

*The International EMF Project*

# Update on WHO EMF Activities

Dr E. van Deventer

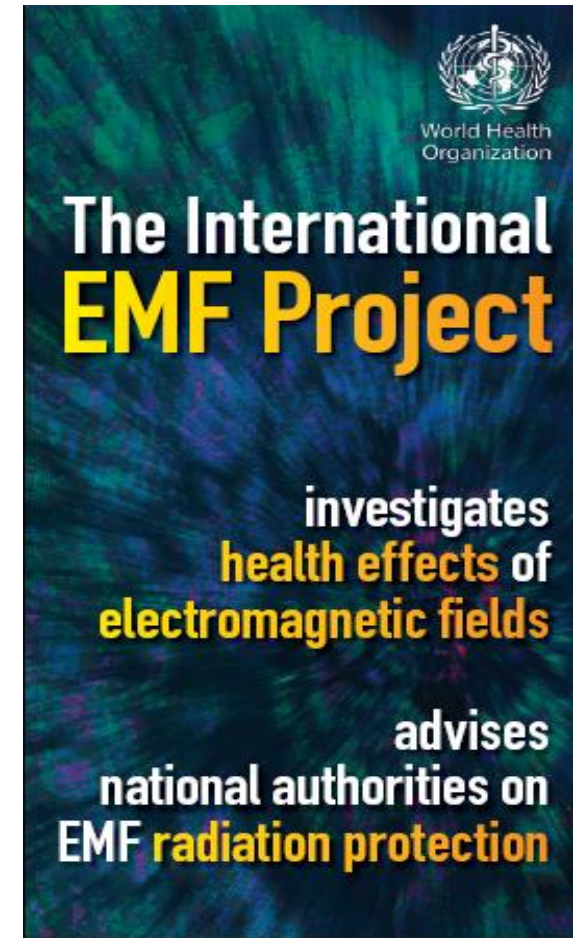
Department of Public Health, Environmental and Social Determinants of Health  
Geneva, Switzerland



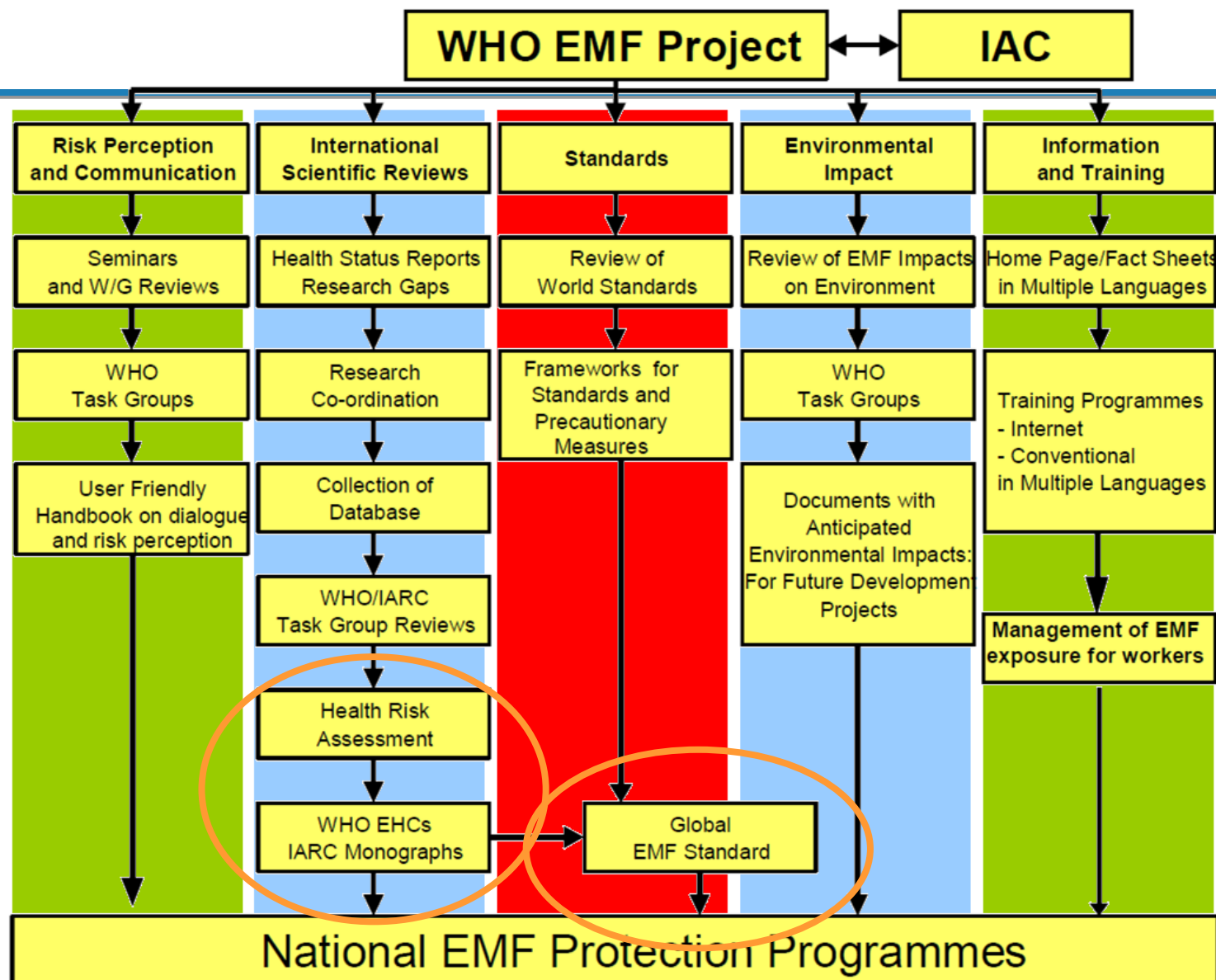
World Health  
Organization

# WHO International EMF Project

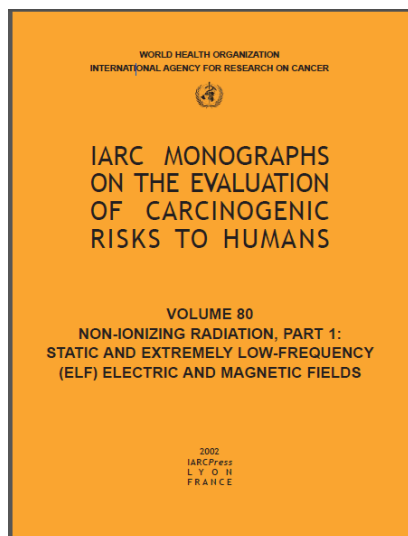
- Established in 1996
- Coordinated by WHO HQ
- Objectives
  - Review the scientific literature on health effects of EMF exposure and formally assess health risks;
  - Promote a focused agenda of high quality EMF research;
  - Encourage internationally acceptable harmonized standards;
  - Provide information on risk perception, risk communication, risk management



- To develop a solid base of scientific evidence
- To facilitate dialogue between stakeholders
- To help countries set their national EMF regulations



