

PROVISIONAL MINUTES
International EMF Project: Standards Harmonization Meeting
Ettore Majorana Centre, Erice, Sicily, Italy
27 November 1999

1. Opening and Welcome

Dr Repacholi welcomed attendees to the second International EMF Project Standards Harmonization meeting at the Ettore Majorana Centre. He noted that the first meeting held a year ago in Zagreb, Croatia had provided an update on the status of standards in many countries world wide and provided a snapshot of the situation as of November 1998. The present meeting would focus on recent contributions toward standards harmonization efforts. Dr Portier had been invited to give a presentation on frameworks and Dr Black would describe recent experience in New Zealand where legislation incorporating a precautionary approach has been put into place with considerable public participation.

This meeting discusses standards frameworks and the need for working groups on various topics related to standards development. The draft agenda shown in Appendix 1 was considered appropriate for the meeting and accepted without amendment by the attendees.

2. Objectives and Recent Activities

The purpose of this activity is to develop a framework for harmonisation of EMF standards, not to draft exposure limits. Once an agreeable framework has been developed the EMF Project generated health risk assessments can be incorporated to arrive at the final standards. Standards refer to voluntary guidelines as well as regulations under national or local legislation. The focus of the standards harmonisation activity the establishment of criteria for and the process of developing standards.

Topics for discussion within the standards harmonisation process are:

- What criteria should be used to evaluate research results?
- What should be the detailed requirements for a scientific rationale to support limits?
- What is the best model for developing standards? Methods for determining compliance should not be overlooked.
- What is to be made of isolated data points at specific frequencies?
- How and with what degree of confidence can results be extrapolated to other frequencies or intensities?
- How should similar concerns about the applicability and extrapolation of animal or cellular studies to humans be dealt with?
- Should one standard cover the whole frequency range from 0 to 300 GHz?
- What about safety factors? Do they or should they address scientific uncertainties in the fundamental research or imprecisions in the techniques used for exposure assessment? Should they also allow for gaps in knowledge?
- Should standards be one or two tiered - i.e. differentiate between occupational or controlled exposure and general population or uncontrolled exposure?
- What account should standards take of social and economic impacts?

Benefits of arriving at EMF standards that are agreeable to countries worldwide are:

- Increased public confidence that governments and scientists agree on health risks
- Reduced debate and fears about EMF -- precautionary principal?
- Everyone protected to the same high level
- Economic benefits with globalisation of trade

Following his brief introduction, Dr Repacholi opened the floor to questions and discussion. Dr Swicord commented that there is much discussion about models for extrapolation of limits from one frequency range or modulation characteristic to another, but there needs to be a solid scientific basis for standards. Dr Repacholi responded that complete coverage of all conceivable exposure regimes would never be achieved therefore models would always play a necessary role in extending coverage of standards beyond the specific conditions.

Dr Israel raised the issue of making the transition from basic restrictions to reference levels. The experience with other exposure standards was noted, e.g. for chemicals, where WHO supports an MSC (Minimum Safe Concentration). By contrast, TLV (Threshold Limit Value) is a very different concept. Will the EMF Project follow the MSC concept for EMF standards framework? Dr Repacholi noted this would be an opportune time to move onto a more in depth discussion of the standards framework and moved on to the next agenda item.

3. Development of a Standards Framework

Dr Repacholi invited Dr Portier, who has been involved with the development of the MSC concept with WHO in the context of chemical agents and a corresponding framework for standards. A summary of the overheads used by Dr Portier for his presentation is given in Appendix 2. Dr Portier reported that NIEHS has been actively developing methods for evaluating health risks for chemical agents for some time. For example, an investigation of dioxin was started about five years ago with a compilation of health standards from around the world. Allowable risk could vary by a factor of 1000 by crossing a national border (e.g. from USA into Canada) and even within a given city (e.g. Washington, DC) where variations by a factor of 30 occur by passing into another jurisdictional area (federal to state). The implications of such situations for standards harmonization were not good. It was also clear that standards and risk were not just a matter of science but also of politics and policy. Dr Portier's experience indicated that definitions were the key. Terminology was the single greatest source of difficulty and misunderstanding. For example, among 15 definitions of risk, it was found that all refer to probabilities but when the term was used it is in an absolute sense of risk existing or not. In the end, risk is rarely used as a basis for standards. The actual basis ends up being exposure. He also pointed out that the situation with regard to EMFs has historically been approached from the viewpoint of fundamental physical understanding and has moved toward observed or observable effects. This is opposite to what has occurred in most other areas, e.g. chemical or biological agents, where epidemics, i.e. observed effects have motivated a move toward the fundamental understanding of the mechanisms behind the observations.

4. Discussion on Standards Framework

Among Dr Portier's overheads was one describing a series of uncertainty factors used by the National Health and Medical Research Council in Australia. The question was raised whether the factors were multiplied together. Dr Portier replied that they were and this occurred in other areas. Dr Repacholi enquired whether there was a minimum uncertainty factor. Dr Portier reported that the minimum used was 30 unless extremely good data was available in which (rare) case a smaller factor would be used.

Dr Lin called attention to the fact that there was information on 'observables' but there is very little on mechanisms in the ELF or RF regions. Dr Portier said there is a strong feeling that there is no basis for harmful effects from low level EMF exposures. Also that data from frequencies above the ELF region would not trigger regulatory action in the USA since there is no clear 'toxic' finding upon which to base legislation. There are concerns but not demonstrable toxicity. Dr Lin elaborated noting there is a clear indication of adverse effects at high levels, e.g. thermoregulatory breakdown. Another example he gave was the BBB where there is general agreement on the existence of a threshold.

Dr Rubtsova raised the issue of definitions and terminology noting difficulties arising in applications of standards and guidelines. Reference was made to the WHO IPCS database of terminology as a model that might be considered for applicability to the EMF area.

The question was raised about safety factors. Their presence in guidelines was routinely accentuated by regulators adding additional safety factors and then regional and local regulators doing the same resulting in an intolerable stacking of safety factors. Was there any way to avoid such stacking? Dr Portier noted that was a policy issue. For example, federal legislation in the USA requires an additional factor of 10 where children are concerned. However, what is still needed is a discussion of the overall safety factor that ends up being applied. This must also be accounted for in establishing compliance, in deciding where to draw the line in the context of manufacturing

variability, usage variability, etc. Safety factors need to be addressed at all levels. Dr Portier noted the existence of web sites discussion such issues. However, decisions ultimately fall back on the 'judgement' of the 'risk manager.'

