Framework of relevant EU regulations and international guidelines related to justification and optimisation, from Radiation Protection and Health sectors

List of European and international regulations and guidelines related to justification and optimisation from radiation protection and health sectors. Guidelines from European societies are incorporated in WP 4 on landscape analysis.

Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
EU regulations		
CETS 164 - Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (coe.int). A convention by the European Commission, Oviedo, 4.IV.1997	Article 3	**Equitable access to health care** Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to **health care of appropriate quality.**
DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare Directive - 2011/24 - EN - EUR-Lex (europa.eu)		Quality issues and HTA (Article 15)
Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom,	Radiation protection	

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Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
97/43/Euratom and 2003/122/Euratom		
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	Medical devices	This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union.
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	In vitro diagnostic medical devices	In vitro means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations…
REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices	Medical devices and in vitro diagnostic medical devices	
DIRECTIVE 2001/83/EC on the Community code relating to medicinal products for human use (“Pharma Directive”)	Pharmaceuticals Article 4	“Nothing in this Directive shall in any way derogate from the Community rules for the radiation protection of persons undergoing medical examination or treatment, or from the Community rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation.” Note: pharma legislation is to be revised, current negotiations happening at EU level between member states and industry. See below this (now old) policy briefing with reference to the BSS Revision of the EU's general pharmaceutical legislation

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Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
REGULATION (EU) No 536/2014 on clinical trials on medicinal products for human use ("Clinical Trials Regulation" or "CTR")	Clinical trials, CTR Article 28	"A clinical trial may be conducted only where all of the following conditions are met: (a) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored" "the clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the protocol and constantly monitored;"
Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU ('HTAR') https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282	HTAR	HTA of medicines and medical devices
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)	AI In particular, see article 16	High level summary: High-level summary of the AI Act | EU Artificial Intelligence Act Impact assessment carried out by the commission: Impact Assessment of the Regulation on Artificial intelligence | Shaping Europe's digital future See also: P9_TA(2024)0138 Artificial Intelligence Act European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts https://www.europarl.europa.eu/RegData/seance_pleniere/textes_adoptes/definitif/2024/03-13/0138/P9_TA(2024)0138_EN.pdf
EC recommendations and guidance		
COMMISSION RECOMMENDATION (EU) 2024/1112 of 18 April 2024	Clinical audits	

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Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
(Commission Recommendation (EU) 2024/1112 of 18 April 2024 on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom) on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom		
COUNCIL RECOMMENDATION of 9 June 2009 on patient safety, including the prevention and control of healthcare Brussels, 19.6.2014 COM(2014) 371 final REPORT FROM THE COMMISSION TO THE COUNCIL The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections	Patient safety, including the prevention and control of healthcare	
COMMISION GUIDANCE ON THE CLINICAL TRIALS REGULATION (EU) NO 536/2014 bd165522-8acf-433a-9ab1-d7dceae58112_en	HTAR Q 7.53	Required documentation regarding exposure to ionising radiation in clinical trials (diagnostic and therapeutic).
EC Conclusions: Justification on medical imaging involving exposure to ionising radiation (2015) https://data.consilium.europa.eu/doc/document/ST-14617-2015-INIT/en/pdf		Old but still valid.
International safety standards		
IAEA General Safety Requirements Part 3 Radiation Protection and Safety of	Paras 3.145-3.185	Medical exposure Jointly sponsored by EC

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Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
Radiation Sources: International Basic Safety Standards RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES:INTERNATIONAL BASIC SAFETY STANDARDS		
IAEA Specific Safety Guide 46: Radiation Protection and Safety in Medical Uses of Ionizing Radiation Radiation Protection and Safety in Medical Uses of Ionizing Radiation | IAEA		Radiology, nuclear medicine, radiotherapy
IAEA, Justification of Practices, Including Non-Medical Human Imaging, IAEA Safety Standards Series No. GSG-5, IAEA, Vienna (2014) Justification of Practices, Including Non-Medical Human Imaging | IAEA	Chapter 2: The principle of justification of practices	Definition of justification, authorization, prohibitions and relation with the other principles of radiation protection
International guidance		
ICRP: The 2007 Recommendations of the International Commission on Radiological Protection Publication 103.		Basis for the regulation on basic radiation protection concepts. Levels of justification, definition of justification
WHO Health technology assessment of medical devices (2011) Health technology assessment of medical devices (who.int) Second edition under open consultation now: Call for public consultation - Health technology assessment for medical devices, second edition (who.int)		HTA Interplay with Medical Device Regulation is mentioned, but not EU-BSS (or IAEA-BSS). Radiation detriment is part of safety, and there is a need for increased awareness of this among HTA-bodies and regulations.
ICRP138: Ethical Foundations of the System Radiological Protection (2018)	Chapter 3	Describes the four core ethical values underpinning the present system: beneficence/non-maleficence, prudence, justice, and dignity
WHO (2022): Ethics and medical radiological imaging: a		

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Name of EU regulation/ international guidelines	Relevant topic/ chapter/ article /paragraph	Comment
policy brief for health-care providers		
ICRP The 2007 Recommendations of the International Commission on Radiological Protection Publication 105.		Levels of justification, definition of justification
IAEA: Bonn call for action, 2012		
IRPA Perspective on "Reasonableness" in the Optimisation of Radiation Protection (2021)		This IRPA perspective identifies the principal key factors which provide a common underpinning across all (or most) optimisation situations and scenarios

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