# WHO EMF Monographs



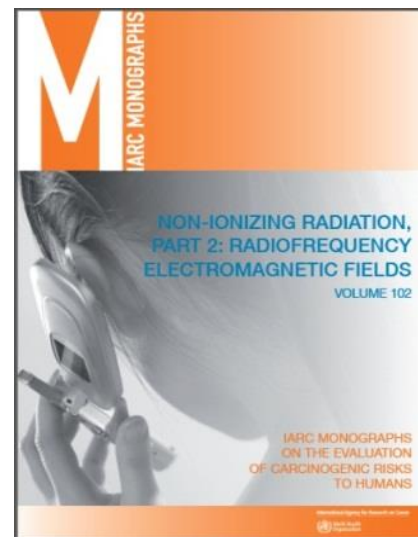
2002



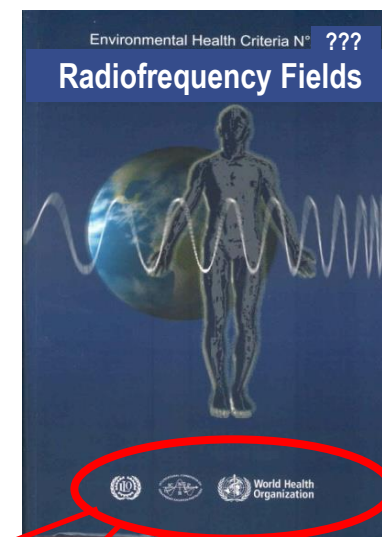
2006



2007



2013

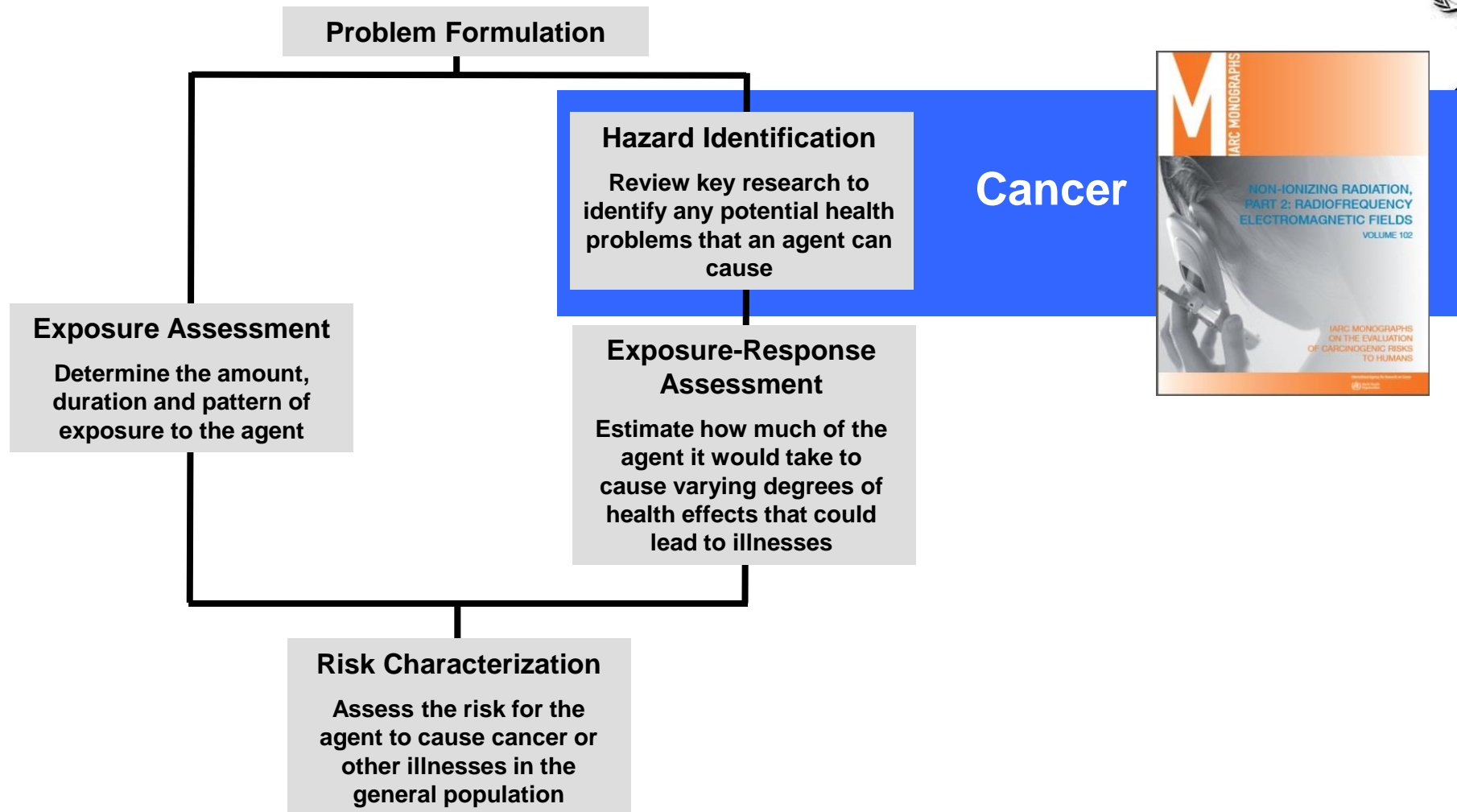


2017

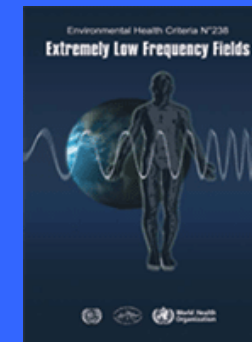
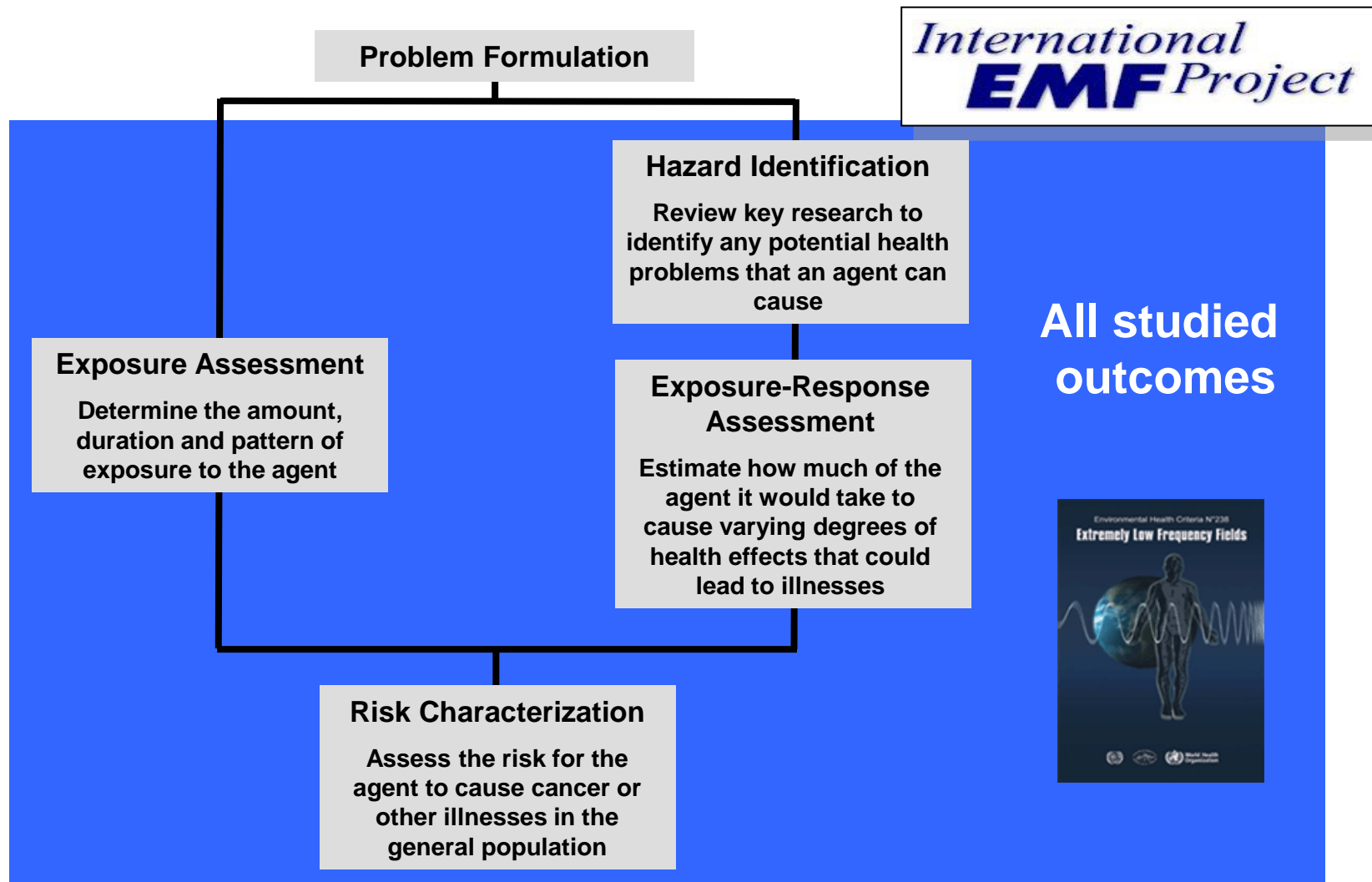