A comment from the floor bemoaned what was characterized as the myopic view of scientists in focussing in detail on risks but that all too often totally ignoring the benefits side. Dr Portier agreed, however, no federal authority has formulated guidelines for establishing 'balanced' risk/benefit ratios. The issue is usually avoided because it gets into the area of the 'value' of a human life.

Dr Murphy questioned whether it was common in the context of chemical agents to have two tiered standards or guidelines. Dr Portier said it was common to have an additional safety factor of 10 for 'uncontrolled' exposures outside 'controlled' occupational situations.

Dr McKinlay asked about the state of epidemiological evidence for RF compared to ELF observing that in particular, the ELF epidemiological evidence has been deemed insufficient and risk factors seem to be small even if they are real. RF evidence upon which to base any concern seems to be still weaker. Dr Portier noted that for ELF there were at least two issues:

- Whether there was data available upon which to quantify a standard: yes there was.
- Whether there was a will to establish the indicated standard.

However, if a comparison of the limits from the epidemiological data reveals a large difference from the limits based on all the evidence, then the relative risk becomes an important factor in the discussion. Dr McKinlay pointed out that the difference is indeed large - namely 200 nT from the epidemiological data and 100 μ T from the standards.

Dr Portier was asked if there was established any particular method for choosing the evidence to use. He stated his preference was to use laboratory data but there still needs to be a balance with human data. However, once it has been decided that there is a hazard, then human data would be favoured. Dr Vecchia said the approach of side-stepping social and economic considerations taken by ICNIRP is justified but there is a clear need for WHO to take a stand on the issue. The cost/benefit calculation is actually relatively easy. Exposure to ELF fields may be associated with one extra cancer per year if exposures are above 200 nT. However, to enforce a 200 nT limit would undoubtedly cost many billions of dollars. Scientists also have to be able to describe what is meant by the NIEHS conclusion that ELF exposure is a 'possible' carcinogen classification. Scientists cannot continue to avoid economic and social aspects, or the need for precautionary approaches.

Mr McManus asked for a 'common sense test' when using data from epidemiology studies. Working back from the level of 200 nT and using the Australian safety factors of 30X and 3,000X would imply a standard of about 0.002 nT! Dr Portier stated he was not inclined to debate epidemiology but recognized there is indeed an inconsistency. However, setting a standard does not imply that everyone is exposed at that level. Whatever actions are taken exposure levels shift and effects on population risk are very subtle and difficult to determine. In regard to Dr Vecchia's comments on the number of cases at risk of leukaemia he added there would be an extra 1.6 cases of cancer per million children based on the epidemiological studies.

Dr He said that in China the epidemiological data is considered important because it is human data. Their present standard used ALARA and is over ten years old. In the meantime, the use of devices like cellular telephones has changed considerably so they will revise the standard and not use ALARA but the levels are yet to be decided. Health effects need to consider exposure duration so that higher levels would be permitted for a short duration. They intend to look at daily averages and two exposure classes. A thermal basis was not considered reasonable because of evidence of effects at levels under 4 W/kg.

Dr Repacholi invited Dr Lin to give a presentation on the NCRP approach to standards setting. See Appendix 3 for a summary of the overheads used. Dr Lin noted that the NCRP process is not documented so his presentation was limited to a personal review. He identified four broad frameworks - A, B, C and D and gave examples to elucidate effects under each one. Russia and China were considered to be within framework A.

Dr Vecchia pointed to the difficulties with getting ideas out to the public. The best example was the attempt to get across the importance of epidemiological or biological studies. Effects are observed and reported but what can be derived from them and which, if any are adverse? There is a need for criteria that can serve as a basis for deciding the extent to which study results can be transformed into policies or better still when they can be ignored. It is not sufficient to continue repeating that absence of risk cannot be proven. Dr Lin expressed agreement with Dr Vecchia's comments. Eventually the processes and rationales need to be clearly delineated. Generally, one has to expect that the 'totality' of results will be considered and their importance 'distilled' by an 'expert' group. However, even with the best of processes and rationales it should be expected that objections would be raised.

Dr Portier expressed agreement with the comments from Drs Vecchia and Lin. Dr Repacholi's asked which of the four frameworks was used by the Chemical Hazards Program. Dr Portier said they used D, but noted that the scientific certainty statement is useful since it implies that policy makers are free to raise or lower standards for whatever reasons they might choose. If level X is deemed to be bad and level Y safe then intermediate level Z can be fixed as 'reasonable' by some stated criterion. Dr McKinlay pointed out that it was important for standards to clearly about what health effects they provide protection. All too often authorities hide behind standards to avoid answering the real concerns held by people. In principle, present standards do not address cancer fears. Dr Lin agreed but added that if the process is made open such matters will raise less concern. Dr Swicord said there was a need for establishing what is a demonstrable effect. It is impossible to proceed if various authorities use other bases for setting standards.

Dr Repacholi invited Dr Petersen to make a short presentation on the IEEE process. A summary of his overheads is given in Appendix 4. He described the IEEE structure consisting of Standards Committees and Standards Coordinating Committees with an emphasis on transparency of the process at all steps. Dr Portier congratulated IEEE on the openness of their process but enquired why the evaluation information from the development of the research database was not being disclosed. Dr Petersen pointed out it arose from concern about the feelings of authors but that the information will be presented in a summarized form where connections of comments to specific authors will not be possible. However, the issue is still up for review. The process has taken a long time to work out and it is hoped it will find application in areas outside EMF.

5. Country presentations

Dr Repacholi opened the floor to short presentations from some of the country representatives.

Russia

Dr Rubtsova presented a summary of the sanitary norms in Russia. The situation with regard to cellular telephones is somewhat tentative in that some regulations are expiring and need to be re-evaluated. Extensive consideration is being given to matters connected with harmonization, combination of exposures from different frequency regions.

Hungary

Dr Thuroczy presented a summary of present concerns in Hungary. Discussions involved the Eastern European limit of $10 \mu\text{W}/\text{cm}^2$ with its historical and, perhaps, political background. It was agreed to continue with the low levels since harmonization would imply raising levels significantly. It has been found that there is public mistrust of the ICNIRP guidelines because of the big gap between the standards and environmental levels. Having the Hungarian standard set at a 'safer' level sends a good message to the public. However, the situation represents a puzzle in terms of dealing with the inherent contradictions. However, in the absence of specific standards Hungary reverted to ICNIRP for guidance.

