



The European Federation of Organisations for Medical Physics

Domus Medica, Mercatorlaan 1200, Utrecht, NL

Mailing address: P.O. box 8003, 3503 RA Utrecht, NL

Telephone: (+31) 30 6866 561

PROPOSAL FOR A NEW WORKING GROUP (WG)

Name of WG¹:	Software as a Medical Device in Medical Physics
Parent Committee(s)²:	Science Committee
Keywords³:	Radiotherapy, Radiology, Nuclear Medicine, Software, Medical Device Regulation
Chair(s)⁴:	Suggested chair: Christina Zacharatou
Expected outcome⁵:	Publication in the European Journal of Medical Physics to summarise current practices in developing in-house software by medical physicists for clinical use, and how the MDR2017/745 has impacted hospitals in different European countries. To increase the user's awareness of medical device regulations/international standards. A questionnaire will be sent to European centres via group members to collect information on their software lifecycle process. A summary of current practices/national guidelines will be published with recommendations for homogenising these practices.
Target audience⁶:	Medical Physics Experts
Rationale⁷:	Not many publications have appeared so far in the literature on the implementation of EU MDR 2017/745 in clinical practice. The Regulation is not always clear to interpret and many grey areas remain. National guidelines are needed to facilitate its clinical integration. EFOMP can help users by creating awareness and proposing the homogenisation of current practice and national recommendations.
Coordination⁸:	EFOMP Science Committee

This proposal form must be filled by the EFOMP parent committee chair.



The European Federation of Organisations for Medical Physics

Domus Medica, Mercatorlaan 1200, Utrecht, NL
 Mailing address: P.O. box 8003, 3503 RA Utrecht, NL
 Telephone: (+31) 30 6866 561

Category:	WGs are classified into the following categories depending on their topic and purpose. Please choose the most appropriate.
	New Horizons. The topic involves new scientific developments, methods, technology or clinical applications that have not yet emerged into clinical practice.
	State of Art. The topic involves codes of practice, protocols, recommendations or guidelines for activity which are expected to become enduring practice.
	Focus Area. The topic involves certain specific area of clinical interest, modality or method which may include a technical or methodological challenge to be solved.
X	Educational or Informational. The topic involves education or informing the members in a relevant area of clinical practise, technology, methods, research or training.
	Consensus Document. The topic involves a consensus of the medical physics community on a certain area of interest that the EFOMP will endorse. This category may include e.g. safety issues or professional issues.
Members⁹:	<p>There has been interest in other major professional associations to formulate a joint Working Group regarding the MDR. The group will be run by EFOMP and the suggested composition is:</p> <ul style="list-style-type: none"> 4 members from EFOMP 2 members from ESTRO 2 members from EANM 2 members from ESR <p>There are no limitations on the number of consultants or observers from each society.</p>
Consultants/Observers¹⁰:	The call for WG members may also produce consultants and observers.
Funding¹¹:	Communication between WG members will be restricted to email and video calls. A possible face-to-face meeting(s) will be agreed with the participants. Travel costs coverage for EFOMP members only, with a cap of 500 EURO/member/year.
Timeline¹²:	<p>WG duration is assumed to be 24 months.</p> <p>Launch of the WG in October 2024.</p> <p>The questionnaire report will be produced after 7 months.</p> <p>The draft of recommendations and current practices will be submitted to the Physica Medica most probably in autumn 2026.</p>



The European Federation of Organisations for Medical Physics

Domus Medica, Mercatorlaan 1200, Utrecht, NL
 Mailing address: P.O. box 8003, 3503 RA Utrecht, NL
 Telephone: (+31) 30 6866 561

Proposed outline of the final report¹³:	Introduction, literature overview, current practices, recommendations.
-----------------------------------------------------------	------------------------------------------------------------------------

Legend

- 1) **Name of WG** - Including an indication of the WG type - i.e. if the WG will be a Joint WG.
- 2) **Parent Committee(s)** - Relevant EFOMP Committee.
- 3) **Keywords** - include at least 3 keywords.
- 4) **Chair(s)** - The chair of the parent committee will propose the chair of the WG.
- 5) **Expected outcome** - Description of the relevant results expected from the WG.
- 6) **Target audience** - e.g. Medical Physicists, Vendors.
- 7) **Rationale** - What is the justification and need for the proposed WG.
- 8) **Coordination** - The parent committee chair has to specify if there is a coordination or collaboration with other EFOMP Committees, WGs and/or scientific organisations.
- 9) **Members** - Proposed list of active members based on the feedback on the WG announcement from NMOs, potentially interested experts within the medical physics community and the EFOMP Governing committee will be composed by the parent committee chair together with the proposed WG chair. The proposed member list has to be approved by the EFOMP Governing committee. WG members have to create an efficient and optimal composition of expertise and professional coverage. WG members can be updated also later if and when needed.
- 10) **Consultants/Observers** - Proposed other WG participants who are indicated as consultants or observers. The parent committee chair together with the proposed WG chair will identify possible consultants/observers.
- 11) **Funding** - Description of the WG funding needs (meetings, etc.) and how the finances will be acquired and managed. This part is optional and can also be zero.
- 12) **Timeline** - WG timetable described by main milestones and reporting. Interim progress reporting must be provided at least in 6 months intervals.



The European Federation of Organisations for Medical Physics

Domus Medica, Mercatorlaan 1200, Utrecht, NL

Mailing address: P.O. box 8003, 3503 RA Utrecht, NL

Telephone: (+31) 30 6866 561

- 13) **Proposed outline of the final report** - What should be included in order to reach the planned outcome.