory. They are based on the science, avoiding established adverse health effects, based on practical hazard assessment experience.

Not result of single studies, studies must meet basic quality criteria and do not take account of anecdotal reports.

#### Guidelines - practicality

- Form basis for technical measurement or emission standards.
- Need some time stability, but must be flexible.
- Be consistent across frequency spectrum.
- Current monitoring instruments must be able to measure the field reference levels.
- Provide a consistent framework for the professional adviser.

Guidelines are health based, leave technical standards to deal with other aspects.

#### Guidelines – the science

- Epidemiology is an observational science looking at real people. Must have rigorous protocols for analysis. Volunteer studies look again at real people, but have to look at population structures to make sure results are transferable.
- Animal studies look at whole organisms, but are results relevant to human?
- Cellular studies are important in understanding the mechanisms in biological interactions. Care again in interpreting results and implications for humans.
- Physics needs to be well understood.

#### Future

- Better relevant scientific data for all fields of interest.
- Need some harmonisation of approach, not the same set on numbers (although IEC may want that).
- To get this still need independently conducted, high quality, relevant research.

## Overview of IEEE C95.1 Standards Development

Vitas Anderson, EME Consultant, Melbourne, Australia

The International Committee on Electromagnetic Safety (ICES) has developed from SCC-28 and has five subcommittees. SC 4 deals with the RF standard from 3 kHz up to 300 GHz. Philosophy for membership is inclusive meaning that the whole international community is brought together aiming at a consensus solution.

Members come from a whole variety of scientific or other backgrounds.

Has a rigorous literature rating system and produces white papers which are submitted to journals for peer review.

Standards are seen as a bridge between science and regulators. There is scope for including social and other factors (judgements) i.e. through the reduction factors.

Literature selection criteria - look for papers that are relevant to health; is peer reviewed; has independent replication; and dosimetrically quantifiable. A risk assessment working group look at all the literature reviews and then they recommend threshold limits and their rationale.

Both ICES and ICNIRP guidelines look for international recognition; lead the debates; seek consensus with each other; and take a conservative approach to reduction factors.

Comparison with other reduction factors applied to other agents, eg noise - people will get hearing loss; lifting, etc. Both recognise heating and neuromuscular stimulation and high energy pulse effects as the basis for the limits. Both agree that low level effects are not sufficiently established to be used in guideline setting. Any differences tend to be in the detail. Both have two a tier approach, but IEEE introduce controlled area concept.

### ICES view

- There are no subgroups of the population who are significantly more at risk from RF exposures that are below the controlled environment limits.
- Exposure duration at the controlled environment limits is not a significant risk.
- There are no long term cumulative effects from RF exposures below the allowable limits.
- Scientific reports of low level ('athermal') biological effects cannot be meaningfully related to human health.

IEEE deal with the environment rather than population. Controlled environments, people are aware of their potential exposures and therefore can be trained how to conduct themselves.

Uncontrolled, people have no awareness or specialist training and knowledge.

IEEE go for MPEs (maximum permissible exposure) and these can be exceeded if basic restrictions are complied with. Similar to ICNIRP with reference levels.

### IEEE and ICNIRP

- For SAR values only difference is for peak SAR in head and trunk with a different averaging mass and slightly different values (IEEE 8 and ICNIRP 10 Wkg<sup>-1</sup>). Proposal on table for IEEE to harmonise with ICNIRP.
- Peak current density limits are different with ICNIRP saying instantaneous and IEEE averaging over one second.

- ICNIRP generally slightly more stringent for time averaged E fields. For H fields differences are greater.
- Peak E fields IEEE have single value whereas ICNIRP has frequency dependent relationship.
- IEEE provide advice on implementing the standard, gives advice on spatial averaging across the volume occupied by a body no closer to 20 cm from an object. Cannot apply to eyes or testis.
- IEEE provide low level exclusions, but exclude devices that radiate within 2.5 cm of the body.

Both IEEE and ICNIRP are conservative standards/guidelines, and each have good technical features that should be shared through harmonisation.

### Standards for EMFs and Harmonisation

Dr Michael Repacholi, WHO, Geneva, Switzerland

Review all RF standards in the world. Dina Simunic has prepared comparison tables which can be viewed on the WHO web site. Reach agreement on framework for developing guidelines, not the standards themselves.

Hope this will increase public confidence and reduce fears. Can have factors of up to 1000 between Russian and western standards. This difference is used by activists as argument to support increased reduction. Everyone should then be protected to the same level.