China

Dr He said China was in the process of revising their standards but they have to take into account the mobile telephones situation. A meeting is being organized in October 2000 to discuss the results of Chinese EMF research and engage Chinese scientists in the discussion of international EMF

issues. The proceedings of the 1999 Beijing seminar have been published and are also available in English.

6. New Zealand Experience

Dr Black was invited to make a presentation summarizing experience in New Zealand. He introduced himself as an environmental physician. The joint Australian/NZ standards programme had been abandoned. However, NZ had adopted the ICNIRP standard but incorporated a precautionary approach that was based on best common practice with all its advantages and pitfalls. The ICNIRP guidelines were expanded with additional graphs and look up tables. ALARA was in an earlier draft but it was recognized as being specific to ionizing radiation so there was a shift to a prudent avoidance or a precautionary approach. The final result was the New Zealand Standard NZS2772.1(1999). There was strong public support for a precautionary approach so that appropriate action had to be taken to incorporate it. Now it has to be applied in establishing the conditions to be met for installation of mobile telephone base stations. In the context of the New Zealand standard they have to deal with the fact that RF is the **main** requirement of the system. It is consistent with other resource use and it satisfies nearly everybody but it requires changes in thinking. It was commented that it undermines science-based standards.

Dr Repacholi asked Dr Portier whether he was aware of any other standards that take a precautionary approach. He replied that, to his knowledge, there were no chemical agents similar to this situation. Dioxin will probably follow a best technology approach. Dr McKinlay raised two points for Dr Black's comment.

- Why was it necessary to embrace the precautionary approach **within** the standard? Shouldn't precaution be a policy matter rather than part of a standard?
- Power densities or field strengths might be suitable bases upon which to establish 'best practice.' But, what is best practice for modulation? What is going to be 'precautionary' in that sort of context?

Dr Black responded that a substantial fraction of the population wanted a precautionary approach and therefore it had to be put in place. It had to be included in order to get the standard passed. Regarding Dr McKinlay's second point he stated that as long as the absolute levels were low it would not raise undue concerns and furthermore there was no specific data to support such concerns. However, in the end it is a matter of doing a bit of reassuring and eliciting trust.

Dr Schuller noted that there was a conspicuous lack of any benefit aspects in the process so that the matter should stay in the political arena. Dr Black replied that while there are phrases like "all other things being equal" and "can be done at reasonable cost" there is no provision in the standard that can STOP any particular project. Dr Portier enquired whether there were any other examples of the 2 μ W versus 200 μ W NZ court judgement. Dr Black replied that there are similar judgements under the New Zealand Resources Benefit Act where the courts have to decide whether or not effects are "less than minor" but otherwise they have to make decisions *de novo*.

Dr Renew pointed out that best practice may not always be best since there was no reason it would inherently reduce levels. Dr Black stated it was not a problem before cellular telephones but in other areas the precautionary approach would not apply if it only led to added costs and no benefits.

7. Other countries

Switzerland

Dr Moser reported that Switzerland has a legal requirement to apply a precautionary approach under an ordinance that has been put forward for final decision. The ordinance uses the ICNIRP guidelines but adds precautionary limits for suspected (not established) health risks taking into account technical and economic considerations with the added requirement that the levels be enforceable. For high frequencies, the precautionary limit is 10% of the ICNIRP guidelines and for low frequencies (power frequency) it is 1%. This implies 4 V/m and 1 μ T respectively. The precautions, however, are based on suspected rather than established risks.

Dr McKinlay pointed out that the 1% applied to low frequency electric fields would imply a limit of 50 V/m and that was acknowledged as being notably low. Dr Swicord wondered what was to be

understood by the term 'suspected health hazard' and suggested that one of the primary tasks of the standards harmonization process should be to identify what are the suspected health effects. It would appear, at present, that effects are taken as established as soon as they are suspected. He enquired what sort of process was in place. Is there a group in Switzerland that will decide? Dr Moser stated that such a group does not exist. All these matters remain subject to debate.

Mr Dolan said that precautionary tools need to be put in place to cover the area of concerns between established and suspected effects. A careful distinction needs to be maintained between a 'common sense' approach and a formal 'precautionary principle.' Dr Schuller stated that there are estimates it would cost millions of Swiss Francs to adhere to the ordinance. The simple consequence is that money spent on precaution will clearly not be available for research that might help distinguish between suspected and established effects.

Dr Leitgeb noted that problems arise from the 'two path' approach. Science can determine the risks but acceptability needs social, economic and political inputs. In the final analysis, prudence cannot be defined scientifically. Dr Moser stated that suspected effects arise from preliminary indications in studies. Dr McKinlay observed that the ultimate costs are always fully borne by the public, which underscores that science needs to be kept separate from the social and economic issues.

Italy

Dr Vecchia was invited to report briefly on concerns and activities in Italy. He presented the newly proposed standard for Italy as an extreme example of prudent avoidance. It has come out amid a great deal of rumour and alarm within the country but there is relatively little detailed information about it outside Italy. It was his hope to clarify what is going on for the attendees.

The proposed standards are based on the precautionary approach. The National Institute of Health has had nothing to do with them to date. He noted he is in the unhappy position of having to criticize his own country but can see no alternative. There are discrepancies in the approach over the whole frequency range. The effective standard at 50 Hz will be 0.2 μ T. There is also a parallel draft in process for occupational exposures. A step function approach has been taken. The legislation may be in place by next spring. The limits will likely preclude live line maintenance. Implications of the precautionary approach are not clear for occupational situations but they are articulated and stipulated for exposures of the public. Precautionary approaches cannot be avoided. They have become a fact of life. There are EC guidelines for applying the precautionary principle running on to twelve pages. Any measures taken must be considered provisional. Based on the experience in Italy, none of the EC criteria have been met. ALARA has been changed in ionizing radiation practice to an optimization process whereby a balance is established between the cost of mitigation and the cost of health care. A 0.2 μ T limit will result in enormous costs for compliance.

Dr Vecchia reported that the very restrictive legislation was based on year long averaging. Mr Barrett queried how a year long average value was to be established. Dr Vecchia continued commenting that it is not at all clear how such a value could be determined since the regulation is contemplating setting as a limit a 'proactive' average to be achieved before the exposures actually occur.

