

ICNIRP Guidelines Setting Process

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Outline

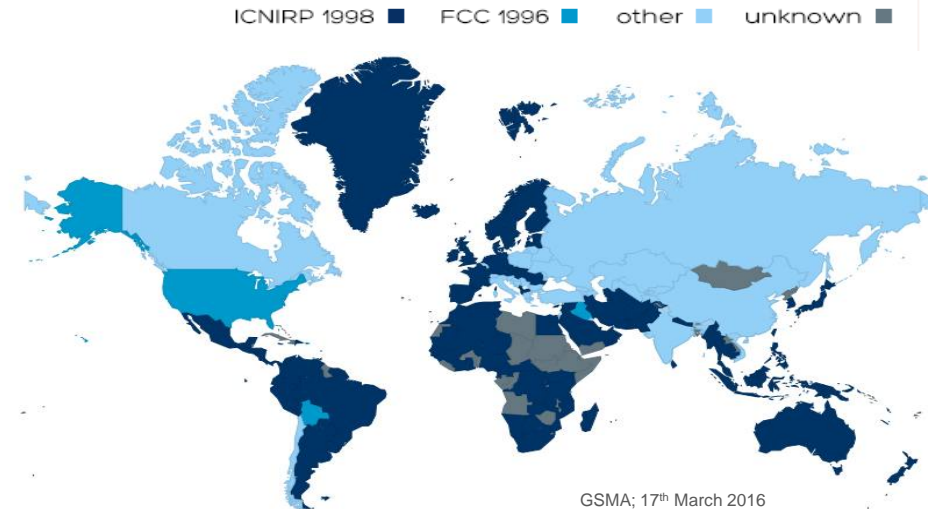
- **Rationale for re-evaluation**
- **Structure and Terms of Reference**
- **Comparison of ICNIRP and WHO Guideline processes**
- **Project Group recommendations**

Rationale for re-evaluation

- **ICNIRP's main role – produce Guidelines**
- **Recent Guidelines**
 - ICNIRP Guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1,000 μm ; Health Physics, 2013
 - ICNIRP Guidelines on limits of exposure to incoherent visible and infrared radiation; Health Physics, 2013
 - ICNIRP Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz – 100 kHz); Health Physics, 2010

Rationale for re-evaluation

- **Can we improve our processes**
 - Continuing goal
- **Potential to link with World Health Organisation (WHO)**
 - ICNIRP Guidelines are used in majority of countries
 - Some countries have difficulties using particular Guidelines if not endorsed by WHO
 - Explore WHO requirements for endorsement in light of current and potential changes to ICNIRP processes



Structure & ToRs

- **Project Group formed July 2015**
 - ICNIRP Main Commission members
 - Rodney Croft, Eric van Rongen
 - ICNIRP Standing Expert Group members
 - Simon Mann, Sharon Miller, John O'Hagan, Sarah Loughran
 - WHO Observer
 - Emilie van Deventer

REPORT FROM PROJECT GROUP;
YET TO BE CONFIRMED BY MAIN COMMISSION

Structure & ToRs

- **Aims**
 - Determine method for ICNIRP Guidelines development, so as to
 - *Meet requirements of WHO*
 - *Enhance current methodology*
 - Radiation Protection
 - Methodology (transparency, consistency)

Comparison of ICNIRP & WHO Processes



INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

ICNIRP STATEMENT

**GENERAL APPROACH TO PROTECTION AGAINST
NON-IONIZING RADIATION PROTECTION**

PUBLISHED IN: HEALTH PHYSICS 82(4):540-548; 2002

WHO

Handbook for Guideline Development

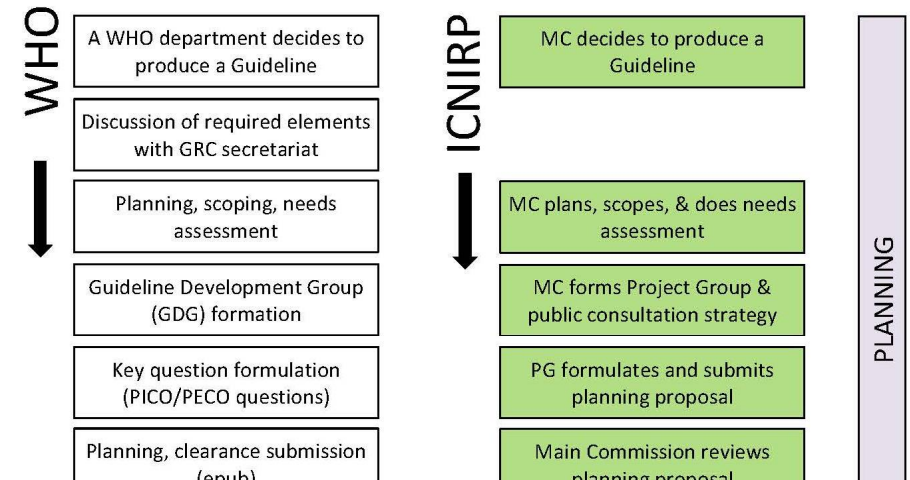
2nd edition



**World Health
Organization**

General Considerations

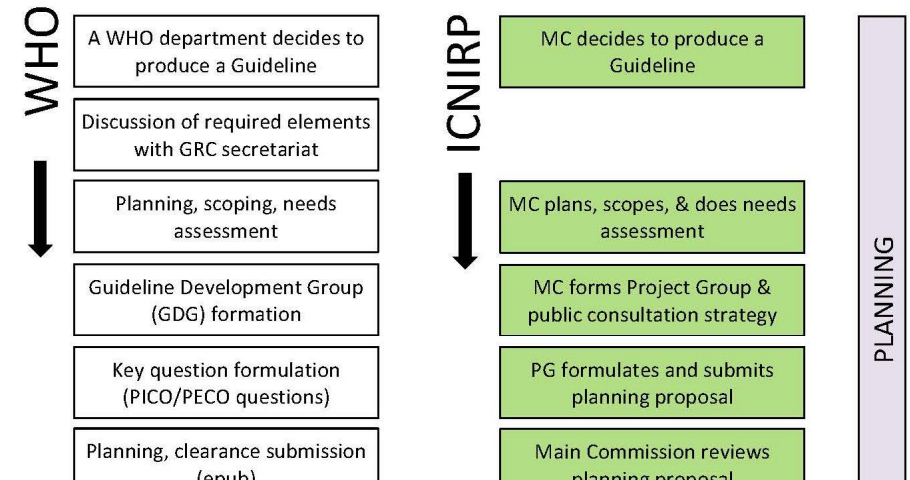
- **No formalised ICNIRP method**
 - ICNIRP methods seen as appropriate, but not transparent
- **Recommend**
 - Formalise ICNIRP methods
 - *Consistency across Guidelines*
 - *Transparent approach*
- **Considerations**
 - Must ensure radiation protection is not sacrificed to method
 - *Method must allow flexibility as required*
 - *Changes would require strong justification*