Political process means that there will probably be some regional variations, according to the will of the people. They must make decisions on best information available. Having different values for different regions or states within a country is not good for public confidence.

Some differences will arise from different interpretations of the scientific data. These tend to alter the reduction factors applied. Different understandings of risk data and environmental risks may influence development. May be communications difficulties between scientists (eg west to east). All members of WTO and signatories of GATT should be looking to international standards.  
[www.wto.org/english/tratop\\_e/tbt\\_e/tbtagr.htm](http://www.wto.org/english/tratop_e/tbt_e/tbtagr.htm)

Forming Working Groups(WG) to deal with key components of the framework.

- WG1: Standard concepts and terminology
- WG2: Criteria to evaluate research results. Scientific rationale to support limits, and comparison of various standards
- WG3: Model for developing standards. Safety factors: how should they address uncertainties
- WG4: Should social and economic impacts be considered? How should precautionary approaches be developed, if needed?
- Draft framework now for discussion

List of topics for discussion:

- Criteria for evaluating science
- Models for developing limits
- Use of safety factors
- One or two tier exposure?
- Form of standard - should it indicate how to assess compliance?
- Scientific rationale to support limits should be provided for transparency?
- Social and economic impacts - should they be considered?
- One standard to cover whole range 0 - 300 GHz?
- Other considerations?

Wants to have framework in place by end of 2003 so that it is ready to use the health risk assessments that will come in 2004 and 2005.

Review of the Australian (ARPANSA) RF Safety Standard.

Dr Colin Roy, WHO, Geneva, Switzerland

In 1998 Standards Australia (AS) and Standards New Zealand (NZS) published an interim standard AS/NZS 2772.1 (int) to allow 15 months for committee to reach agreement. Australians were not able to agree, NZS did agree and published NZS 2772.1 (1999).

Current Australian regulations are based on the expired interim standard. Australian Communications Authority and ARPANSA agreed that ARPANSA would create standard with long public consultation period. Would also develop a code of practice alongside, but separately. This CoP could include precautionary principle aspects. Must also meet government guidelines on public consultation and on a Regulatory Impact Statement.

Expert group set up under ARPANSA Radiation Health Committee (RHC) included representatives of many groups, unions, communities, etc. Draft released in March 2001 for comment by May 2001. WG provided comments in form of responses to all respondents. Gone to RHC for their approval, before going to the ARPANSA Advisory Council and final approval by the ARPANSA CEO. Publication is expected late in the first quarter of 2002.

The WG started with AS/NZS final draft that failed before and has added value in areas including the following:

- low level effects (processes where a non-thermal mechanism may be operating). Community groups have been critical of the apparent lack of attention to papers detailing biological effects at levels well below the limits. Pulled together what they thought were probably the 100 most significant papers on this. The review by the WG concluded  
 “exposures leading to SAR values below the basic restrictions - - - do not lead to unambiguous biological effects indicative of adverse physiological or psychological function or to increased susceptibility to disease. Whilst these low level effects have not been established, they cannot be ruled out and so more research is needed.”
- epidemiology (review of literature post publication of the ICNIRP Guidelines)

“The epidemiological evidence does not give clear or consistent results which indicate a causal role of low intensities of radiofrequency exposures in connection with any human disease. On the other hand, the results cannot establish the absence of any hazard, other than to indicate that for some situations any undetected health effects must be small.”

- clear definition of temporal and spatial properties

Annexes include review of literature; units; coupling mechanisms; field measurements; precautionary approach. The standard and supporting papers will be available at the ARPANSA web site: [www.arpansa.gov.au](http://www.arpansa.gov.au)

Occupational exposures requires risk analysis and risk management and control regimes. Minors are excluded.

Pregnancy - women should not be exposed above public limits and should declare their pregnancy to their employer. Wanted to avoid risk of accidental exposure going above occupational limits.

#### Public:

- Decide boundaries
- Restrict public access
- What signs are needed?
- Notify public authorities
- Minimise as appropriate, RF exposure which is unnecessary for the achievement of service objectives provided it can be achieved for reasonable cost. Did not want to include arbitrary additional reduction factors.

#### African Standards

Dr Solomon Wanguru, Ministry of Health & Social Services, Namibia

Implementation should be on basis of a legal framework. Need to derive powers from the law. Group also regulates ionising radiation activities. In some countries ionising radiation work activities are regulated within hazardous substances group.

IAEA visit to Moscow and other parts of CIS in 1991 looking at regulation. Was not surprised that 1986 Chernobyl happened. Chain of command and information was extremely long and slow. Wants to have a very short link regulator to Minister. Will require the Governments to take the action, but WHO can initiate the process.