Dr McKinlay recalled Dr Vecchia's statement that the National Institute of Health had not been consulted on the legislation and asked what the source of the proposed legislation was after all. Dr Vecchia stated it was a committee consisting largely of politicians and other officers of various ministries of the Italian government. It appeared their lone scientific consultant was a single epidemiologist among their number. The consequence of what has occurred is that the National Institute of Health will now be in a very difficult position in having to evaluate the proposal.

8. Establishment of Working Groups

Dr Repacholi asked the attendees to turn their attention again to the standards framework issue. Some of the issues remaining to be addressed were: standards terminology; how to assess the science; what is the difference between hazards and effects; what should be in the research database; and so on. Based on the discussions it was apparent that a terminology working group would be essential. Dr Bernhardt reminded the attendees of the requirements arising from the standards setting

process, namely, assessment of possible health effects; assessment of social and economic impacts; information needed to assess compliance; and establishing compliance. Consequently, working groups might be as follows:

- Terminology,
- Criteria for relevance of scientific reports,
- Criteria for evaluating established health effects,
- Evaluation of judgements of uncertainty,
- Criteria for accountability and adoption of protection systems.

Dr Repacholi suggested starting with definition of terms, what is being protected against, philosophy of protection, uncertainty and safety factors, approaches to caution (fact sheet in process - will form a basis for discussion). The final output will be a report covering the principles and definitions that will be used in future standards setting by national governments. Mr McManus noted that the EMF Project itself has been a great success. Perhaps, following its lead, a timetable should be considered for the harmonization process. Dr Repacholi stated that harmonization was included within the Project's overall timetable so it would be anticipated to terminate within three years or so. For the moment, the main task is to determine what working groups to form, identify what documents need to be generated, and have small groups draft and circulate them to the wider group.

Dr Portier suggested combining Dr Bernhardt's groups 1 and 2 for non-cancer focus and standards setting including the side issue of dealing with qualitative data. Dr Repacholi noted that dose response curves are not sufficiently developed. It was commented that, based on the inputs to the meeting regarding recent or pending legislation, the framework will not come out soon enough. Can a shorter timetable be established? Dr Repacholi said the process has been in progress for over 25 years so in that context 3 years is still short. However, any shorter time would probably preclude achieving a sufficiently broad consensus. There needs to be time for a logical succession of steps. Mr Barrett commented that Dr Bernhardt's fourth group would only come into operation toward the end of the process. Perhaps it would be useful to add in an earlier group on technical advice in complicated exposure situations. Dr Cleveland noted that topics from the list given in the morning could be included in such a group's terms of reference.

8. Future Work and Schedule of Activities and Deadlines

Dr Repacholi noted by way of summary that three working groups had been identified. He will undertake to draft terms of reference for them that will be circulated for comments. Then a few people will set up preliminary draft documents and get the working groups together. There will be a number of opportunities for the groups to meet at other scheduled meetings. Preliminary drafts should be available for a possible meeting in Sofia. Then follow up meetings can be scheduled in association with the BEMS meeting in Munich (June) and later in Xian (October). Any basic starting documentation or other input can be sent to Dr Repacholi at WHO. He will compile the material for inclusion in the drafts. Dr Cleveland enquired about the mechanism for the process. Dr Repacholi stated that preliminary drafts including time schedules and lists of topics to be addressed would be sent to all attendees for comment. The final steps will be decided based on input over the next year from the attendees.

9. Next Meeting and Close

Attendees were asked to note any meetings of interest in the coming year. COST244bis is holding a meeting on transients, 4-6 April, Madrid, Spain. Meetings on risk assessment for chemical agents are being held through the coming year and information will be forwarded to Dr Repacholi for dissemination to the other attendees. A workshop covering all of non-ionizing radiation is being held by ICNIRP 22-25 May, Kyoto, Japan. There are EMF related meetings scheduled in Armenia, Crete, China (Xian) and New Zealand (BEMS) at various dates through October, 2000.

It is anticipated that the next full standards harmonization meeting will be held in Xian, China next October. Dr Repacholi thanked the attendees for their spirited participation and adjourned the meeting at 1730 h.

APPENDIX 1

**International EMF Project
Standards Harmonization Meeting
Ettore Majorana Centre, Erice, Italy
27 November 1999**

Agenda

09.00 Opening and Welcome (Dr MH Repacholi)

Update on objectives and recent activities

Development of a standards framework (Dr C Portier)

Discussion

10.30 Coffee

11.00 Discussion (cont'd)

12.30 Lunch

14.00 New Zealand experience (Dr D Black)

(Adopting a health standard with precautions and public participation)

Discussion

15.30 Coffee

16.00 Establishment of Working Groups

Future work and schedule of activities and deadlines

17.00 Close

**Appendix 2: Dr Portier's Slides
Slide 1**

Slide 2

3. Harmonization

- Terminology
- Methods
- Hazard Identification
- Dose-Response Analysis
- Exposure Characterization
- Uncertainty
 - observed
 - assumed
- Scientific Limitations

4. Terminology

- largest source of misunderstanding
- common terminology can lead to common assessments
- key to careful communication
- sometimes tied to federal laws
- sometimes field specific
- lots of opinions

5. Adverse Effect

- Change in morphology, physiology, growth, development or life span of an organism. (USES, 1994)
- Change in morphology, physiology, growth development or life span of an organism **which results in impairment of functional capacity or which increases susceptibility to the harmful effects of other environmental influences.** (IPCS, 1978, Holland, 1996)
- Change in morphology, physiology, growth, development or life span of an organism which results in impairment of functional capacity or **impairment of**

capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences. (EHC170, 1994, ACDH, 1996)

6. Safety Factor

- A factor applied to reduce the no-observed-effect level (NOEL) to derive an acceptable daily intake. (Last, 1995)
- A number which **accounts for the uncertainty or variability** in an estimate of a no effect level by adding an extra margin of safety and therefore differs from assessment or application factors. (OECD, 1995b)
- A factor applied to an observed or estimated toxic concentration or dose **to arrive at a criterion or standard that is considered safe**. Safety factor and uncertainty factor are often used synonymously. (Leeuwen)
- A factor applied to the no-observed-effect level to derive **acceptable daily intake (ADI)** (the no-observed-effect level is divided by the safety factor to calculate the ADI). The value of the safety factor depends on the nature of the toxic effect, the size and type of population to be protected, and the quality of the toxicological information available. (EHC70, 1987)