World Health Organization

# Health Risk Assessment



# Health Risk Assessment



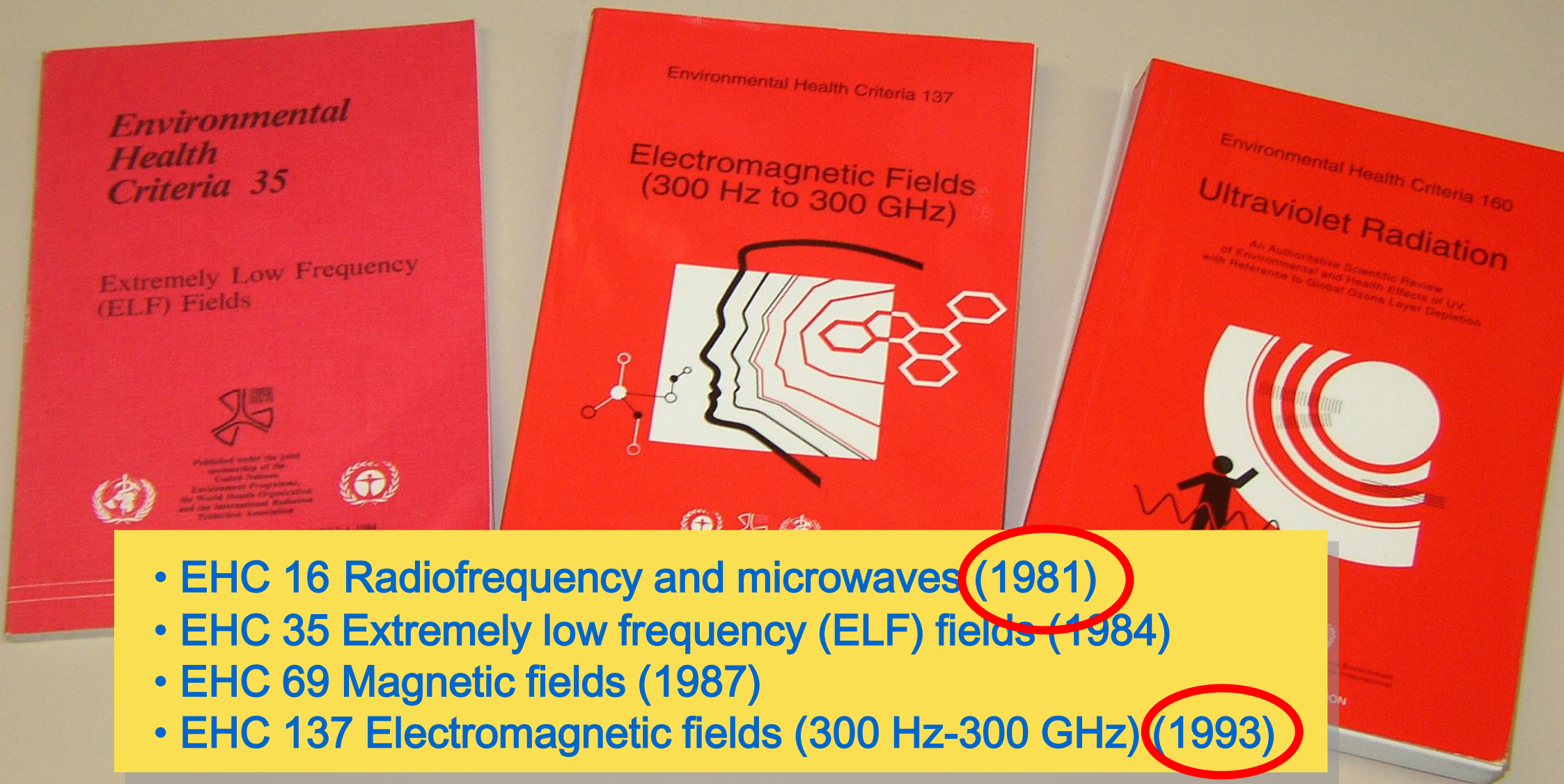


# Environmental Health Criteria

- Target audience
  - National and international authorities
- Reason for development
  - To assist them in making risk assessment and subsequent risk management decisions
  - Mandate
  - Update



# EMF EHC Monographs





# EMF EHC Monographs

- Comprise:
  - Systematic and critical review of evidence for EMF effects on health
  - Health risk assessment
  - Risk management measures
  - Research recommendations



# RF EHC: Scope

- Frequency range:
  - 100 kHz - 300 GHz
  - Include UWB, pulses, mm-waves
- Sources:
  - wireless networks, broadcasting, industrial RFID, EAS, radars,...
- Health benefits not included
  - Hyperthermia, MRI, medical treatments, diathermy, RF ablation surgery



# RF EHC: Contributors

- Systematic review team (around 25 contributors)
- Task Group members
  - Individual scientists, not representatives of their organizations
  - Composition dictated by range of expertise and views, gender and geographical distribution
  - Membership approved by Assistant Director General
  - Role: assess risks to health, reach agreements by consensus, make final conclusions and recommendations that cannot be altered after the Task Group meeting
- Observers
- WHO Secretariat



# RF EHC Core Group

- Physics, dosimetry: Simon Mann, UK
  - Epidemiological studies: Maria Feychting, Sweden
  - Humans studies: Gunnhild Oftedal, Norway
  - Animal studies: Eric van Rongen, Netherlands
  - In vitro studies: Maria Rosaria Scarfi, Italy
  - Public health: Denis Zmirou, France
- 
- Monthly teleconferences
  - Annual face-to-face meetings



# Assistance

- Additional experts to help drafting sections

Azadeh Peyman

Olga Zeni

Giorgio Aicardi

Jukka Juutilainen

Kerstin Hug

Sarah Loughran

Carmela Marino

James McNamee

Jonne Naarala

Giuseppe Curcio

+ .....

Martin Röösl

James Rubin

Minouk Schoemaker

Brahim Selmaoui

René de Sèze

Zenon Sienkiewicz

Myrtill Simko

Susanna Lagorio

Vijaylaxmi

Lawrie Challis (reviewer)





# Declaration of Interests

## DECLARATION OF INTERESTS FOR WHO EXPERTS

WHO's work on global health issues requires the assistance of external experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a potential conflict of interest (i.e., a situation in which an expert's personal or financial interests may be affected by the work of the WHO or the work of the WHO's partners).

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### Code of Conduct for WHO Experts

*Should be sent with the DOI form*

WHO values and relies upon the normative and technical advice that is provided by leading subject matter experts in the context of similar processes. Such advice contributes to the development of policies and programmes that are promulgated by WHO for the benefit of the world.

### **CONFIDENTIALITY UNDERTAKING**

*Should be sent with the invitation or appointment letter*

1. The World Health Organization (WHO), acting through its Department of [redacted], has access to certain information relating to [redacted], which information WHO considers to be proprietary to itself or to parties collaborating with it (hereinafter referred to as "the Information").
2. The Undersigned, as a member of the [redacted] advisory meeting, group or committee (collectively referred to as the "the Advisory Process"), may have access to the Information in the course of his/her participation in the Advisory Process (whether



# RF EHC: Contents

## Preamble

1. Summary and recommendations for further study
2. Sources, measurements and exposures
3. Electric and magnetic fields inside the body; SAR and heat
4. Biophysical mechanisms; tissue heating
5. Biochemical and biological effects
6. Brain physiology and function
7. Auditory, vestibular and ocular function
8. Neuroendocrine system
9. Neurodegenerative disorders
10. Cardiovascular system and thermoregulation
11. Immune system and haematology
12. Fertility, reproduction and development
13. Cancer
14. Health risk assessment
15. Protective measures

**By health endpoint**

## Annexes



# Relevant studies

- Development of an extensive database
  - Peer-reviewed scientific publications
  - Meta-analyses not included
    - May not have used the same inclusion and quality criteria as used in the EHC
    - Conclusions may partly be based on studies excluded from the EHC
- Search period: Jan 1992 – present
- Languages