Problems come from geographical distribution and also language (English and French). Francophones are also very independent and want to do things their own way. Algeria, Tunisia and Morocco, and former Zaire (produces uranium and has reactors), Senegal, Guinea, Mali, Congo, Ivory Coast have infrastructures that are not very clear. Egypt, Sudan, Namibia, Zambia, Angola, Zimbabwe and Mozambique all do it under hazardous substances acts.

Policy on Radiation Protection, Cabinet has to agree on systems to establish. Must be separated from regulated organisations that includes the government. Must also have an advisory body that can promote activity and develop the standards representing all

stakeholders then submitting them to a minister to agree them and then institutionalise them in statutes.

In some countries if included in Department of Health get problems as they don't understand the physicists and engineers. Will have regulatory authority that is independent and separate from Health Ministry. Have powers to authorise and revoke permissions. Regulations are made by Minister. These would include standards. Include in law the definitions and the standard that has to be maintained, ie as said by ICRP, ICNIRP or WHO or other standard specified in the regulations. No need to mention again in any detail.

Problems in Namibia arise in part from its history. Namibia was a German colony, handed to British after war (WW I) by League of Nations. But British asked South Africa to administer it. Following WW II Namibia was amalgamated as Northern Province of South Africa. No science taught in schools as the population were only contracted labour. Still a problem and need to do more to improve science teaching. Need to start developing research centres in region so that capacity to develop human resources is improved.

Q - Adding a draft legal framework is perhaps a good idea, doing it in occupational health. What is time frame for Namibia for an EMF regulatory package?

A - In Namibia they had effectively South African law and will repeal and replace in next six months. Still have companies coming with licence from South Africa, want to change this.

#### South Africa

Leon du Toit, Department of Health

Directorate of radiation control, controls all ionising and non-ionising radiation applications. Accept 1998 ICNIRP. Do not have Radiation Protection Act, but use Hazardous substances regulations. List of RF emitting electronic products that are licensed. Can set requirements on installations and require compliance with ICNIRP for EMFs. Cell phones and base stations are not included in list. Lower limit on power of devices. Power lines do not require licences either.

Q - ICNIRP as a regulation?

A - No, as a licensing requirement.

Q - When?

A - Not many licenses for commercial operations. Developing CoP that will go with it. But it is adopted in principle some time ago.

Q - How do you get cell phone and base stations exclusions?

A - three categories are licensed. One is RF producing devices (<300 MHz) power < 200 W. > 300 MHz the power level is 400 W. Below this is limit on 25 W.

Q - heaters and sealers?

A - separate category.

#### South African Bureau of Standards

Dr Zen Fourie, Groenkloof, Pretoria, South Africa

Reviewing ISO standards, in South African Development Community. Standards are voluntary, but if going to make it compulsory, then it goes through WTO and Ministers.

## Discussion

Q - How does WHO see the application of the framework to the developing countries.

A - Framework is based in science and each country uses the framework and the health risk assessment

Q - Why are the standards different?

A – AF McKinlay - UK has single tier standard, but children are treated differently with resonance factors. Foetus is treated specifically in UK. Experts agree on fundamentals and then there are shades where things are viewed slightly differently. UK revision of view of standards in the middle of 2002. Politics plays a role as UK is a member of EU (519/99/EC). IEGMP recommendations for mobile telephony ICNIRP should be used for public. Science is still the same.

A – V Anderson - standards are very similar. Metrics for compliance and basic philosophies are similar. Differences are in the detail. Different stakeholder groups are part of the answer. IEEE has responded in different ways, as they are basically an engineering group. Industry has most experience of applying limits, feels that this brings a lot of practicalities to the table. Perhaps should use probabilistic risk assessments as a tool to establish uncertainty factors. One or two tiers, proposal to collapse into one is at early discussion stage. Socio-political point of view this is difficult to see happening.

A - C Roy – Much of work had already been done by the previous committee – there was no justification in discarding this. Australia needed a standard that included a well-reasoned rationale, not just numerical guidelines. How to apply the numbers was part of the reason for developing further. The ICNIRP guidelines were a good starting point because of their wide international acceptance. Both the community and industry were represented and the telecommunications regulator was an observer.

Q - Jo Wiart - some misunderstanding about limits and standard. Why do you have 1 g and 10 g SAR limits? Need to look at how this was arrived at and come to agreement.

A -AFMcK - WHO workshop should look at this.

Four working groups were formed to discuss WHO standards harmonization framework document.