7. Uncertainty Factor

- A factor applied to an exposure or effect concentration or dose to correct for identified sources of uncertainty. (Leeuwen)
- Factor in toxicological assessment for **extrapolation of data from experimental animals to man** (assuming that man may be more sensitive) or from selected individuals to the general population. (Holland, 1996). For example an uncertainty factor is generally applied to the no-observed-effect level to derive an acceptable daily intake.
- One of several, generally 10-fold factors, used in **operationally deriving the Reference Dose (RfD)** from experimental data. UFs are intended to account for **(1) the variation in sensitivity among the members of the human population; (2) the uncertainty in extrapolating animal data to the case of humans; (3) the uncertainty in extrapolating from data obtained in a study that is of less-than-lifetime exposure; and (4) the uncertainty in using LOAEL data rather than NOAEL data.** (US-EPA, 1992)

8. Uncertainty Factor

- In assay methodology, **confidence interval or fiducial limit used to assess the probable precision of an estimate.** (Duffus, 1993)
- In toxicology, value used in extrapolation from experimental animals to man (assuming that man may be more sensitive) or **from selected individuals to the general population**: for example, a value applied to the no-observed effect level (NOEL) or no-observed-adverse-effect level (NOAEL) to derive an acceptable daily intake or reference dose (RfD) (the NOEL or NOAEL is divided by the value to calculate the acceptable daily intake or RfD). The value depends on the **nature of the toxic effect, the size and type of population to be protected, and the quality of the toxicological information** available. (WHOTERM)
- A **product of several single factors** by which the NOAEL or LOAEL of the critical effect is divided to derive a TI. (EHC170, 1994)

9. Dose-Response

- A quantitative relationship between the dose of a substance (e.g., a chemical) and an effect caused by the substance. (CEQ, 1989)
- How a biological organism's response to a toxic substance **quantitatively shifts as its overall exposure to the substance changes** (e.g., a small dose of carbon monoxide may cause drowsiness; a large dose can be fatal.) (US-EPA, 1993)

- The relationship between the dose of a chemical and the extent of the **toxic effect** produced by the chemical in a biological system. (ACDH, 1996)

10. Threshold

- Dose or exposure concentration below which no effect expected. (Duffus, 1993)
- Dose or exposure concentration below which an effect is not expected **to occur**.
- Concentration of a pesticide in an organism or environmental compartment below which an **adverse** effect is not expected. (Holland, 1996)
- Dose or exposure below which no **significant** adverse effect is expected. (EPA, 1992)
- The lowest dose of a substance (e.g. a chemical) at which a specified **measurable effect is observed and below which it is not observed**. (CEQ, 1989)

11. Risk

- The probability of a substance to cause adverse effects. (USES, 1994)
- The probability of an adverse effect on man or the environment resulting from a given exposure to a chemical or mixture. It is the **likelihood** of a **harmful effect** or effects occurring due to exposure to a risk factor (usually some chemical, physical or biological agent). (Leeuwen)
- The **combination of a consequence and the probability of its occurrence**. (OECD, 1992)
- A measure of the probability that **damage to life, health, property, and/or the environment** will occur as a result of a given hazard. (US-EPA, 1993)
- In risk assessment, the probability that something will cause injury, **combined with the potential severity of that injury**. (CEQ, 1989)
- The likelihood of suffering a harmful effect or effects resulting from exposure to a risk factor (usually some chemical, physical, or biological agent). (EHC, 1979)

12. Risk

- A **function** of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food. (WHO/FAO, 1995, ALINORM 95/31, 1995)
- The **probable rate of occurrence** of a hazard causing harm and the degree of severity of the harm. (ISO51, 1990)
- The **chance** of something adverse happening. (HSE, 1995)
- A **quantitative probability** that a health effect will occur after a specified "amount" of a hazard has exposed an **individual**. (WHO/PEP, 1989)
- The probability that an adverse outcome will occur in **a person, a group, or an ecological system** that is exposed to a particular dose or concentration of a hazardous agent, i.e. it depends on both the level of toxicity of hazardous agent and the level of exposure. It is expressed in values ranging from **zero (certainty that an effect will not occur) to one (certainty that an effect will occur**. (ACDH, 1996)

13. Hazard Identification

- IARC preamble (www.iarc.fr)
- NTP list of carcinogens, bioassay review, genetic risk (www.ntp-server.niehs.nih.gov)
- EPA guidelines (www.epa.gov)
- NHMRC guidelines (www.health.gov.au/nhmrc)

14. Hazard Identification

- How? written guidelines
- objective review
- Who? committee formation
- perception of bias

- Communication? back to terminology
- When? where is the trigger
- laws
- Mechanism? does it play a role
- importance

15. Dose-Response Analysis

- What data sets?
- All (compare estimates of point-of-departure?)
- Lowest effect
 - adverse?
 - tied to adverse?
 - outliers
- How?
- NOAEL/LOAEL
- Benchmark Dose
- Extrapolation

16. Dose-Response Analysis

- Species Extrapolation
- does it belong here (exposure?)
- Route Extrapolation
- Technical abilities
- can you even do further analyses
- can you understand complicated analyses (mechanistic models)
- Mechanistic data
- shape of dose-response curve
- extrapolation

Slide 17

18. Exposure Analysis

- Field Characteristics
- grouping
- measurement
- time
- Field Effects
- Epidemiology
- Real World versus Laboratory

19. Uncertainties

- Quantifiable
- statistical variation
- physiological/biochemical variation
- exposure
- Unquantifiable
- assumptions
- extrapolations

20. Uncertainty/Safety Factors

- modification factors for extrapolations
- species (1-10)
- variability (1-10)
- lower risk???
- modification factors for data quality
- database (1-10)

- endpoint (1-50)

These are the different types of extrapolation. There are other methods....direct extrapolation to lower risks, mechanistic data ... these use different assumptions but sometimes more data

21. Some Guidelines

www.ntp-server.niehs.nih.gov
www.dir.niehs.nih.gov/dirlcbra
www.health.gov.au/nhmrc/publicat/synopses/eh21syn.htm
www.who.int/pcs/
www.epa.gov

22. Mike's Questions

What criteria should be used to evaluate research results?

