Impact of a Potential Per- and polyfluoroalkyl substances restriction on medical imaging and radiotherapy equipment

Part 2: Final submission

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The persons identified above have signed off each stage of this report in accordance with RINA's BMS/QA procedure.

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ABOUT THIS SUBMISSION

This document is COCIR's **second and final submission** with detailed information on technical reasons for a long derogation and a more complete socio-economic impact assessment of the proposal.

COCIR submitted a preliminary submission (**Part I**) in May 2023. This submission concerns medical imaging and radiotherapy equipment including proton therapy, but also other medical devices that are an integral part of modern imaging and radiotherapy suites.

SUMMARY OF ANALYSIS AND RECOMMENDATIONS

COCIR members intend to phase out the use of per- and polyfluoroalkyl substances (PFAS) in all applications where it is identified if alternatives are available that provides the same or better clinical performances, in the interest of patients and healthcare institutions.

COCIR members use PFAS in a wide variety of electrical and non-electrical applications in the European Union (EU). These materials cannot be easily substituted as they form an integral part of the medical device and have unique combinations of properties. Any alternative with inferior performance could degrade the clinical performance of the medical devices and would significantly negatively impact the health of millions of EU citizens. It should be pointed out however, that medical devices are in scope of the Medical Devices Regulation for which Notified Body approval is required before sale in the EU. This regulation may not permit inferior overall reliability or performance if this compromises patient safety or their treatment and so substitution of PFAS will be difficult. Substitution of most of the components that contain PFAS and are used for the manufacturing of medical devices covered by this submission will be performed by their respective manufacturers. Once such PFAS free versions are available, medical device manufacturers will be able to start testing and validation of these parts. However, if no drop-in replacements are available or even worse, substitutes have inferior performances, then redesign is likely to be the only option to accommodate less-than-optimal performance substitute materials and components although substitution may prove not to be technically possible for some current applications. The COCIR assessment of uses of PFAS suggests that substitution of PFAS may be possible in 13.5 years for at least some uses in medical imaging and radiotherapy equipment and associated accessories, although some uses may need longer than 13.5 years. Substitution within 13.5 years is based on the assumption that all components purchased from suppliers will be PFAS free by 2026/2027, however COCIR believe that this will not be possible.

At the time of publication of this Part II, September 2023, COCIR's members are still reviewing PFAS uses, working to collect information from their long and complex supply chains, and this is not expected to be complete for at least 3 years. Experience shows that applications of restricted substances can be identified by suppliers very late in the process due to the complexity of sourcing information from sub-suppliers. The lack of a list of CAS numbers makes it even harder for suppliers to identify PFAS in a timely manner.

The most common uses of PFAS are as fluoropolymers, mainly as flame-resistant polymers used for cable assemblies and in various types of components, such as the following example uses:

- Cables and wiring and electrical connectors, in Magnetic resonance imaging (MRI) scanners, X-ray equipment and ultrasound imaging. Such applications will be particularly difficult to replace due to the unique combinations of properties provided by fluoropolymers.
- PFAS are used in printed circuit boards and plastic electrical and electronic components, such as relays, transformers, inductors, sensors, etc.
- PFAS are also used in lubricants, adhesives, sealants, and elastomers.
- Polycarbonate and polycarbonate blended with acrylonitrile butadiene styrene (ABS) is flame retarded with a PFAS.

Currently no substitutes are available for most current uses of PFAS that have the same performance and comply with applicable safety standards. COCIR members will also have to ensure that any potential substitutes are not regrettable substitutions.

PFAS are used because they provide unique combinations of essential performance, such as flexibility, low coefficient of friction, suitability at high and low temperature, dielectric properties, fire resistance, resistance to sterilising chemicals, biocompatibility, etc.

The following elements, analysed in this report support the request for a derogation with an initial 13.5-year duration.

Technical aspects (Chapter 3)

Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers per company and identify possible alternatives that could be tested will take at least 3 years. Alternatives cannot be tested until the PFAS, and potential substitutes have been identified.

PFAS-free components can only be tested and integrated into new designs once they have been developed and are available from suppliers. We learned by the submissions to the ECHA consultation page that many substitute components will become available just before the expiry of their applicable multi-year derogations. If, for instance, a derogation of 13.5 years is granted for a type of components, COCIR's members will not be able to start testing and redesigning equipment with many of these alternative components probably until a short time before that expiration date. The design cycle of medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11 years, so potentially, it could take 19 to 25 years (or more) after entry into force (EIF) before new designs are completed.