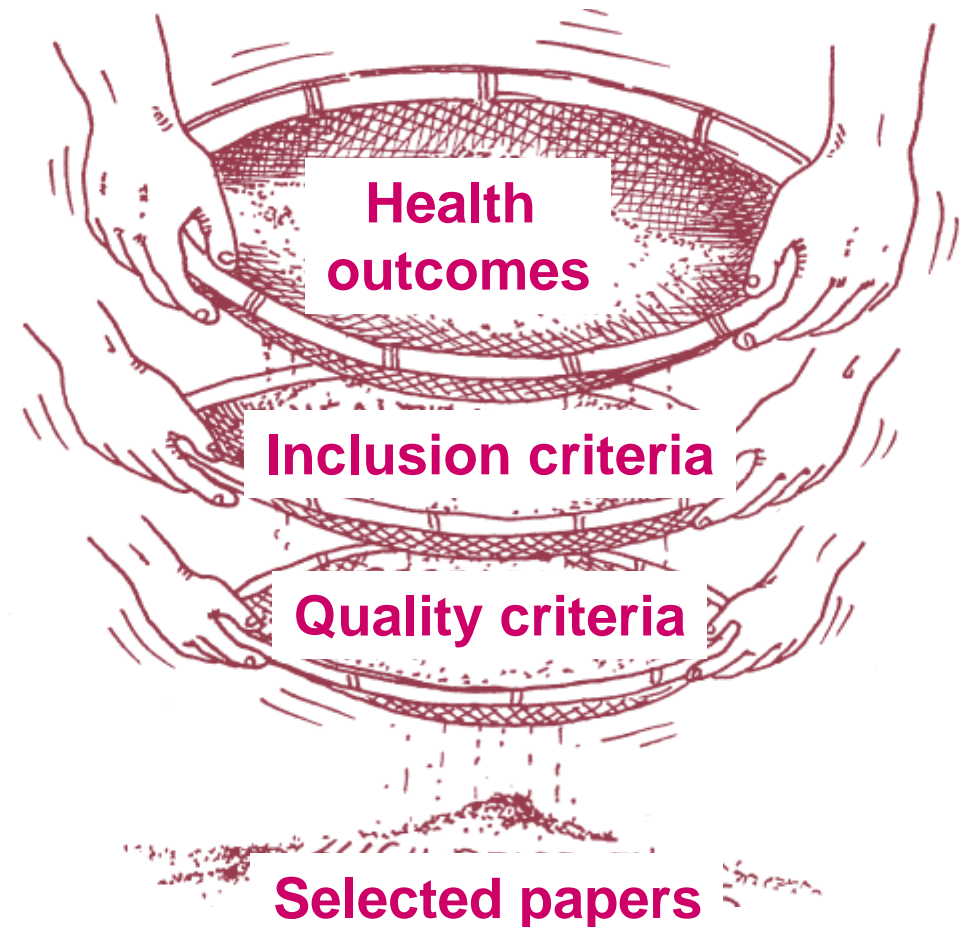
# Relevant studies (cont'd)

- Epidemiological studies
  - Diff. categories of study designs (no case-report or case-series)
- Human studies
  - Laboratory, intervention studies
- Animal studies
  - Laboratory (including ex vivo studies), observational studies (domestic animals)
- In vitro studies
  - Cell cultures, isolated tissue samples



# Process

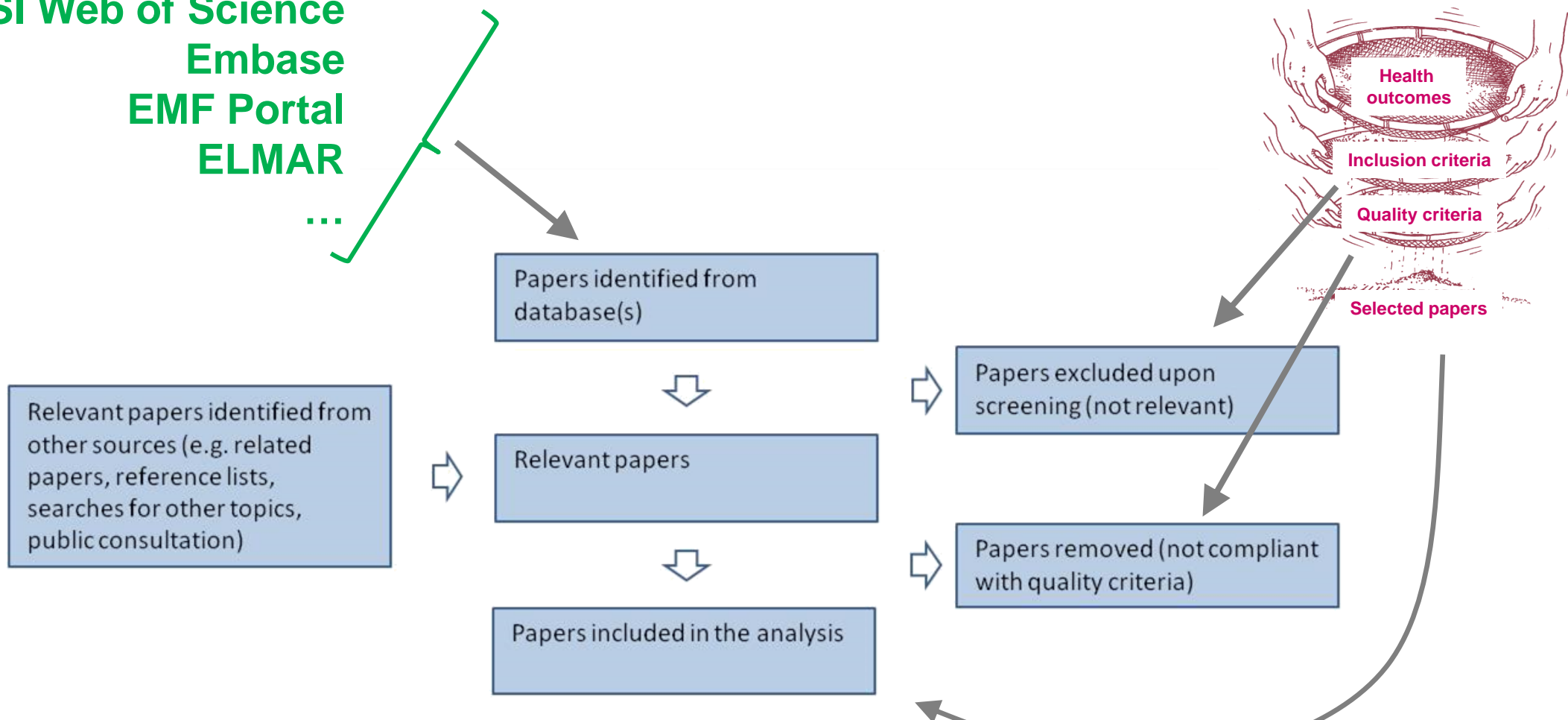
- Search strategy
  - Predefined and registered search criteria
- Screening
  - Predefined and registered selection criteria
- Analysis





# Process

PubMed  
ISI Web of Science  
Embase  
EMF Portal  
ELMAR  
...



# Quality criteria

- Epidemiological studies
  - STROBE checklist, GRADE, Newcastle-Ottawa Scale
- Volunteer studies
  - CONSORT statement and checklist, Gold Standard Publication Checklist
- Animal studies
  - Gold Standard Publication Checklist
- In-vitro studies
  - Dosimetry, statistical analysis, T control,...



# Quality criteria (cont'd)

- Statistical precision/statistical power (width of confidence intervals when provided, primarily study size)
- Potential biases
- Consistency and plausibility of results and, when relevant, exposure-response relationship
- Directness (validity in relation to, e.g. study population, exposure, time lag between exposure and outcome assessment, and endpoints)

# Public consultation

October 1 to  
December 15, 2014

## Radio Frequency fields: Environmental Health Criteria Monograph

Consultation on the scientific review for the upcoming WHO Environmental Health Criteria

The public consultation is now closed

The World Health Organization is undertaking a health risk assessment of radiofrequency electromagnetic fields, to be published as a monograph in the Environmental Health Criteria Series. This publication will complement the monographs on static fields (2006) and extremely low frequency fields (2007), and will update the monograph on radiofrequency fields (1993).

The draft chapters of this document which contain the scientific content are now open for technical consultation by RF experts. We are seeking comments on the accuracy and completeness of the information contained in these chapters. Please note that the literature searches have been done up to December 2012 (in a few instances to December 2013), so the more recent studies are currently not yet included. While the searches and chapters will be updated before finalization of the document, any suggestions for inclusion of peer reviewed studies are welcomed.