- What is the best model for developing standards? Methods for determining compliance should not be overlooked.
- How and with what degree of confidence can results be extrapolated to other frequencies or intensities?

23. Mike's Questions

- How should similar concerns about the applicability and extrapolation of animal or cellular studies to humans be dealt with?
- What about safety factors? Do they or should they address scientific uncertainties in the fundamental research or imprecisions in the techniques used for exposure assessment?
- Should they also allow for gaps in knowledge?

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What account should standards take of social and economic impacts?

**APPENDIX 3: Summary of Dr Lin's Overheads
PHILOSOPHICAL APPROACHES TO EXPOSURE LIMITS**

Basis for Maximum Permissible Exposure (MPE)

- **A. No Demonstrable Effect**
- **B. Observable Effect with No Known Physiological Consequence**
- **C. Minimal Physiological Consequence**
- **D. No Adverse Effects on Bodily Function and/or Tissue**

NO ADVERSE EFFECTS ON BODILY FUNCTION AND/OR TISSUE

- **Cataract Induction in the Eye**
- **Permeability Changes in the Blood-Brain Barrier**

MINIMAL PHYSIOLOGICAL CONSEQUENCES

- **Auditory Sensation of Pulse Modulated RF Radiation**
- **Behavioral Thermal Regulation**
- **Temperature-Related Interruption of Work Schedule**

OBSERVABLE EFFECTS WITH NO KNOWN PHYSIOLOGICAL CONSEQUENCES

- **Transient Change in Stress Gene Expression**
- **Calcium Efflux in Chick Brain**
- **Variation in Firing Patterns of Isolated Neurons**

A NO-EFFECT MPE FOR RF SPECTRUM

Comparable to legislating Human Beings Back to:

- **Signalling by Smoke or Flag Waving**
- **Communication by Emissary or Pony Express**
- **Navigation by Stars or Compass**
- **News through Day or Week Old Newspaper**
- **Pre-RCA Radio or Television Entertainment**

**APPENDIX 4: Summary of Overheads Used by Dr Petersen
Revision of IEEE C95.1-1991**

Issues being addressed:

- Spatial averaging
- Averaging time
- Peak-power limits
- Single versus two tiers
- Peak spatial-average SAR (value and averaging volume)
- Measurement distance
- Spark discharge / RF burns
- Low-power device exclusion

Literature evaluation is in progress

- ~1300 citations in Literature Surveillance Working Group database
- non-peer reviewed papers, e.g. book chapters and reports are included
- evaluations by topic
- computerized process
- independent biology and engineering evaluations

IEEE Standard for Safety Levels with Respect to Human Exposure to Radiofrequency Electromagnetic Fields, 3 kHz to 300 GHz (IEEE C95.1-1991)

Membership: Principle Disciplines - SCC-28/SC-4

Physical Sciences	41	(33%)
Life Sciences	54	(43%)
Medicine	12	(10%)
Radiology,	4	(3%)

Pharmacology, Toxicology		
Others (Law, Medical History, Safety, etc.)	14	(11%)

Membership: Affiliations - SCC-28/SC-4

Research: university	37	(30%)
nonprofit	8	(6%)
military	15	(12%)
government (non-military)	30	(24%)
Industry	12	(10%)
Industry - Consulting	4	(3%)
Government - Administration	5	(4%)
General Public & Independent Consultants	14	(11%)

IEEE SCC-28 Standard-Setting Process

RF Safety Standards: Who Develops the Standards?

IEEE Standards Coordination Committee 28 (SCC-28)

- open consensus process
- IEEE membership not required
- Large committee (over 100)
- Balance of interests and disciplines

SCC-28 Parent Committee

Technical Subcommittees	Administrative Subcommittees
SC-1 Measurements/Computations	Executive Committee
SC-2 Warning Symbols/Hazard Comm.	Membership
SC-3 Safety Levels 0 - 3 kHz	International Liaison
SC-4 Safety Levels 3 kHz - 300 GHz	Interpretations
SC-5 Electroexplosive Devices	

IEEE SCC-28 is an international committee with representation from:

Australia	Ireland
Canada	Italy
China	Switzerland
England	United States
Finland	Wales

Institute of Electrical and Electronics Engineers (IEEE)

The IEEE is today the world's largest professional societies in the world with more than 325,000 members, one-third from outside the US.

- Within IEEE are a number of professional societies, e.g., MTT, EMC, EMB, AP, VT that sponsor standards committees.

- **Standards pertaining to subjects that are of interest to more than one society, e.g., RF safety standards, are developed by *Standards Coordinating Committees* sponsored by the IEEE-SA Standards Board.**

Appendix 5: Dr Black's Presentation

PRUDENT AVOIDANCE, PRECAUTIONARY APPROACH, OR SIMPLY BEST CONTEMPORARY PRACTICE?

Dr David Black MBChB FAFOM MARPS

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ABSTRACT

There is a public demand in some countries for a precautionary approach to be applied to the application of new radiofrequency technology. Such a requirement may be entirely correlated with best contemporary engineering practice, particularly in modern communications technology. Such an approach also requires standardised techniques and reporting methodology to be used for field measurements and confirmation testing. There are some potential pitfalls in the application of a precautionary approach which have been identified in the New Zealand experience, however these can be overcome.

Introduction

1. Recent experience in the application of new RF technology in New Zealand has been characterised by substantial and sometimes quite well organised public protest. In New Zealand, environmental law is governed in accordance with the Resource Management Act, a statute which, to decide whether or not an activity is permissible, in the absence of other compelling justification, depends on whether any adverse effects to any affected parties are, in the words of the Act "*less than minor*".
2. The first New Zealand Standard for RF, NZS6609 included suggestions of a precautionary approach and used the acronym ALARA, which had inappropriately been adopted from the literature about ionising radiation. The concept of ALARA is based on there being a confirmed stochastic hazard, as is the case with ionising radiation. The 1998 Australasian Interim Standard, which was in reality a draft document but was issued for one year, mentioned the principle of "*prudent avoidance*". However the new current and fully approved New Zealand Standard expresses its precautionary approach as
 - i. "industry best contemporary practice" and a requirement to
 - ii. "Minimise, as appropriate, RF exposure which is unnecessary or incidental to achievement of service objectives or process requirements, provided that this can be readily achieved at modest expense.