General Considerations

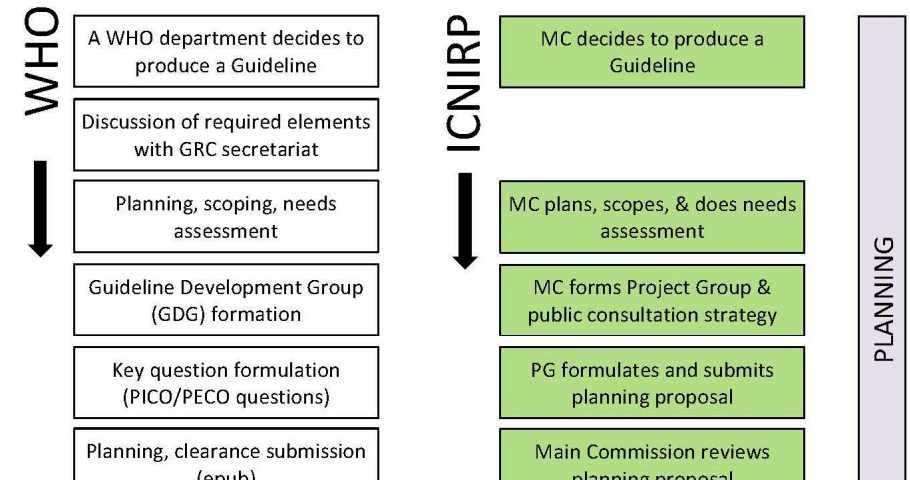
- **WHO is a BIG organisation, which allows greater separation of function**

- *WHO Technical Unit (WTU)*
 - *Guideline Review Committee (GRC)*
 - *Guideline Steering Group (GSG)*
 - *Guideline Development Group (GDG)*
 - *Systematic Review Team (SRT)*
 - *External Review Group (ERG)*
- Internal WHO Groups
- WHO Managed Groups

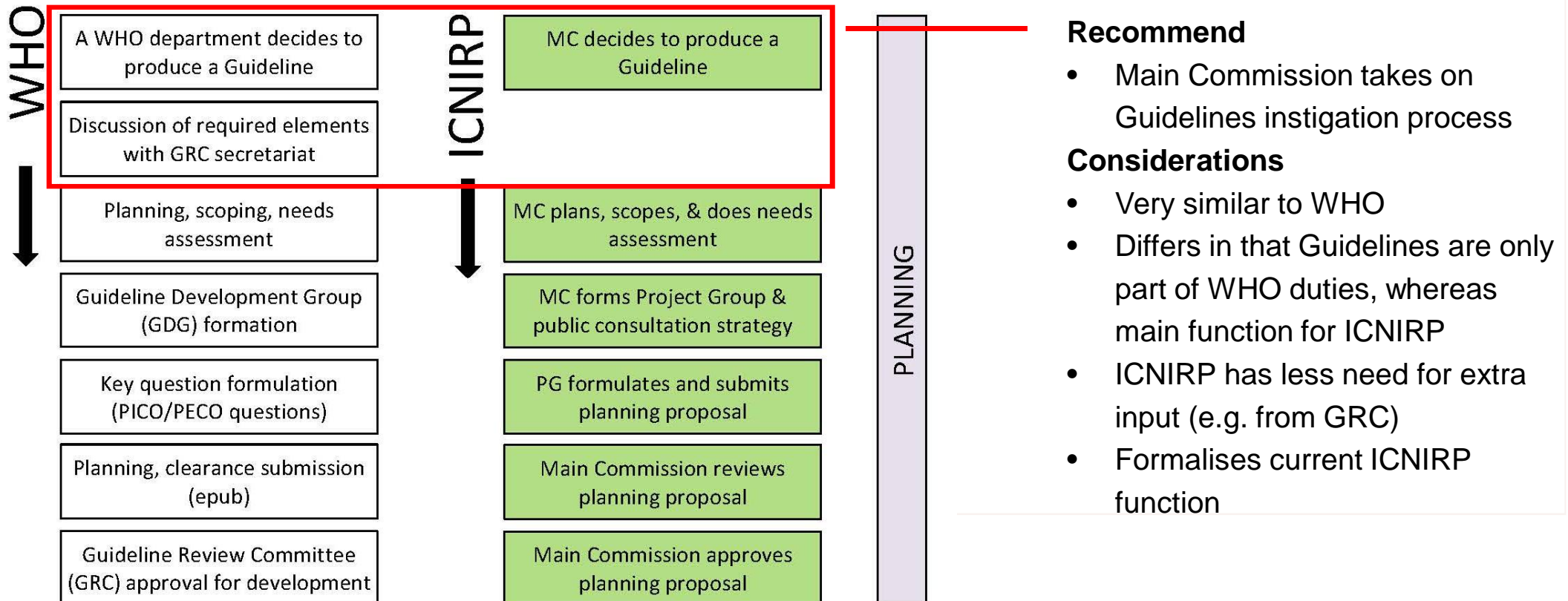


General Considerations

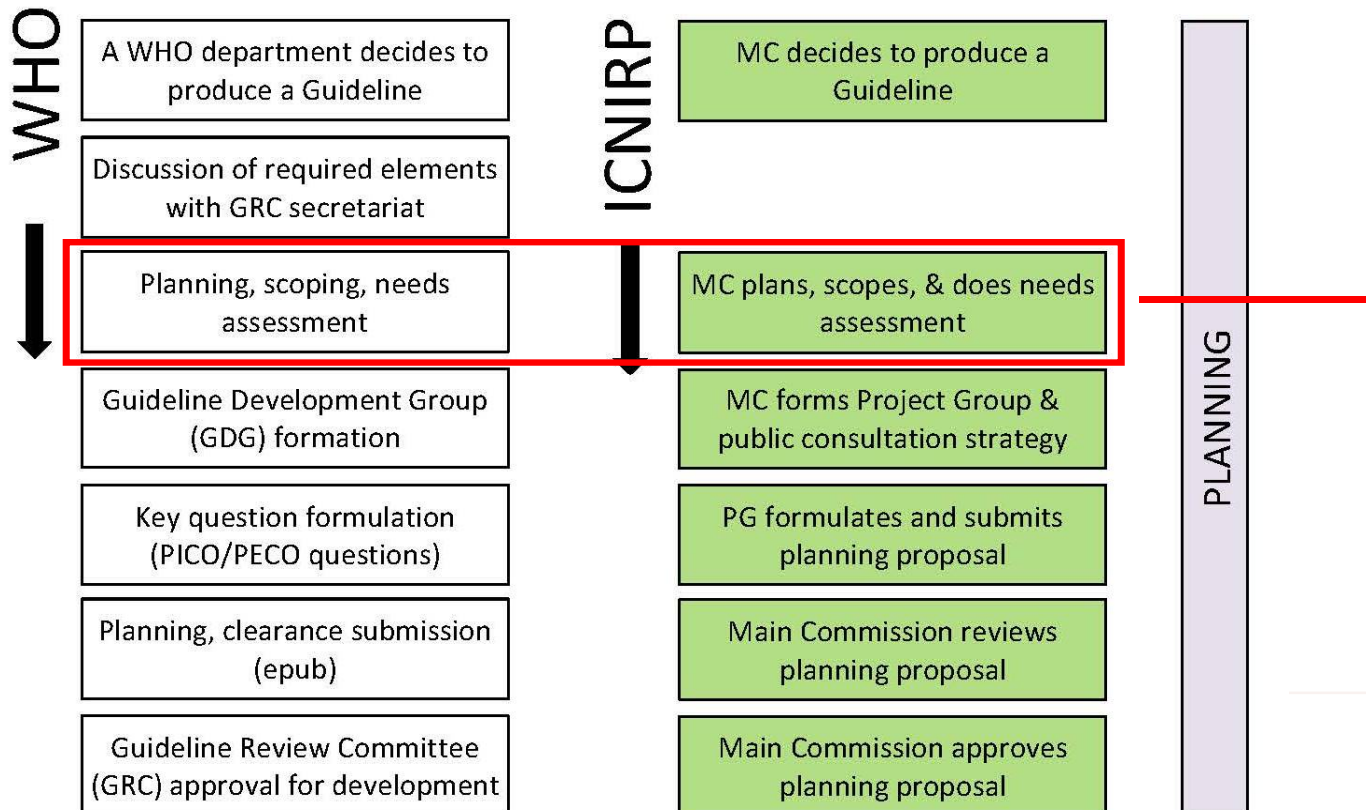
- **WHO is a BIG organisation**
 - ICNIRP cannot achieve this level of separation
- **Recommend**
 - No change
- **Considerations**
 - Reduces degree of 'checks and balances'
 - Maintains depth/continuity of knowledge across groups. For example
 - *WHO GSG sets questions to be answered by the GDG, but this may require 'development' from the GDG*
 - *WHO GDG sets Guidelines, but GSG writes the guidelines*