Companies have limited specialised technicians and engineers while having a wide portfolio of applications. As already proven under the Restriction of Hazardous Substances Directive (RoHS), redesign takes time and resources. It is not possible to have too many models being redesigned in parallel.

For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required.

Despite most companies in this sector are using some of the best commercially available substance tracking tools, there are still likely to be unidentified uses which will not be found by companies until late in the restriction process. Even a 13.5-year derogation cannot shield companies and healthcare providers from the consequences of suppliers' mistakes.

Regarding emissions of PFAS, medical device manufacturers are not required under current EU legislation to measure PFAS emissions and so COCIR has no data. However, all COCIR members use PFAS in solid form in production processes which are mostly assembly lines and in products at temperatures where emissions will not be expected to occur. At end of life, most COCIR's members' products are collected under the WEEE Directive system, for recycling within the EU for the valuable metals content by smelting and melting. The WEEE Directive and other EU waste legislation aims to prevent harmful emissions and recover valuable materials including critical raw materials. Materials are not sent to landfill and those that are not recovered are incinerated at approved EU waste facilities.

COCIR currently estimates that about 26.3 tonnes of PFAS per year is present in newly placed on the market medical imaging and radiotherapy equipment.

Impacts on society (Chapter 6)

This chapter adds additional information to chapter 4 of Part I. Without a derogation for a sufficient number of years the following consequences can be expected.
Most medical imaging and radiotherapy devices will need to be discontinued with a consequential **reduction in access to healthcare for hundreds of millions of patients** from EIF to at least 2040. It would take probably a considerable time after 2040 before availability of medical devices would normalize improving access to critical healthcare (see Part I, chapter 4).

COCIR estimates that over a 15-year period, about **1 to 6 billion fewer imaging examinations** may not be carried out due to unrepairable older devices having to be disposed of and new replacements not being available. This is on average about 90 to 400 million examinations per year.

In Part I COCIR described the correlation between a reduction in MRI density and the impact on cancer patients that may not receive proper care (2.5 million). Extending the findings to other modalities which are routinely used for cancer diagnosis, contouring and staging, the reduction in density can possibly cause **tens of millions of cancer patients** not to receive proper healthcare and maybe reduce their chances for better outcome at least until (and beyond) 2040. A 13.5 year derogation could lower such numbers to a few thousand. In addition:

- The impact on cancer patients is compounded by the recent surge in cancer cases, reportedly up by 40%, that will require an even larger increased availability of radiotherapy and proton therapy centres.
- The already serious problem with waiting times for healthcare getting longer in the EU will be exacerbated and add to the negative impacts so far experienced.

Impacts on economy (Chapter 6)

Manufacturers with factories in the EU will lose competitiveness compared with companies who manufacture outside of the EU.

COCIR estimate that **at least 100,000 jobs** will be lost from EU medical device factories and more by EU refurbishers and also by COCIR's members suppliers. Also, as products cannot be sold in the EU, additional job losses would be expected including sales, marketing, and other roles. There may also be job losses of medical professionals if equipment they would normally be using is no longer available.

COCIR have estimated the cost of redesign, testing and approvals. The cost will depend on whether a long (e.g. 13.5 years after EIF) derogation is granted because, manufacturers periodically redesign their products and would need to test and gain approvals for these new designs. However, they do not and could not do this for all of their products at once. COCIR's estimate of the cost for substitution even with a derogation, based on previous experience will be several billions of euros. Without a derogation, EU manufacturers expect to fully lose all revenue from EU-based customers from medical imaging and radiotherapy equipment after EIF and so may be forced to cease trading.

Loss of global sales from EU factories, if there is no derogation, is estimated at about **€10 billion per year.** This loss will be permanent as companies will have to relocate their EU factories out of the EU to be able to serve the non-EU market.

Disposal of components and parts in warehouses is predicted to be about **€100 million,** based on previous experience with EU substance restrictions.

COCIR cannot determine suppliers' costs but expect this to be very significant based on previous experience with the RoHS Directive, which was calculated to have cost the electronics industry **$32 billion** to replace just six substances.

PFAS emissions from use phase and end-of-life (Chapter 7 and 8)

Manufacturing

COCIR Members mostly use components and parts manufactured by other suppliers.