NOTE: Notwithstanding that ICNIRP considers that the basic restrictions and reference levels in this Standard provide adequate protection, it is recognized that community concerns over RF exposure may be able to be addressed by further minimization of exposure...."

The purpose of this paper is to discuss the experience in New Zealand with various attempts at a precautionary approach into applying the merit or otherwise of these options.

1. Firstly, I need to make clear my interpretation of the current science, and of the spectrum to which this discussion is limited. My work is with RF, and in this context in the communication spectrum from medium frequency (MF) to ultra high frequencies (UHF), 500 kHz to 1 GHz, or, the broadcast band to cellphone frequencies. In my opinion, and therefore forming the basis of my approach, the current ICNIRP principles as in the 1998 Guideline provide protection against any effects at UHF by a wide margin and against most effects at lower frequencies by a satisfactory margin.

Public Concern

2. Nevertheless, there is public concern, and I have reviewed public submissions in opposition to 3 applications for cellphone base transmitter stations in 1999 in an attempt to categorise public concerns.

3. It is clear that there are a small group of people, about 10% of submitters in opposition, who believe that there are proven health effects of UHF RF at low levels and that the existing standards are not safe.
4. There is another group, which I have found to be about 15%, who believe that there is genuine scientific doubt about possible adverse effects of environmental RF levels, that there is an ongoing unsettled debate and therefore any installation of cellphone base stations in populated areas can only be regarded as an unacceptable experiment which is putting people's health at risk.
5. The balance of submitters in opposition on grounds of health concern, (that is the remaining 75%), are more cautious about attempting to interpret any scientific debate, however have a generalised view, based to some extent on an unwillingness to have to make any decision, that radiofrequency installations are generically inappropriate for populated areas and therefore should not be allowed. A majority of this group if asked will admit to accepting the current science as adequate and the standards as a correct interpretation, but nonetheless requiring application of technology in a precautionary, or at least careful way. Many such people can be reassured by a more detailed explanation of the nature of the science and the standards setting process.
6. In the process of developing the Australasian Standard, there were many submissions advocating a precautionary approach of some sort or other, and a substantial number mentioned the concept of "*prudent avoidance*". Unfortunately, this term has come to mean different things to different people. For some, prudent avoidance means "be prudent, therefore avoid doing it at all".

Concept of Prudent Avoidance

7. Professor Granger Morgan, from Carnegie Mellon University, defined his ideas of prudent avoidance in the late 1980's, and his most commonly referenced publication is from 1992 (Morgan 1992). He does not appear to have pursued the idea much since that time, and when I spoke to him about it in 1996 he told me that he considered that the science of risk management had become more advanced than that of knowledge about EMR safety and the Carnegie Mellon group had moved on to other work.
8. In the original description of the principle, Morgan makes it clear that the concept is based on the idea that in our everyday lives we are often confronted with two paths, one of which appears to be safer, or less risky than the other. It is human nature to take the safer path, and therefore it will be more acceptable to parallel this behaviour in the introduction of technology which has any actual or perceived risk. In stating this, it is clear that Morgan, in coining the term "*prudent avoidance*" was talking about a behavioural phenomenon, and hence the term.
9. Avoidance responses are well established in behavioural psychology and can be elicited by a variety of means in experimental animals, and analogous behaviour is often seen in humans. With this understanding, it is problematical to simply transfer the terminology across to an approach to an environmental control. A safety standard is designed to prevent the need for a behaviour such as prudent avoidance. Morgan's approach seems to have been that if, for instance, a company building an RF emitting facility, exercised a planning approach which was analogous to this human avoidance behaviour, a human population response would be more sympathetic. This idea definitely has some merit. However, the consequence of applying it has, in retrospect turned out somewhat differently because the implied fear in corporate behaviour, is either transferred, or at least suspected in the public mind and so does not necessarily alleviate concern. In fact the perceived action of the operator may actually enhance public concern. It is this that is the nub of the problem with the way in which prudent avoidance has been employed, and having been an advocate of the approach for some years, it is my opinion that a rethink is called for.

10. To come back to the public's wishes in New Zealand. There are in fact only a small minority of people who opposed the development of new RF based technology and in reality many of these concerns are tied up with other political issues such as a generic concern about the involvement of multi national companies in what often used to be state owned utilities supplying telecommunications. A much greater number of people who have concerns will be reassured by an approach which is at least careful and goes ahead with the use of RF based technology but in a way that uses the resource in an efficient and economical way. In recent times, this has been correlated with "best engineering practice" and certainly in the case of radio transmitters, this approach does satisfy such environmental requirements. The reasons for this are that the goal in a radio communication or broadcasting system is to convey RF energy from the antenna to the receiver, and any energy which is not part of this circuit is effectively wasted. It is also a characteristic of radio systems that the RF is not a side effect, or analogous to a waste emission, the RF is deliberately radiated in a controlled manner which is central to the design of the system. It therefore follows that "best engineering practice" will usually correlate with lowest human exposure, as the goal is to limit radiated energy to that which is part of the communications circuit.
11. It is possible to take this even further, for example to discuss the question of the absolute power level required for a transmitter to achieve a defined purpose, although this becomes more difficult in some parts of the radio industry. For cellphone operators, it is easy. A cellphone operator has an allocation of spectrum which has to be used and reused, and avoidance of interference is a critical issue. It therefore follows that no cellphone operator is ever going to transmit a higher level or more widely distributed signal than that which is needed for achievement of the service objective. Therefore, with cellphone systems, best contemporary practice in both engineering, coverage and spectrum usage terms are easily analogous to those required to keep human exposure to a minimum.
12. For a radio or television broadcaster, this can be different. The broadcaster may have an interest in maximum coverage, and in maximum quality of coverage within their area of interest. In terms of the efficiency of energy used, a broadcasting system achieves a lot with the power used. For instance a 20 kW urban radio transmitter could serve millions of receivers. The question of the amount of power required to achieve this is a matter which is traditionally subject to spectrum use and commercial considerations. This is however made easier by the fact that any real issues of human exposure, even at levels of a few percent of current standards, are only an issue within a very near proximity to the transmitters. If these are situated in a more remote location, then the problem is solved but this is not always possible, and is not always in the best interest of spectrum management, or for that matter best engineering practice so there is a move, if anything, to build more central urban broadcasting transmitters. For example in my own city of Auckland on the newly constructed City Skytower. If there are a number of FM radio and television station in the middle of the city a health based standard was applied to control the power output of a commercially competitive broadcasting system, there would be substantial concerns. However, a system designed to minimise incidental exposure near to the transmitter by the use of beam forming antennas thereby making more of the power available at more distant receivers, would be in both the interest of the broadcaster and might alleviate any possible local concerns about human exposure.
13. So I conclude that, although the ideas of prudent avoidance have run into difficulty for various reasons, the underlying concept remains a useful explanation of an inevitable human response and best engineering practice may well be a way to avoid the "prudent avoidance" response.