Comparison of Methods



Comparison of Methods



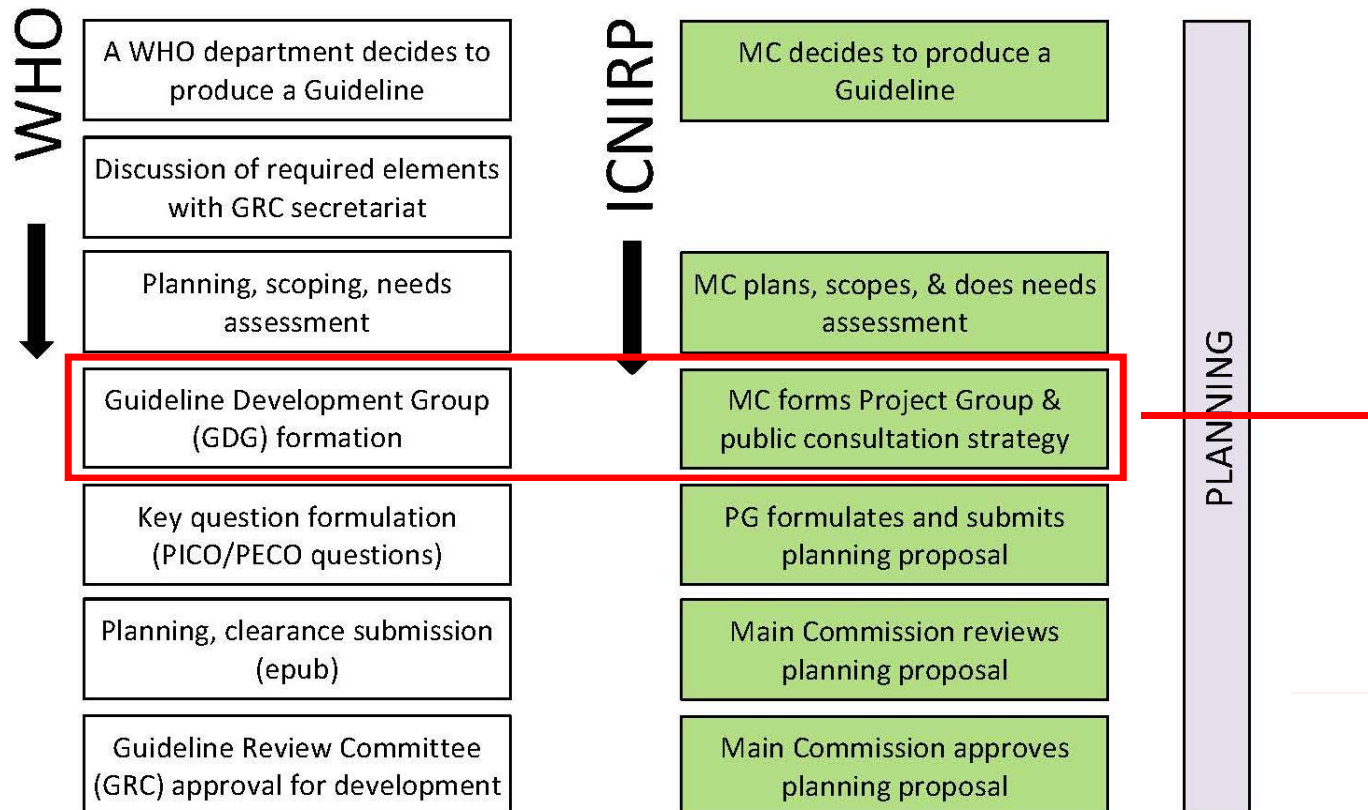
Recommend

- Main Commission takes on planning & oversight role

Considerations

- Very similar to WHO, but no extra help required by MC
- Formalises current ICNIRP function

Comparison of Methods



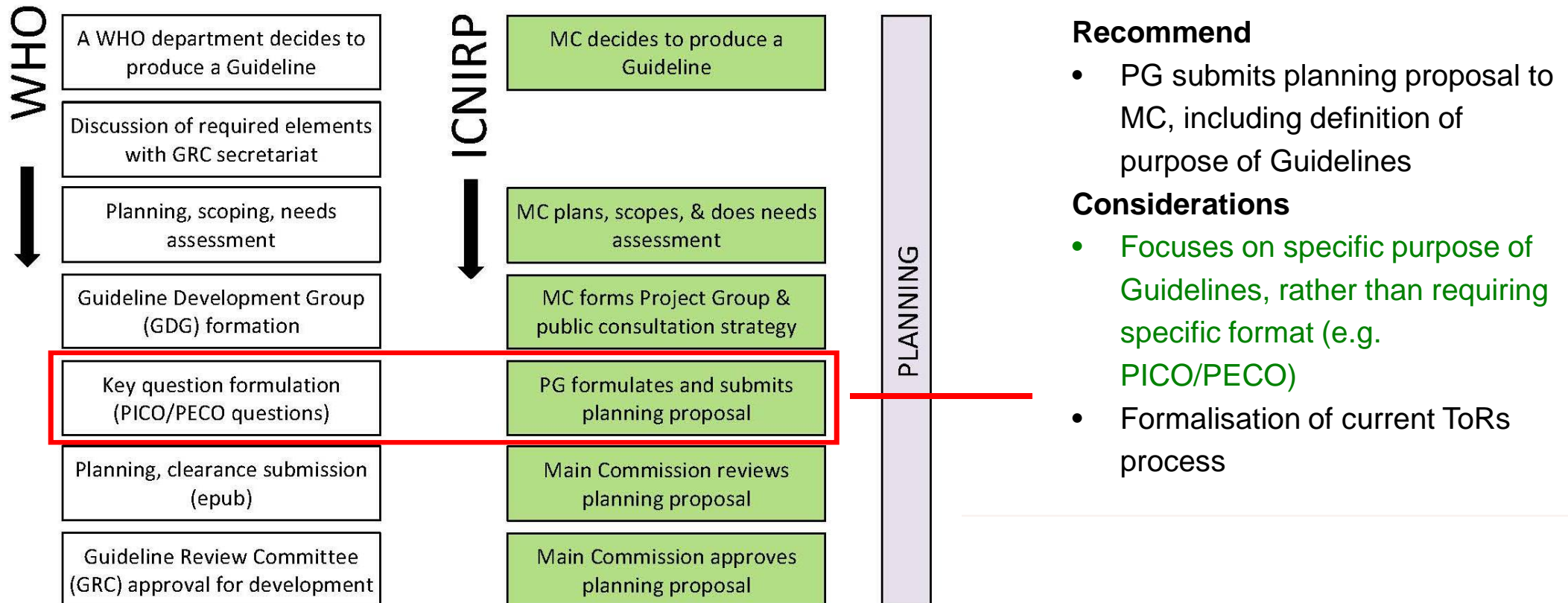
Recommend

- MC forms PG, including
 - Demographic balance
 - Guidelines expertise
- MC plans public consultation strategy