During use

The forms of PFAS used in medical imaging and radiotherapy equipment are mostly polymeric, or as non-volatile additives in polymers, lubricants, or adhesives. Medical imaging and radiotherapy equipment operates at ambient temperature in hospitals with a few non-relevant exceptions. At and below ambient temperature, there will be no vapour emissions of PFAS during the use of the equipment and fluoropolymers will not decompose to form monomers. Emissions of PFAS from use and disposal of medical imaging and radiotherapy equipment are expected to be negligible.

During disposal and recycling

Disposal of equipment made by COCIR members is regulated by the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU). COCIR's members' equipment is valuable metal-rich and so is always recycled to recover the metal content. Due to the heavy nature and high value of most of COCIR members' equipment, almost all is believed to be recycled within the EU and the recycling processes used are regulated by EU waste legislation, including the Industrial Emissions Directive (2010/75/EU).

COCIR's members' equipment does not contain volatile PFAS such as hydrofluorocarbons and so these substances should not cause emissions during collection, storage, dismantling or sorting of scrap materials. Electrical equipment recycling is efficiently carried out in the EU and strongly regulated by EU legislation.

Evidence that all PFAS are destroyed by high temperature incineration is available from several recent studies and a recent study shows that no harmful PFAS emissions occur with well-run incinerators.

Derogation needs

For the above-mentioned technical reasons and in order to avoid the socio-economic impacts, **COCIR recommends derogating medical imaging and radiotherapy devices and all other medical devices used in a modern imaging or radiotherapy suite for at least 13.5 years.**

At the end of the derogation period it is expected that some uses will be identified for which alternatives will not be available, there has been insufficient time for redesign or where the alternatives would be regrettable substitutions so should not be used. In these cases, a mechanism to renew the derogation would be essential. As such, a review clause is included in our proposal, supposing that 3 to 3.5 years for the evaluation of requested derogations and adoption of an amendment to the legislation will be sufficient.

The "repair as produced principle" is essential to allow continued servicing and repair of medical imaging and radiotherapy equipment already in use at hospitals and clinics in the EU. The Medical Device Regulation does not allow for spare parts different from the validated ones to be used, therefore it would be impossible to repair or maintain any device with parts containing PFAS with PFAS-free parts.

In the spirit of the EU's Circular Economy Policy the PFAS restriction must also allow equipment that has been placed on the market before EIF can continue to be leased, re-sold, or loaned between hospitals, brokers, and manufacturers. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such, the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits for sustainability.

It has been already proven (and published) under the RoHS Directive, for Exemptions 31a and 47 that the reuse of spare parts is always better from an environmental and health perspective than generating waste and manufacturing new parts (which may use critical raw materials or other Substances of Concern (SoCs)) so the same principle enshrined by the RoHS Directive should also be reflected in the PFAS restriction.

COCIR's recommendations for the wording of additional PFAS derogations

1.	***By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices, their accessories and other medical devices required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, and other ancillary equipment that are needed***

to use these types of medical devices, until 13.5 years after EIF.

Justification: A derogation for 13.5 years after EIF is needed to allow continued supply of medical imaging and radiotherapy (including proton therapy) equipment as well as ancillary equipment that is needed to use these medical devices.

2. ***Paragraphs 1 and 2 shall not apply to PFAS for the use in new spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before 13.5 years after EIF.***

Justification: A derogation is also needed for spare parts to repair existing products in hospitals and clinics, for 13.5 years after EIF. The above wording is based on wording used in the RoHS Directive that allows the use of spare parts that contain RoHS substances:

3. ***Paragraphs 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging suite or radiotherapy procedures, placed on the market for the first time before EIF+13.5.***

Justification: The above wording is required for medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) so that it can continue to be sold, transferred, leased, donated between hospitals, taken back, and refurbished to increase safety and performance for the useful life of the equipment. Such reuse should be supported under EU circularity principles.

4. ***Paragraphs 1 and 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other medical devices, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.***

Justification: A time unlimited derogation is needed to allow circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.

5. ***The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other medical devices required in a modern imaging or radiotherapy suite and submit proposals for amending the regulation, by 10 years after EIF years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation or add new derogations for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation***.

Justification: Wording needs to be included to ensure that the PFAS restriction and its derogations are reviewed after, for example 10 years after EIF to allow the continued use of PFAS for any uses that are discovered to have no possible substitute materials or

designs. Enough time is needed for the EU to assess requests for derogations and amend the legislation to allow them to be adopted and enter into force before the initial 13.5 year period expires.