The process used in developing the chapters is described in Appendix X. Note that the chapters 1, 13 and 14 which will provide a summary, health risk assessment and protective measures are not available for this consultation. The drawing of conclusions from the literature and the drafting of these chapters is the remit of a formal Task Group that will be convened by WHO at a later stage in the process.

If you have questions, please contact us at: [emfproject@who.int](mailto:emfproject@who.int)

Share

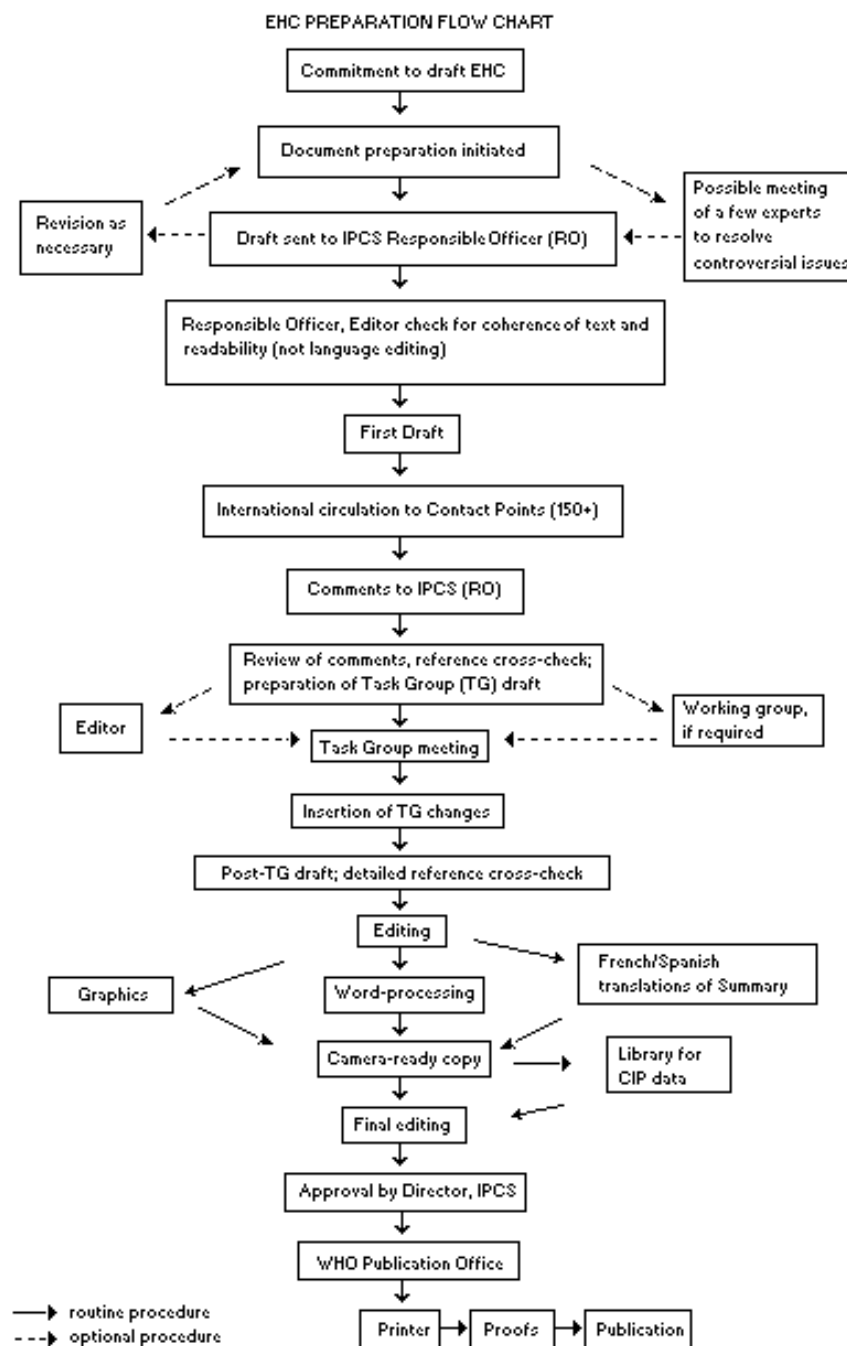
Print

Last update:

8 April 2015 16:44 CEST

- 686 comments
- 73 respondents through website + several by email
- 300 missing papers





**Kick-off meeting**  
*Jan 2012*

**First draft**  
**Public consultation**  
*Sept – Dec 2014*

**Second draft**  
**Task Group meeting**  
*Fall 2016*

**Monograph**  
**publication**  
*2017*





# **Non-Ionizing Radiation**

## **Basic Safety Standards**



# WHO's core functions

1. **Articulate ethical and evidence-based policy positions**
2. **Setting norms and standards, and promoting and monitoring their implementation**
3. **Shaping the research agenda, and stimulating the generation, translation and dissemination of valuable knowledge**
4. **Providing technical support, catalysing change and developing sustainable institutional capacity**
5. **Monitoring the health situation and assessing health trends**
6. **Providing leadership on matters critical to health and engaging in partnerships where joint action is needed**



# WHO's core functions

1. Articulate ethical and evidence-based policy positions
2. **Setting norms and standards, and promoting and monitoring their implementation**

3. Shaping the translation and implementation of evidence into policy, practice and the knowledge base
4. Providing technical support and capacity building to countries
5. Monitoring and evaluating progress
6. Providing leadership and partnerships

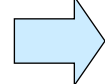
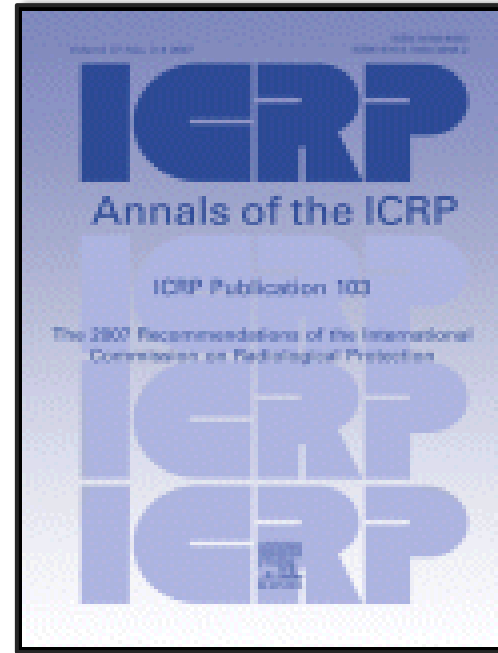
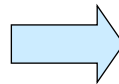
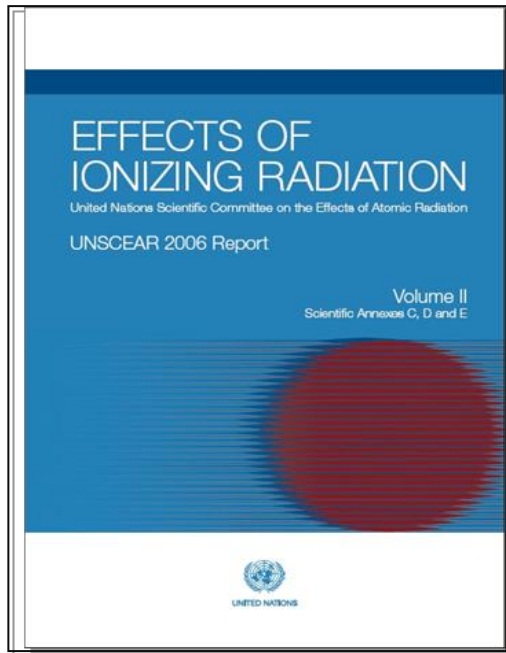


# Motivation for NIR standards

- Member states are increasingly interested in clear guidance based on harmonized standards and their application within an international framework of protection
- Currently, a number of non-governmental organizations have developed guidelines or standards for limiting exposure to non-ionizing radiation (NIR)
- Gaps in and lack of consistency amongst guidelines in certain areas have proved to be challenging to regulators, policy-makers and their advisors in their efforts to develop national standards