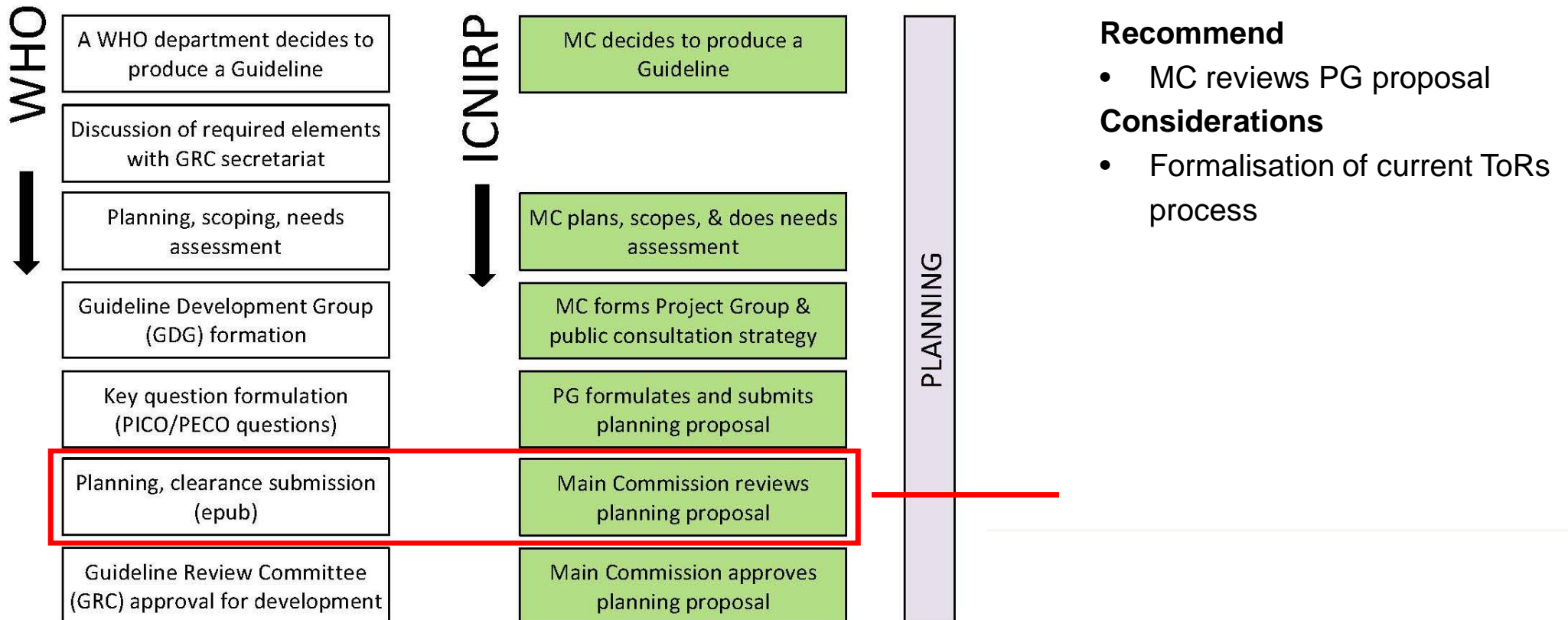
Considerations

- Less separation of function than WHO (overlap of PG and MC membership)
- Guidelines rather than Methodology expert
- Proactive consultation strategy in place of external review group