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ABBREVIATIONS AND ACRONYMS

3D- CRT	Three dimensional conformal radiotherapy
ABS	Acrylonitrile butadiene styrene
BOMcheck	A software tool for identifying and managing hazardous substances within product parts
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
Covid	Coronavirus disease 2019
CT	Computed tomography – multi-directional X-ray for diagnostics
DEHP	Diethyl hexyl phthalate
ECHA	European Chemicals Agency
EDI	Electronic data exchange
EEE	Electrical and electronic equipment
EIF	Entry into force
ETFE	Ethylene tetrafluoroethylene
EU	European Union
FDA	Food and Drug Administration, USA
FEP	Tetrafluoroethylene-hexafluoropropene copolymer
G-force	Gravitational force
IC	Integrated circuits
IGRT	Image guided radiation therapy
IMAT	Intensity modulated arc therapy
IMRT	Intensity modulated radiation therapy
LINAC	Linear particle accelerator, used for different treatment procedures (3-D CRT, IGRT, IMRT, SBRT, IMAT)
MDD	Medical Devices Directive
MDR	Medical Device Regulation
ME / ME device	Medical electrical / Medical electrical device
MR signal	Magnetic resonance signal
MRI	Magnet resonance imaging – detailed imaging of soft tissues
OEM	Original Equipment Manufacturer
PA	Polyamide
PC	Polycarbonate
PET	Positron emission tomography – A type of nuclear imaging technique used for diagnostics

POF	Polydioctylfluorene copolymer
PTFE	Polytetrafluoroethylene
PVC	Polyvinyl chloride
PVDF	Polyvinylidene fluoride
R&D	Research and development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation
RF	Radiofrequency
RINA	RINA Tech UK Limited
RoHS	Restriction of Hazardous Substances Directive
RT	Radiotherapy – a photon-based X-ray cancer treatment
SBRT / SABR	Stereotactic body radiotherapy / stereotactic ablative radiotherapy
SoCs	Substance of Concern
SPECT	Single photon emission tomography – A type of nuclear imaging technique used for diagnostics
SVHC	Substance of Very High Concern as defined in the REACH regulation, and on the Candidate List for Substitution
TEE	Transesphageal Echocardiography
TV	Television
US/USA	United States of America
VDF	Vinylidene fluoride
WEEE	Waste electrical and electronic equipment

1 INTRODUCTION

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health information and communications technology (ICT) and electromedical industries. RINA Tech UK Limited (RINA) and COCIR have gathered information from COCIR members and other sources to respond to the call for comment on the restriction of per- and polyfluoroalkyl substances (PFAS). COCIR submitted a preliminary document (Part I) in June 2023, mainly to highlight the urgent need for a derogation for medical imaging and radiotherapy equipment.

Part I included:

- A profile of COCIR membership, its products, and the unique difficulties that a PFAS restriction would have on this sector (section 1).
- Preliminary examples of uses and substitution issues (section 2), a more comprehensive list of uses and description of substitution issues are provided here in Part II.
- A detailed description of the processes to develop new products and the timescales involved. Part I also covered spare parts and refurbishment timescales (section 3). A summary of timescale dates is provided in Part II.
- An initial socio-economic assessment was included in Part I with a detailed estimation of the impact of the proposed restriction on the future provision of MRI scanner examinations (section 4). Part II assesses the impact for all medical imaging devices.
- Social impact on EU patients from the effect of the proposed restriction on MRI equipment (section 4.4).
- The impact on enforced obsolescence: spares / repairs / maintenance and refurbishment (section 4.5), economic impact on hospitals and healthcare (section 4.6), the impact on circular economy and refurbishment (section 4.7) and on innovation (section 4.8)
- Preliminary data on emissions of PFAS (section 5). This section has been expanded in Part II with additional data.

2 USES OF PFAS WITHIN COCIR MEMBER COMPANY PRODUCTS

Some example uses were included in Part I of COCIR's submission. All PFAS and their uses identified by COCIR's members, so far are described below. Note that other uses will exist but have not yet been identified because of the long and complex supply chains. Previous experience with substance restrictions has shown that the data gathering could take at least 3 years to complete, although COCIR members should be able to identify most uses after about one year from now. This mostly depends on the capability of suppliers and sub-suppliers, to identify substances as PFAS within their application.