# The IR Paradigm

## Science, recommendations, standards



**Scientific basis**  
Effects, risks,  
sources, levels,  
trends, ...

**Recommendations**  
System of RP  
(philosophy,  
principles, dose  
criteria, ...)

**Standards**  
(safety requirements,  
regulatory  
language,...)

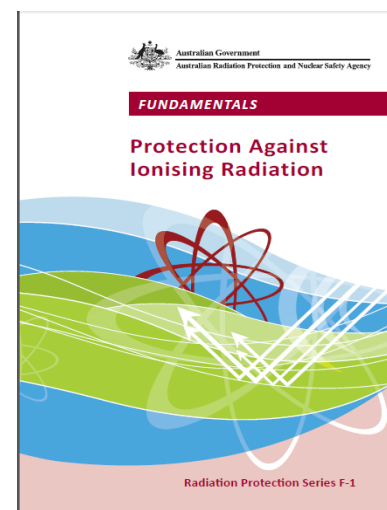
**National  
regulations**



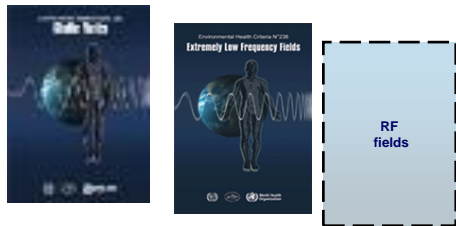




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EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO



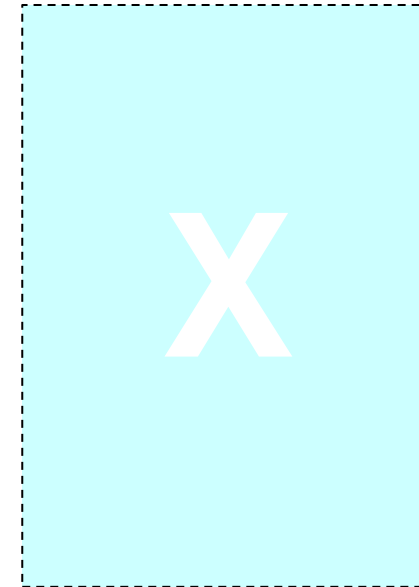
# The NIR landscape



**Scientific basis**  
Effects, risks,  
sources, levels,  
trends, ...



**Recommendations**  
System of RP  
(philosophy,  
principles, limits,  
...)



**Standards**  
Safety  
requirements,  
regulatory  
language,...



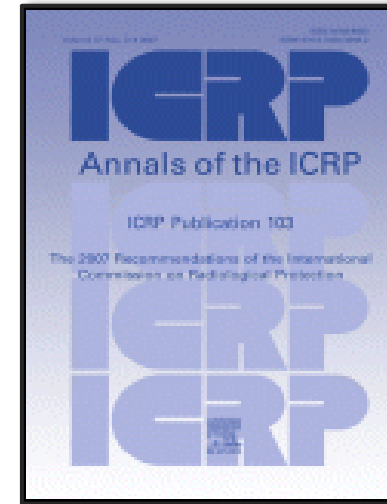
**National  
regulations**

# Radiation Protection

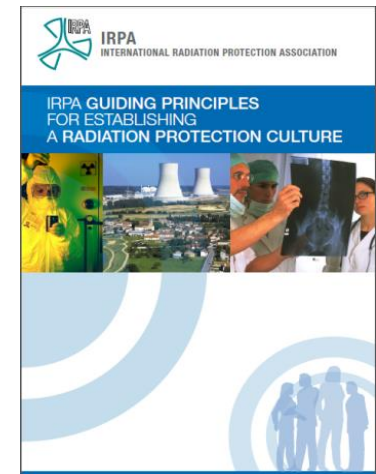
## Ionizing radiation

The primary aim is to:

- provide an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure
- without unduly limiting the benefits that may be associated with such exposure



RP philosophy



RP culture

# The System of Radiological Protection



- Three exposure situations
  - Planned
  - Existing
  - Emergency
- Three categories of exposure
  - Public
  - Occupational
  - Medical
- Three principles
  - Justification
  - Optimization
  - Limitation

# NIR Protection



- Three exposure situations
  - Planned
  - Existing
  - ~~Emergency~~
- Three categories of exposure
  - Public
  - Occupational
  - Medical
- Three principles
  - Justification
  - Optimization
  - Limitation

# ICNIRP Guidelines

## EMF Radiation

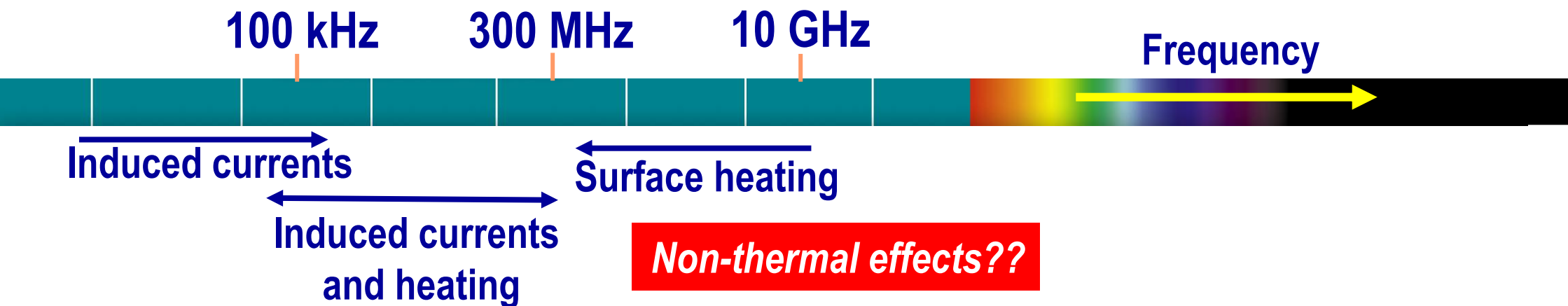
- Guidelines for Limiting Exposure to **Electric Fields** Induced by Movement of the Human Body in a **Static Magnetic Field** and by **Time-Varying Magnetic Fields below 1 Hz**. 2014
- Guidelines for Limiting Exposure to **Time-Varying Electric and Magnetic Fields (1 Hz - 100 kHz)**. 2010
- Guidelines on Limits of Exposure to **Static Magnetic Fields**. 2009
- Guidelines for Limiting Exposure to **Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz)**. 1998
- Guidelines on Limits of Exposure to **Static Magnetic Fields**. 1994