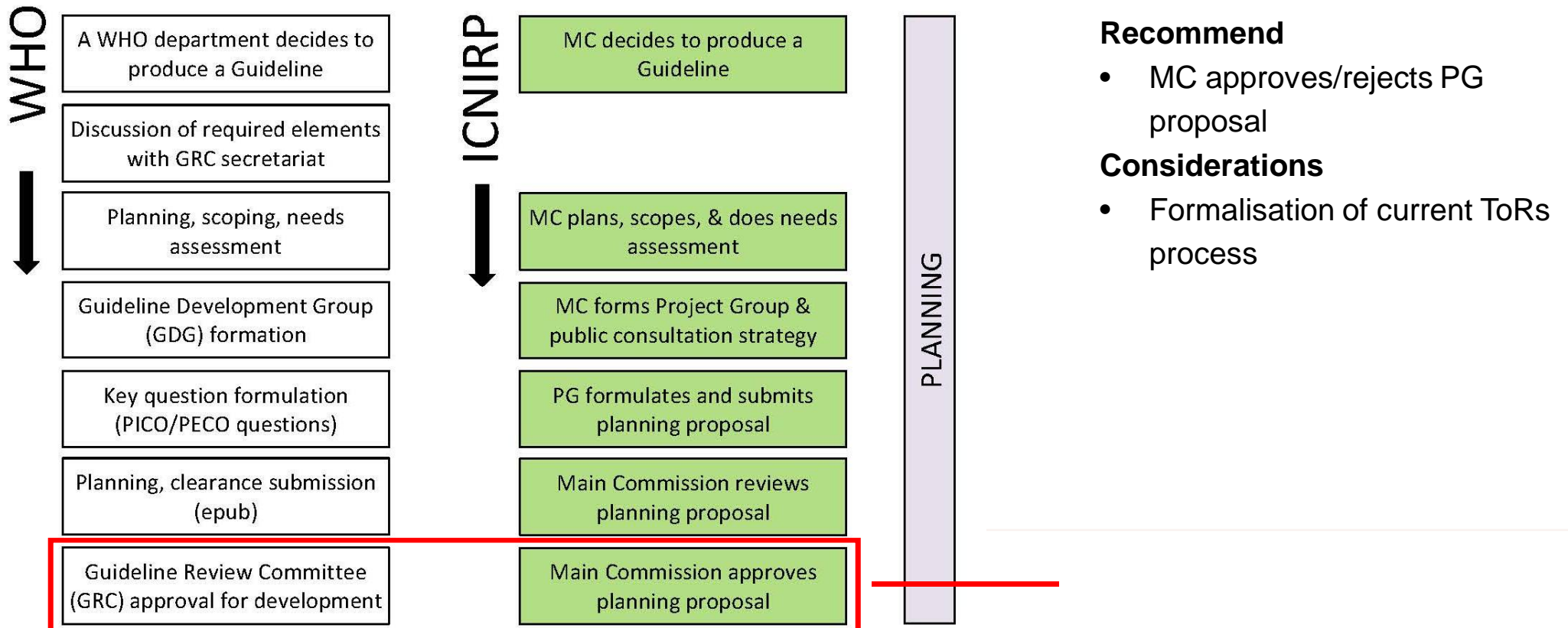
Comparison of Methods



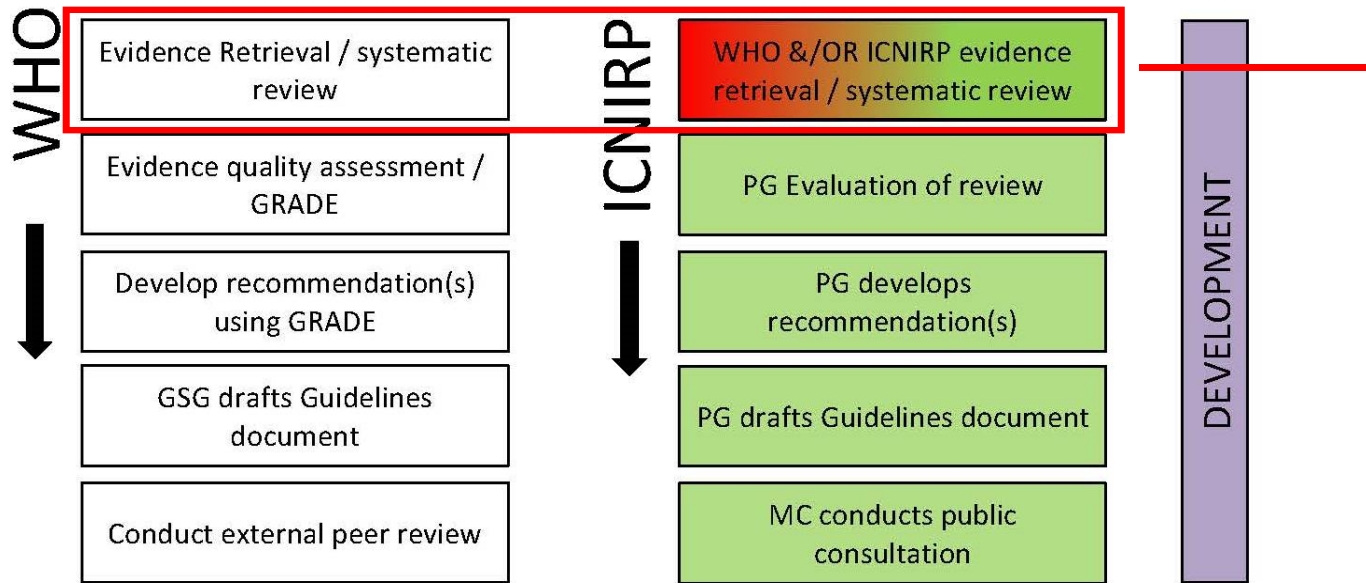
Comparison of Methods



Comparison of Methods



Comparison of Methods



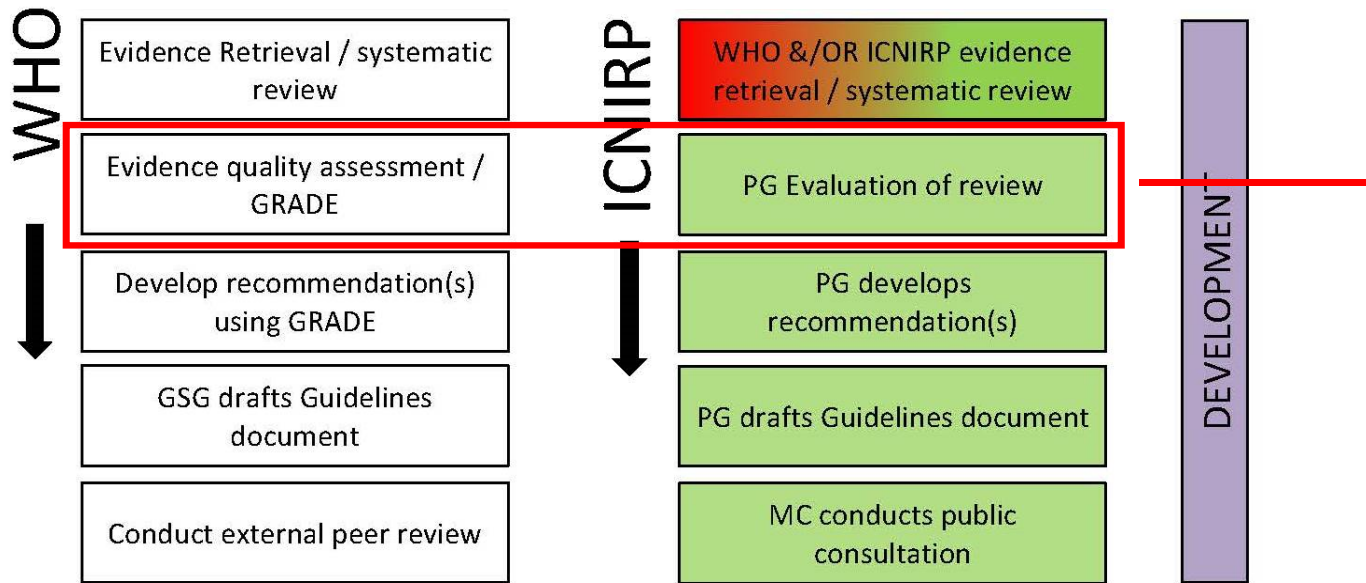
Recommend

- ICNIRP liaise with WHO to conduct formalised evidence retrieval (where possible)

Considerations

- Important not to require this collaboration, as WHO will not always be in a position to collaborate
- Allows internal ICNIRP review where appropriate (may be logistically necessary)

Comparison of Methods



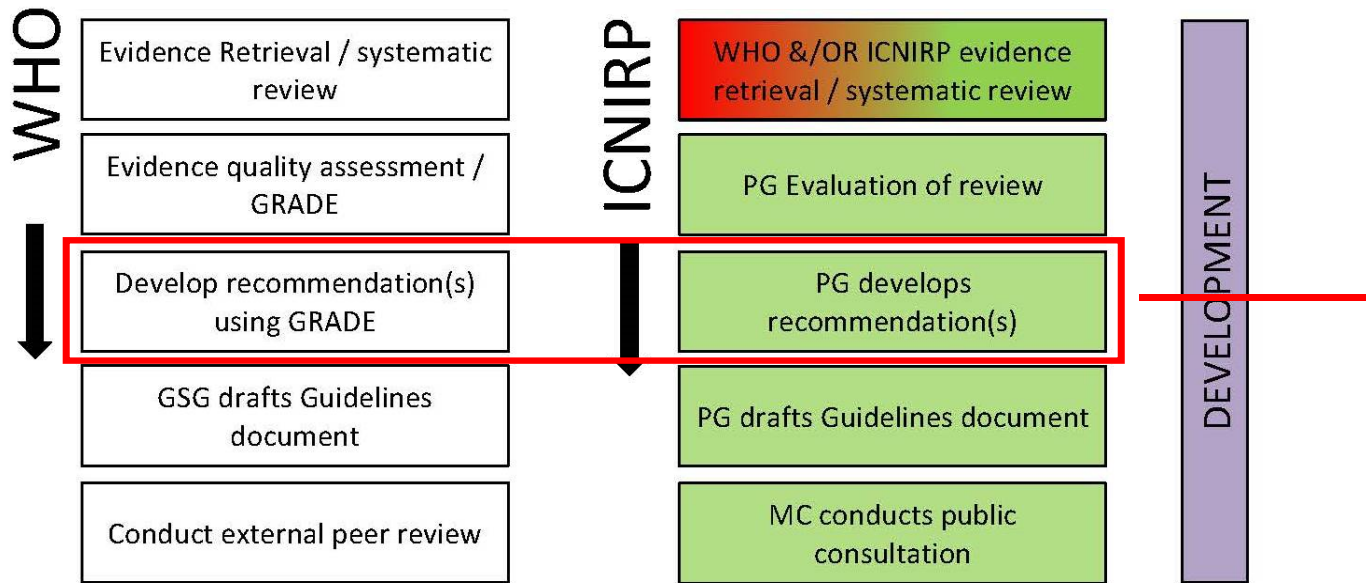
Recommend

- PG provide 'appropriate' evaluation of the evidence retrieval output
- PG should not take into account cost/benefit

Considerations

- Allows evaluation method to develop as part of the PG work (important as NIR science is rapidly changing, and we need to be able to adapt with it)
- Evaluation conducted by those who will set the limits (**less independence**, but ensures relevance to Guidelines)