Practical Application of a Precautionary Approach

14. There is published literature providing both advocacy and criticism of the precautionary approach, of prudent avoidance and about risk communication in which concepts such as

outrage are introduced. In the control of electromagnetic radiation, issues in terms of RF and ELF are substantially different in that for RF the radiated signal is a deliberate intent of the operator whereas in ELF, the fields are an inevitable by-product. There is concern, based on some confirmatory experience that overt adoption of a prudent avoidance approach, particularly in the electricity industry can actually increase concern in the public mind, because it may be conceived that the reason for an industry adopting this approach is or must be related to some knowledge of actual risk. Thus, an approach which began as a well intentioned concession to unsubstantiated public concern may become reinforcement for the basis of that concern. There are therefore some very important messages which I have concluded from my experience in this area.

- i. It is essential to clearly state the basis of, and the degree of certainty about the validity of protective standards. For example, the current standards for ultra high frequencies provide protection against known adverse human health effects by a margin of safety which is large by any standards. The chance that this protection falls short of perfect, because of an unknown effect not yet taken into account can never be really entirely ruled out, however the magnitude of this risk (in reality a risk of a risk) can be estimated. The magnitude of this risk in the public mind is usually grossly over estimated.
- ii. For some technology, the nature of intrinsic best engineering practice will provide maximal limitation of potential human exposure without any need for further intervention. This is however not always easy to understand, when for example it may be seen by the public that one large transmitter on a hilltop is preferable to hundreds of much smaller transmitters situated in the community. Acceptance of this can only be achieved by patient and repeated explanation and eventual public understanding, and this will not always be successful. Eventually, implementation of such technology will be against the wishes of a small minority of people and so a majority community acceptance must prevail.

RF Monitoring

1. It is more or less intrinsic to RF installation design, and also to planning applications in many jurisdictions that the RF field strengths around the site are predicted before it is built. Environmental law usually requires an assessment of predicted and potential effect.
2. In our experience in New Zealand an issue which has been repeatedly addressed at local council level, and in the Environment Court, is the requirement for monitoring of facilities by field strength measurements after commissioning.
3. It is often suggested that part of the approval process for an RF installation is the requirement for monitoring. Sometimes, this can carry the connotation of a periodic inspection. In New Zealand, this has arisen in the past, however it has been vigorously opposed by both the industry, and by scientists. The reason for this is that such an approach is a relatively meaningless way of understanding RF levels in the community.
4. A New Zealand Environment Court Case in 1995 (McIntyre Environment Court (NZ) Decision 1998) had, as part of the application a prediction that the highest power flux density level at a nearby defined dwelling would be less than $2\mu\text{ W/cm}^2$. In allowing the appeal, the judge commented that the "*community was entitled to have the application held to their prediction*" and therefore effectively imposed a limit of $2\mu\text{ W/cm}^2$ at this point, to be confirmed by monitoring. This approach had several adverse consequences which later had to be rectified. Firstly, it was misinterpreted by some as meaning that the court had effectively lowered the environmental standard to this level. Secondly, the rationale for measurement was not clearly spelled out.
5. Subsequent environment court cases have cleared this up, and I have been involved as an expert witness in all of these. This work has resulted in what is now known in New Zealand

as the "*closed loop approach*". The basis of the closed loop approach is that the designer of a site provide predictions of surrounding RF field strength levels for both the maximum configuration of the site ever envisaged, but being applied for, and also for the levels at the expected startup configuration if it is built. The application then invites the approving authority to apply a condition the approval requiring an assessment within 3-6 months of commissioning which includes field strength measurements by a competent biophysicist. This one-off procedure provides a report which validates (or otherwise) the predictions.

6. Provision of public information about site parameters is an area in which my experience has taught me that there is substantial room for improvement of public confidence by provision of full and unequivocal clear information and also correlation of theoretical predictions with real world measurements. The importance of the latter in no small part arises because of a minority, but nonetheless reasonably widespread public perception that the radiofrequency radiation from radio transmitters is an intangible, untoward and improperly understood side effect which engineers prefer to avoid and don't understand but will eventually turn out to be more dangerous than anybody will now admit. It is interesting that the analogy is constantly drawn to the story of tobacco, asbestos, thalidomide and other hazards which were recognised too late. The idea that radio waves are a carefully controlled deliberate output of a transmitter can sometimes change this mind set altogether.

Summary

7. The current standards provide a good level of protection for human exposure to electromagnetic radiation. It is paradoxical that in the ultra high frequency area of radiofrequency fields, the level of protection provided is probably extremely high, and yet this part of the spectrum has attracted substantial public interest and concern. Submissions made to the Australasian Standards Committee demonstrate a clear requirement from the general public for the inclusion of a precautionary approach to be formerly incorporated in the standard. The principles which were identified and described by Morgan a decade ago are still of significant value in understanding the difficulties with a precautionary approach, which this paper argues arise from the direct translation of an observed behavioural response to a precautionary strategy. Nevertheless, the experience of application of prudent avoidance in the last decade has demonstrated some difficulties but more importantly provided at least a clear understanding for the reasons for the difficulties, and some potential solutions. Difficulties arise from the behaviour of an RF operator being perceived as based on an underlying hidden concern rather than on the basis of a general principle of good environmental practice. The solutions include, full, consistent and clear documentation of nature and magnitude of EMR and a clearly understandable rationale for the approach taken in accordance with best industry practice. Efforts to achieve this have been successfully used for several years in New Zealand.

References

1. McIntyre Environment Court (NZ) Decision (1998). McIntyre, J.M. v Christchurch City Council RMA125/95 BellSouth NZ (Appeal RMA134/95). Christchurch City Council Decision No A15/96, New Zealand Environment Court.
2. Morgan, G. (1992). "Prudent Avoidance." Public Utilities Fortnightly.