# ICNIRP Guidelines

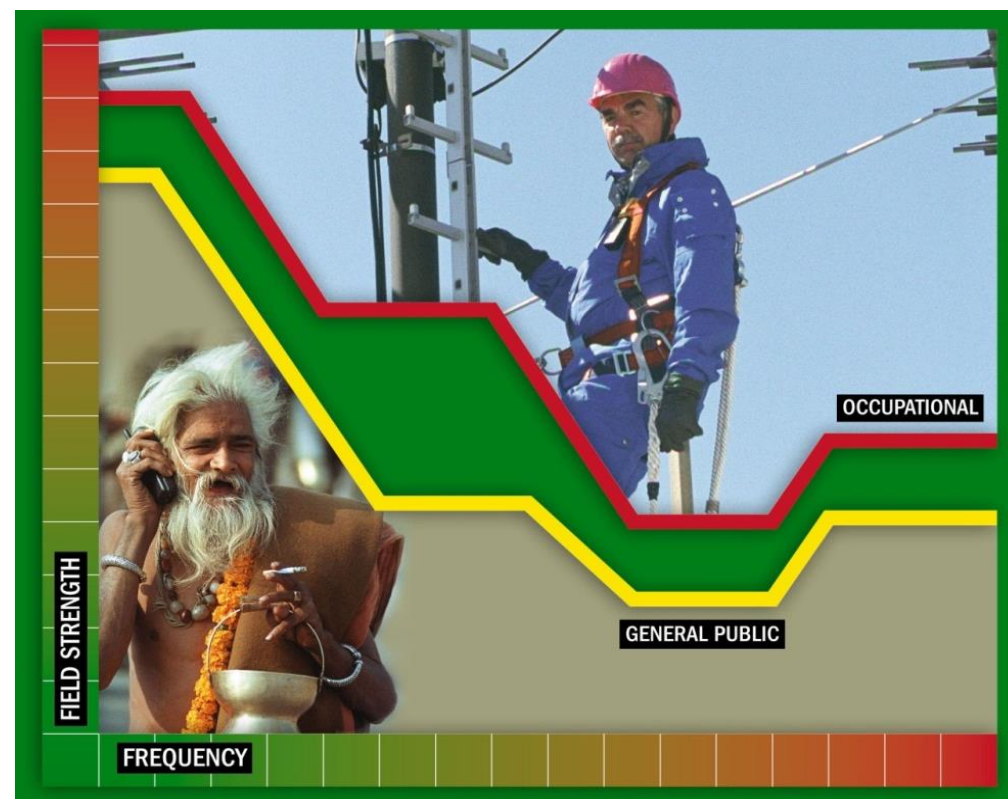
## Optical Radiation

- Guidelines on Limits of Exposure to **Laser Radiation** of Wavelengths between 180 nm and 1,000  $\mu\text{m}$ . 2013
- Guidelines on Limits of Exposure to **Incoherent Visible and Infrared Radiation**. 2013
- Guidelines on Limits of Exposure to **Ultraviolet Radiation** of Wavelengths Between 180 nm and 400 nm (Incoherent Optical Radiation). 2004
- Revision of the Guidelines on Limits of Exposure to **Laser radiation** of wavelengths between 400nm and 1.4 $\mu\text{m}$ . 2000
- Guidelines on Limits of Exposure to **Broad-Band Incoherent Optical Radiation** (0.38 to 3 $\mu\text{m}$ ). 1997
- Guidelines on **UV Radiation** Exposure Limits. 1996
- Guidelines on Limits of Exposure to **Laser Radiation** of Wavelengths between 180 nm and 1 mm. 1996



## Electromagnetic fields

- Current exposure limits based on mechanisms of interaction with threshold (deterministic effects)
- **Limitation** has been primarily applied

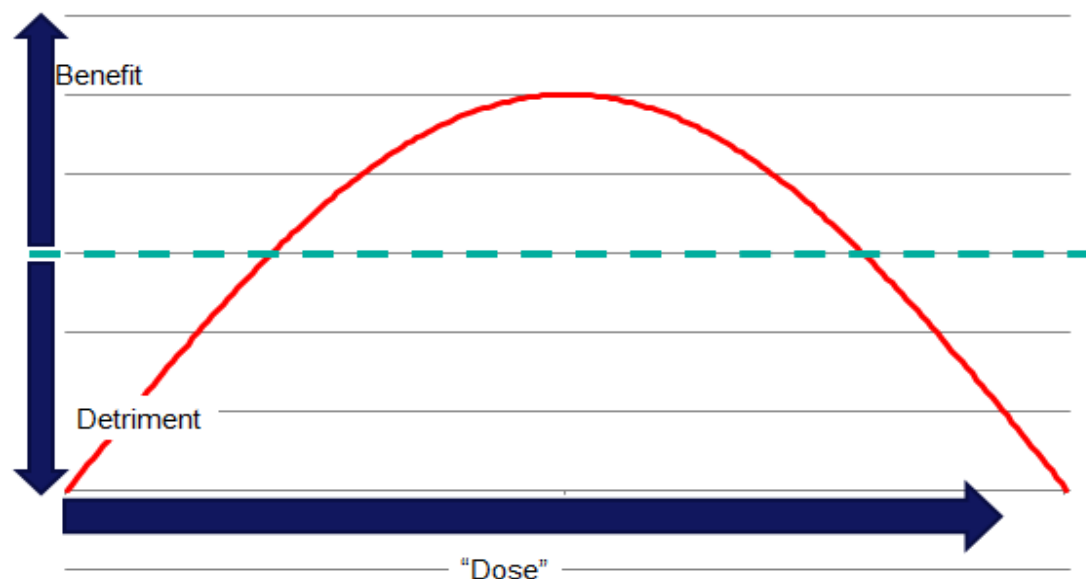




## Optical radiation

- Known benefits as well as risks, therefore **optimization** principle applied
- For sources that present a risk of injury or ill health, justification and limitation also apply

### Risk vs Benefit



Source: John O'Hagan, CIE



# Ultrasound in medicine

Diagnostic  
Therapeutic  
Aesthetic medicine



# Acoustic output over the years

- Before 1976: no limits to the permissible acoustic output from diagnostic ultrasound equipment.
- In 1976, the US Food and Drug Administration began regulating the output levels of machines to be no more than 94 mW/cm<sup>2</sup> spatial-peak temporal-average (SPTA) intensity for fetal use.
- National Council on Radiation Protection and Measurements (NCRP). NCRP report 140, Exposure Criteria for Medical Diagnostic Ultrasound, II: Criteria Based on All Known Mechanisms. Bethesda, MD: NCRP; (2002)



**FDA mandated** (together with AIUM, NEMA, public representatives): **the Output Display Standard (ODS)**

**Manufacturers may increase maximal output (up to 720mw/cm<sup>2</sup> for fetal use) on the condition that two indices appear on-screen:**

- Thermal index (TI) for thermal effects**
- Mechanical index (MI) for non-thermal (a.k.a. mechanical) effects**
- AND: a particular effort is to be made to educate the end-users about bioeffects, safety and TI and MI**



● *Review*

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**INTERNATIONAL RECOMMENDATIONS AND GUIDELINES FOR THE  
SAFE USE OF DIAGNOSTIC ULTRASOUND IN MEDICINE**

STANLEY B. BARNETT,\* GAIL R. TER HAAR,<sup>†</sup> MARVIN C. ZISKIN,<sup>‡</sup> HANS-DIETER ROTT,<sup>§</sup>  
FRANCIS A. DUCK<sup>||</sup> and KAZUO MAEDA<sup>¶</sup>

\*Division of Telecommunications and Industrial Physics, CSIRO, Lindfield, Australia; <sup>†</sup>Joint Department of Physics  
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Hospital, Bath, UK; and <sup>¶</sup>Seirei Hamamatsu General Hospital, Hamamatsu, Japan

“Although the ODS is sometimes referred to as a *de facto* international standard, it is only used for regulatory purposes **in the USA**. No **international** safety standard exists to guide the user in the safe and effective application of diagnostic ultrasound in medicine.”

# Infrasound

- Also referred to as low-frequency sound, is sound with frequency  $<20$  Hz
- National and international agencies: almost completely silent on standards or recommendations for protection from infrasound.
- Usually managed as a subset of considerations on protection from noise (Jakobsen, 2003; NOHSC, 2003).
- However, the relevant EU directive on noise protection (European Communities, 2003) omits specific reference to protection levels for infrasound.

## A world standard

- ✓ Would improve knowledge of bioeffects and safety of various forms of ultrasound among end-users, given the blatant lack of education in this field;
- ✓ Would regulate modalities that are used all over the world, multiple times daily;

But more importantly

- ✓ Would protect the public and particularly millions of fetuses from potential harmful effects, if ultrasound is used indiscriminately



# Developing NIR Standards

## Vision

- ***A coherent set of **fundamental principles and basic requirements** which shall***
  - ✎ Cover EMF, optical radiation, ultrasound and infrasound
  - ✎ Cover all exposure situations and exposed populations - but with clearly defined exceptions
  - ✎ Be based on existing scientific evidence – but consider uncertainties and lack of knowledge
  - ✎ Be justified and optimized by taking account risks-costs-benefits
  - ✎ Be realistic considering implementations
  - ✎ **Be useful!**

# Developing NIR Standards Challenges

- Diversity of spectrum, exposures, health effects
- Level of evidence - missing data, uncertainties
- Strong and rapid technological developments
- Philosophy, e.g. precaution, ethics
- Criteria for exceptions, or inclusions
- Risk-cost-benefit analysis
- Non-medical applications on humans



# Developing NIR Standards Opportunities

- Involvement
  - of developed and developing countries
  - endorsement by relevant UN organizations
- Translate criteria and principles into regulatory terms
- Support governments in
  - applying basic safety principles
  - implementing of guidelines
- Useful for
  - Health protection
  - risk communication
  - the international labor market
  - the global roll out of modern technology
  - international litigation



# WHO "NIR BSS" Project

- 2012: Request from a Member State
- 2013: Discussion with the WHO IAC (June 2013, Paris)
- 2014: Consultancy meeting of experts and representatives of int. organizations and NGOs
- 2015: Core Group Meeting (27-28 April 2015)