Comparison of Methods



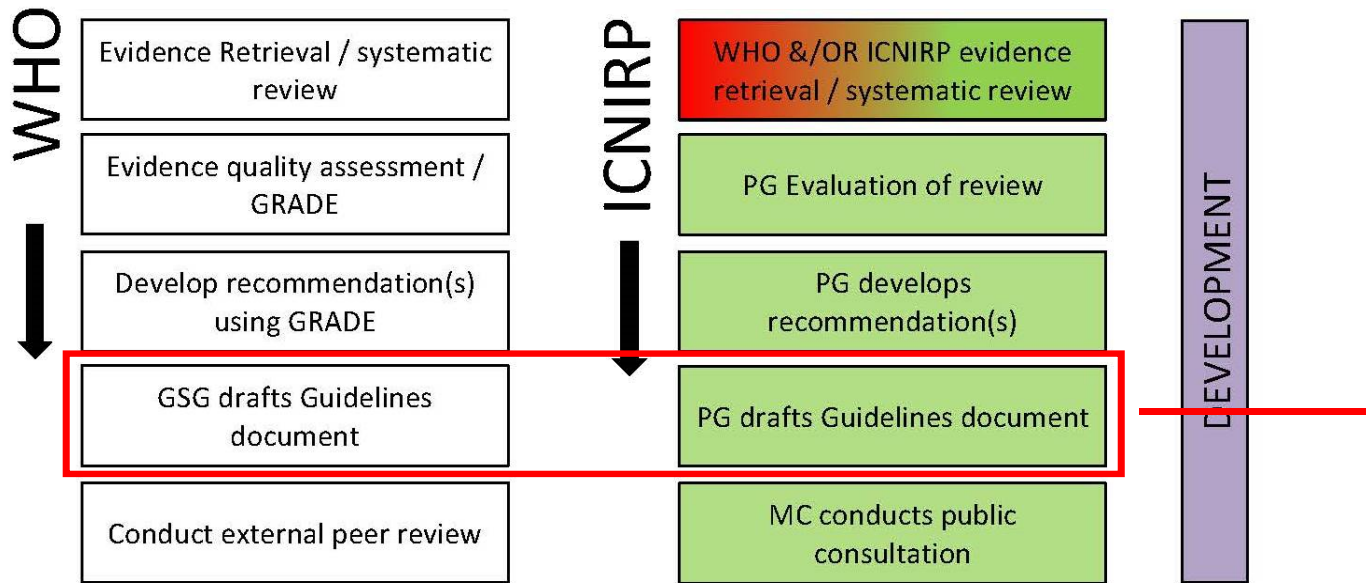
Recommend

- PG provide limits based on evaluation of evidence retrieval

Considerations

- Consistent with WHO
- Formalisation of current ICNIRP procedure

Comparison of Methods



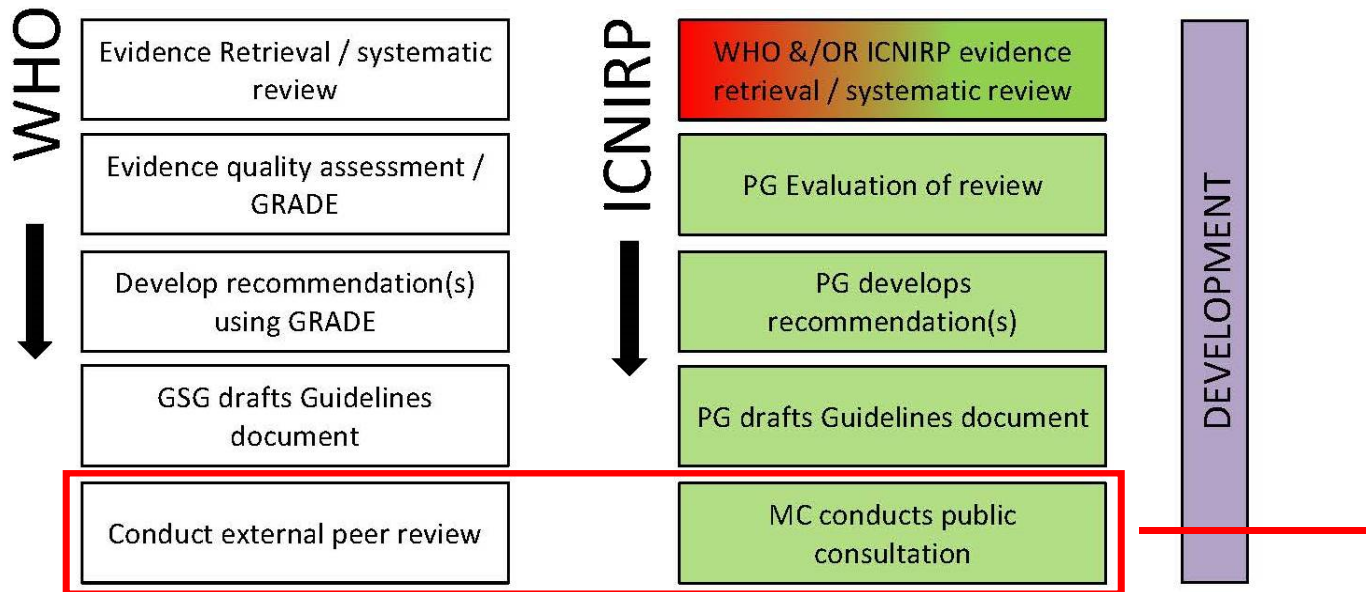
Recommend

- PG draft Guidelines

Considerations

- Ensures that document is written by those who understand it most (the PG)
- Less separation of functions

Comparison of Methods



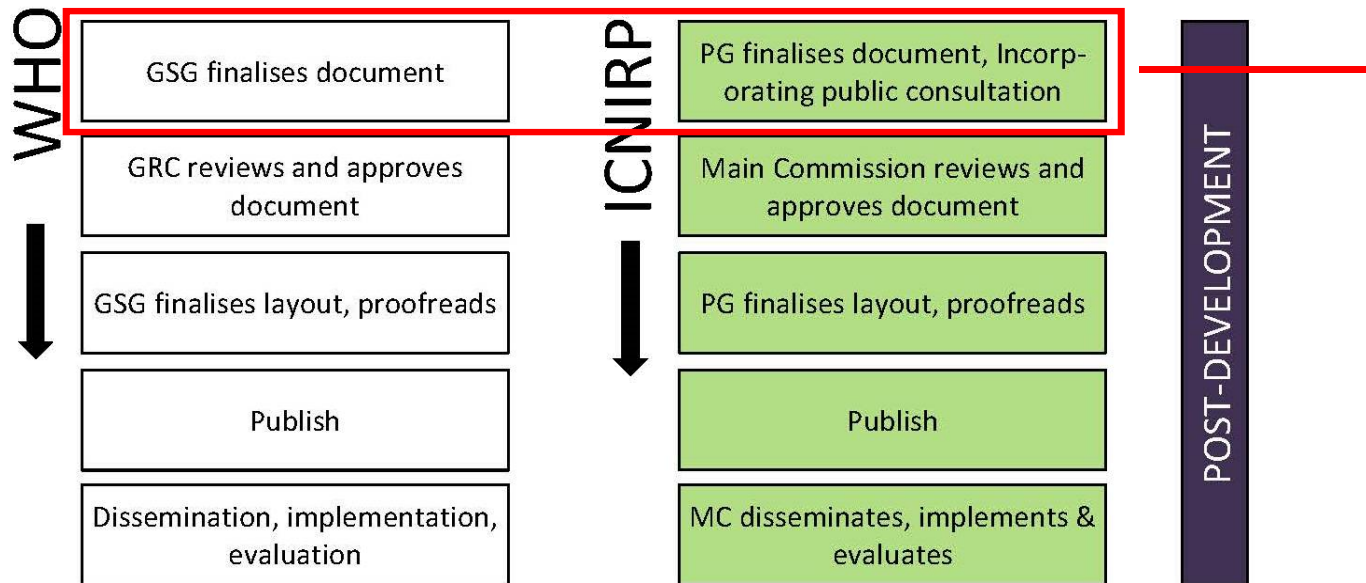
Recommend

- MC conducts public consultation

Considerations

- Similar to WHO, except a formal group is not used
- This is appropriate given that the intention is to get detailed feedback, not to have a group consensus as to the merits of the document

