Session Coordinator
Policy & Regulatory Affairs Council

EU Affairs Track
Monday, October 19, 16:30-17:15

Session Title
From Medical Devices Regulation revision to Euratom alignment: Ensuring easy access to radiation-based medical devices

Chair
Dr. Klaus Bacher, EANM Policy & Regulatory Affairs Council, Ghent University, Belgium

Programme

16:30-16:35	**Introduction and policy context Evidence Generation for Amyloid PET: registries, Real-world Data, and Clinical Utility in Europe** • Dr. Klaus Bacher
16:35-16:50	**Medical devices using ionising radiation: the regulatory complexity. Technopolis study, key findings & policy implications** • Dr. Anoushka Dave, Managing Principal Consultant, Technopolis, Brighton, UK
16:50-17:05	**MDR revision: what may change in practice** • Dr. Bernhard Sattler, EANM Policy & Regulatory Affairs Council, University of Leipzig, Germany • Prof. Alan Fraser, BioMed Alliance, Cardiff University, UK
17:05-17:15	**From policy to action: What should EANM focus on and what are the top policy asks?** • Panel discussion • Q&A with the audience • Concluding remarks

Summary
This session will explore the implications of the ongoing revision of the Medical Devices Regulation (MDR) for innovation, market access, and regulatory pathways. Drawing on findings from the Technopolis/SAMIRA study, speakers will discuss the unique challenges arising from the interaction between the MDR and Euratom legislation and consider opportunities for greater regulatory coherence. The aim of the session is further to discuss EANM's role in the MDR revision process and broader EU regulatory alignment, identifying priorities to support effective implementation, improve consistency across Member States, and ultimately enhance patient access to medical devices.