# Core Group Members

## **Dr Jacques S. ABRAMOWICZ**

**World Federation of Ultrasound in Medicine and Biology (WFUMB)**

**Professor and Director of Ultrasound Services  
Department of Obstetrics and Gynecology**

**Wayne State University**

**Hutzel Women's Hospital**

**UNITED STATES OF AMERICA**

## **Dr Efthymios KARABETSOS**

**Head of the Non-Ionizing Radiation Office**

**Greek Atomic Energy Commission**

**GREECE**

## **Dipl-Ing Rüdiger MATTHES**

**Chair of the ICNIRP**

**(now retired from German Federal Office for  
Radiation Protection (BfS))**

**GERMANY**

## **Dr Mirjana MOSER**

**Independent expert in radiation protection**

**(now retired from the Radiation Protection  
Division, Swiss Federal Office of Public Health)**

**SWITZERLAND**

## **Dr John O'HAGAN**

**International Commission on Illumination (CIE)**

**(Director, Division 6, Photobiology &  
Photochemistry)**

**Group Leader, Laser and Optical Radiation**

**Dosimetry Group**

**Public Health England**

**UNITED KINGDOM**

## **Dr Rick TINKER**

**Director Radiation Health Services**

**Australian Radiation Protection and Nuclear Safety  
Agency (ARPANSA)**

**AUSTRALIA**

## **Dr Sigurdur MAGNUSSON**

**Director**

**Icelandic Radiation Safety Authority  
ICELAND**

## **Dr Shengli NIU**

**International Labour Organization**

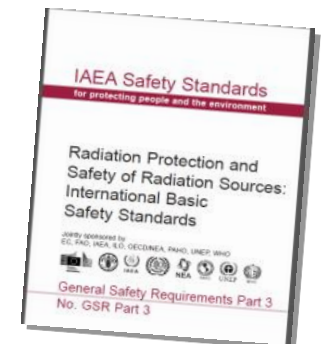
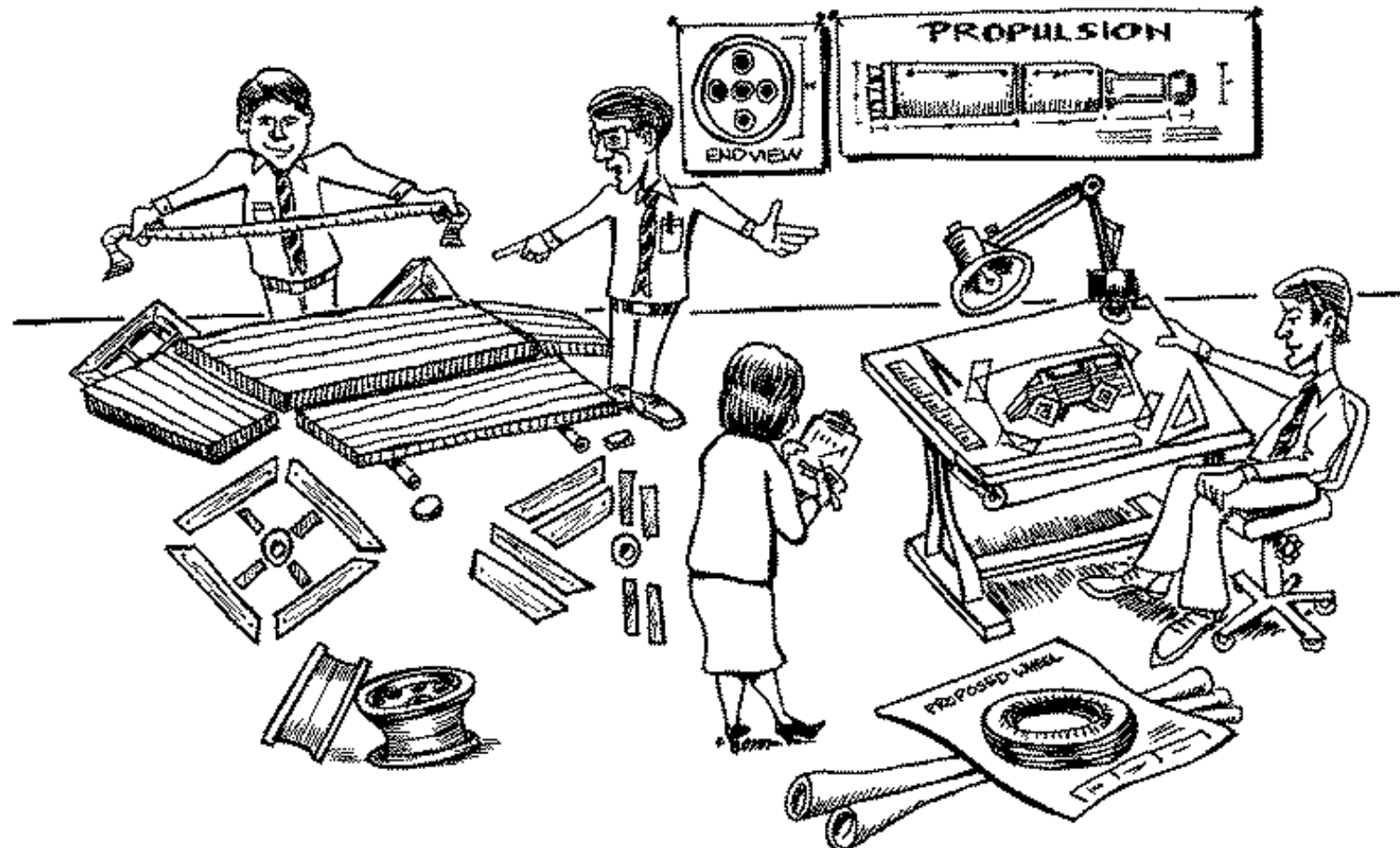
**Geneva**

**SWITZERLAND**

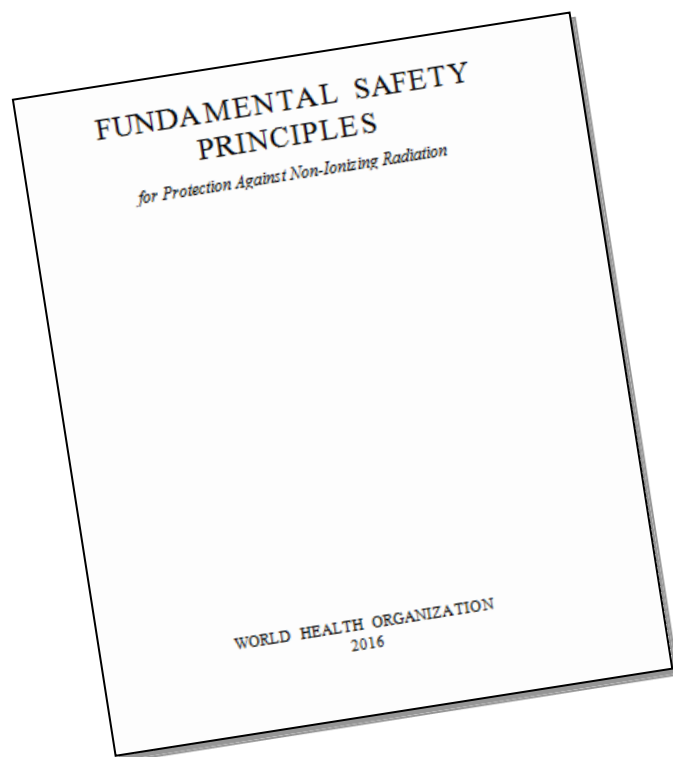


**World Health  
Organization**

# NIR Regulatory Framework



# "Fundamental Safety Principles"



- Develop a draft "Fundamental Safety Principles for Non-Ionizing Radiation" (April 2015- May 2016)
- Circulate for consultation (Spring-Summer 2016)
  - Member States
  - International organizations, professional bodies, and other relevant NGOs

# "Basic Safety Standards"

- Setting responsibilities for Requirements
  - Government
  - Regulatory body
  - Responsible persons or organizations
  - Registrants and licensees
  - Relevant parties
- Establishing a legal framework and defining responsibilities
- Notification, authorization, licensing, exemptions and clearance
- Justification, optimization and dose limits
- Information, protection, training



# Discussion