Comparison of Methods



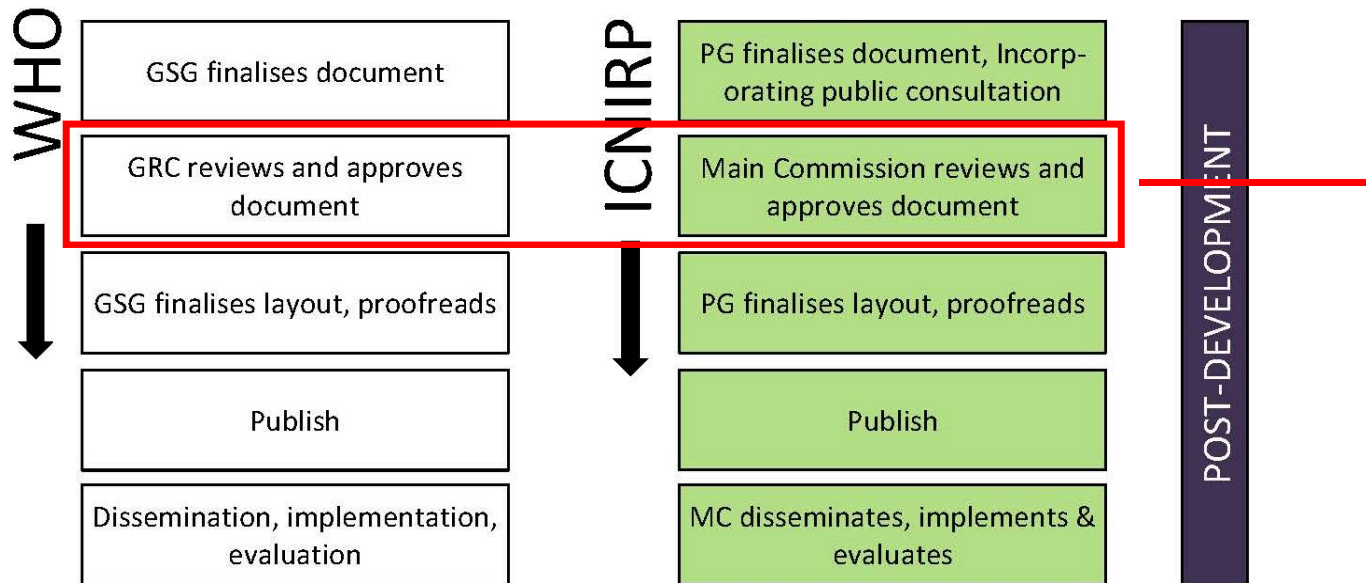
Recommend

- PG finalises draft, based on public consultation

Considerations

- Ensures that limits are set by those who understand the new Guidelines best (the PG)
- Less separation of functions

Comparison of Methods



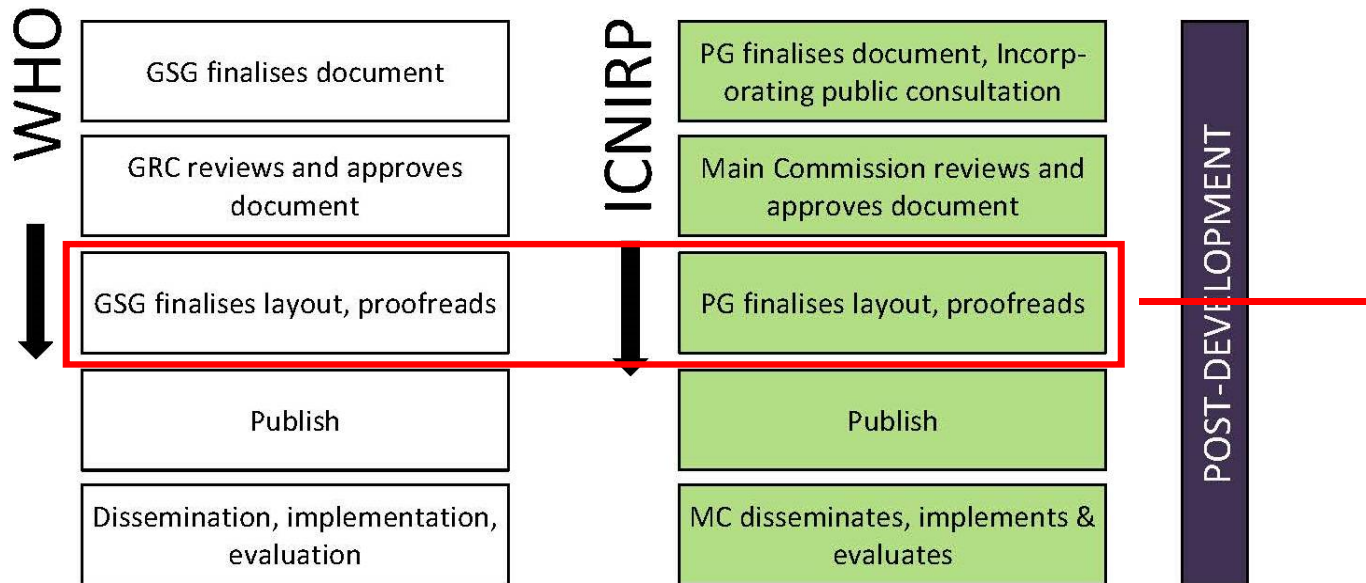
Recommend

- MC reviews and approves draft (as appropriate)

Considerations

- Although less separation of functions, the GRC is an administrative step to ensure consistency with WHO rules, rather than for separation of function
- MC review provides additional benefit (relative to GRC) as it has NIR expertise

Comparison of Methods



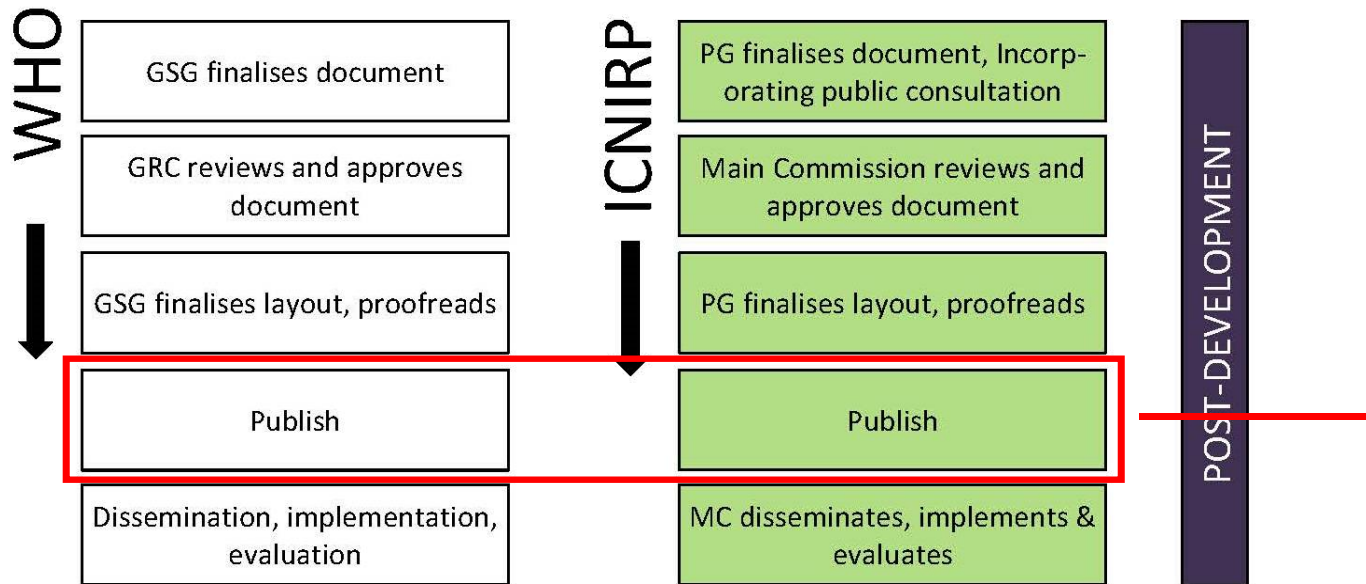
Recommend

- PG takes responsibility for final document

Considerations

- PG may be 'too close' to the work to see some issues (e.g. clarity)
- PG would be better suited to see other issues (e.g. substance)

Comparison of Methods



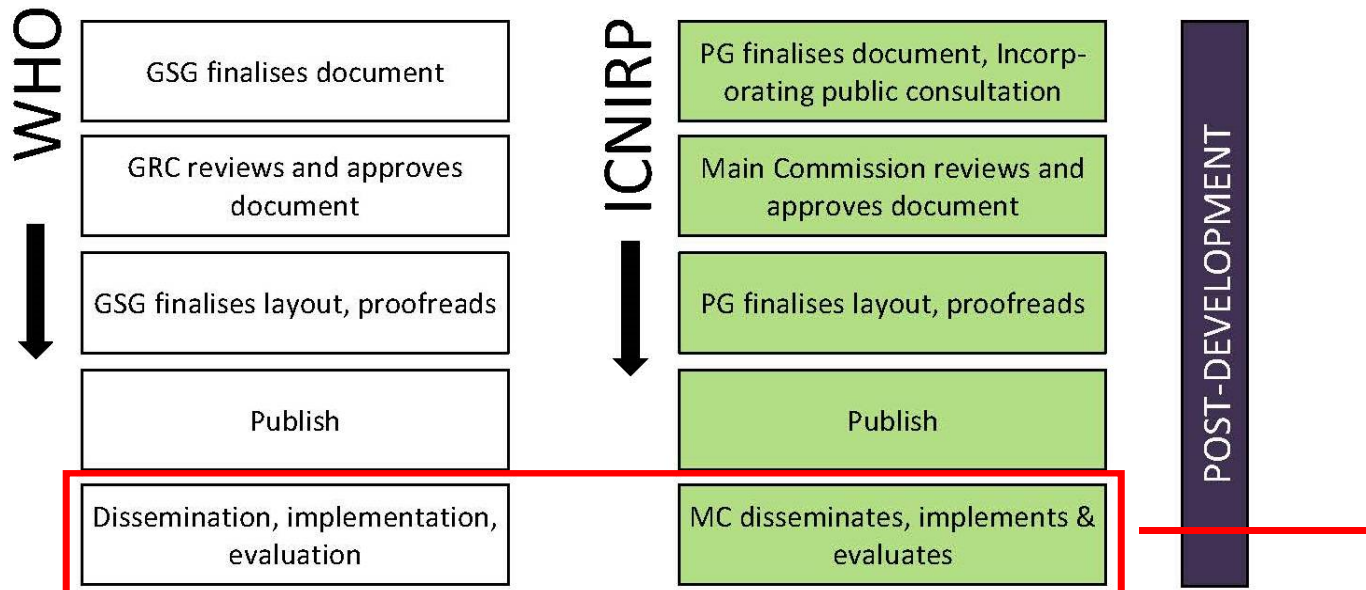
Recommend

- PG submit for publication

Considerations

- WHO have specific requirements as to the format of Guidelines (e.g. section headings and size of each)
- The appropriateness of these prescriptions needs to be evaluated by the PG

Comparison of Methods



Recommend

- MC take role of dissemination, implementation & evaluation (where appropriate)

Considerations

- Not clear that ICNIRP should be trying to persuade the use of its Guidelines; the Guidelines PG believed that 'good science' should be the only selling point
- Similarly, evaluation of success of sales did not seem relevant

Comparison of Methods

- **Overall, the Project Group**
 - saw great merit in formalising the current ICNIRP procedure
 - saw strong commonality between the current ICNIRP procedure and the WHO requirements (for all important steps)
 - provided recommendations for an ICNIRP Guidelines Development Methodology that is similar, but potentially an improvement to the WHO Guideline Development requirements

Comparison of Methods

- **Main Differences**

- ICNIRP would have restricted separation of functions (tasks divided between MC and PG, as opposed to the WHO's 6 groups)
 - *Necessary restriction given ICNIRP's size*
 - *In most cases we see this as a strength (e.g. those evaluating the literature also set the limits)*

Comparison of Methods

- **Main Differences**

- ICNIRP would not engage the community and stakeholder input until late in the process (to check for problems and provide improvements to the Guidelines), whereas WHO involves these inputs at the start (to influence the process itself)
 - *The PG values criticism, but does not believe that 'early' input would improve the science of radiation safety (and may hinder it)*

Comparison of Methods

- **Main Differences**

- ICNIRP would have greater focus on technical expertise, whereas for the WHO, “technical expertise in a guideline’s subject area...should not dominate the group [i.e. GDG]”
 - *The PG believes that technical expertise is the most important factor*
- ICNIRP would not provide the cost/benefit analysis, but would stick to the ‘science’ of radiation safety
 - *The PG believes that it is best for National Authorities to deal with cost/benefit, and that dealing with the evaluative side would weaken the scientific message*

Adoption of ICNIRP's Guidelines by WHO?

- **Not Possible**

- Substantial discussion occurred regarding how much ICNIRP could alter its methods to accommodate WHO requirements, in order to have ICNIRP Guidelines adopted by WHO
- *BUT, in essence, WHO requires their whole method to be adopted (including a lot of the work to be done by the WHO and WHO-designated groups, rather than by ICNIRP)*

Joint ICNIRP/WHO Guidelines?

- **Not Possible**

- Substantial discussion occurred regarding potential joint Guidelines
- *BUT, as per the previous slide, WHO would require their whole method to be jointly adopted*

Why not adopt WHO procedures in toto?

- **Different purposes**
 - WHO includes representation of population, opinions, practicality, value judgements etc
 - ICNIRP tries to be separate from values, and focus on the science

Why not adopt WHO procedures in toto?

- **Not clear what the role of ICNIRP would be?**
 - ICNIRP would lose ability to take responsibility for appropriate radiation safety
 - Perhaps valuable 'in addition to' ICNIRP Guidelines
 - To develop a politically acceptable set of limits based on ICNIRP Guidelines, where the science is not the sole arbiter

SUMMARY

- Useful to systematise ICNIRP Guidelines so long as the science is not lost (consistency & transparency)
- Useful to make Guidelines suitable for WHO, BUT not *currently* possible
- PG recommends that ICNIRP adopt the above ICNIRP Guideline method (regardless of WHO-adoptability)