Medical imaging and radiotherapy devices are very complex and can contain more than 100,000 components. Each of these devices may contain several hundreds or thousands of parts that contain PFAS although most COCIR members do not yet know the full extent as they are still waiting for responses from their supply chains. COCIR members identify PTFE

as the most commonly used PFAS in their products, with one COCIR member stating that a typical patient monitor will contain at least 90 parts containing PTFE plus other parts with different PFAS. One supplier of parts to a COCIR member has however identified 56 different types of PFAS in widely used components such as capacitors, connectors, cable assembles, switches, filters, inductors, labels, and many others.

The majority of PFAS containing parts used by COCIR member contain <1g of PFAS, for example, an electronic component containing 25µg of PTFE and a part with lubricant containing only 1µg of PFAS are used. There are also a limited number of parts containing more PFAS such as PTFE sleeving.

2.1 PFAS and their uses in medical imaging, radiotherapy and associated equipment

PFAS and their uses identified so far by COCIR's members include the following:

Table 1. Examples of identified PFAS and uses in electrical components and parts used in medical devices.

Full name of PFAS	CAS number	Uses
Ethene, 1,1,2,2-tetrafluoro-, homopolymer (PTFE)	9002-84-0	Sleeving, tubes, heat-shrink tubing, wire insulation, rubber boots for cables, dust caps, adhesives, lubricants, insulation for special lamps. These component parts and materials are widely used in printers, AC/DC power supplies, many types of electronic components such as crimp and other types of connectors, transistors, diodes, etc.
PTFE	9002-84-0	Used as an additive in paints and adhesives, and as a mold release agent (used for polyurethane foam, polycarbonate and other polymer moldings).
PTFE	9002-84-0	Additive in anaerobic acrylic sealant used to construct medical displays and other parts of medical devices. Also used in adhesives for alkali and nickel metal hydride batteries.
PTFE	9002-84-0	Lubricating grease for assembly of anesthesia gases seals and gaskets. Also used in grease

Full name of PFAS	CAS number	Uses
		used to lubricate internal moving parts of equipment and in production machinery. This is also used in wire pulling lubricants (mainly for multistrand wire as it aids flexibility) so thin films may occur on wire surfaces (with any type of insulation).
PTFE	9002-84-0	Sliding bearings and gear wheels used for X-ray imaging diagnostics device, Computed Radiography and Dry Imagers.
Propane, 1,1,1,2,2,3,3-heptafluoro-3-[(1,2,2-trifluoroethenyl)oxy]-, polymer with 1,1,2,2-tetrafluoroethene	26655-00-5	Wire insulation, co-axial cables. Also used in high voltage (5kV) transformers.
1-Hexene, 3,3,4,4,5,5,6,6,6-nonafluoro-, polymer with ethene and 1,1,2,2-tetrafluoroethene (ETFE)	68258-85-5	Wire insulation including transformers. Also used for cable ties that can be used at high temperatures.
Potassium nonafluorobutane sulphonate (often used with PTFE or other PFAS)	29420-49-3	Additive flame retardant in polycarbonate (PC) and PC/ABS used for housings of medical display housings and patient monitors (This substance is a REACH Substance of Very High Concern (SVHC) and is not a polymer). Also used in backlight units, insulation sheets and chokes (an electronic component).
PVDF (polyvinylidene fluoride), PFA (perfluoroalkoxyalkane), PTFE, 1,1,2,2-Tetrafluoroethyl 2,2,3,3-tetrafluoropropyl ether, etc.	4937-79-9, 6655-00-5, 9002-84-0, etc.	Used in lithium-ion batteries[1]. Batteries are widely used in medical devices.
Tetrafluoroethylene-hexafluoropropene copolymer (FEP)	25067-11-2	Cable insulation.
Polymer containing: • Potassium nonafluorobutane sulphonate • Perfluorobutane sulphonic acid	29420-49-3, 375-73-5, 59933-66-3, 25628-08-4	Parts contained in AC power adaptors.

[1] More details available from PFAS submissions from RECHARGE and Battery Association of Japan (BAJ).

Full name of PFAS	CAS number	Uses
• Nonafluotobutane sulphonic acid hydrate • N,N,N-triethylethanaminium 1,1,2,2,3,3,4,4,4-nonafluorobutane-1-sulfonate		
Hexane1,1,1,2,2,3,3,4,4,55,666-tetradecafluorohexane	355-42-0	Additive in adhesives.
Diammonium N-ethylheptadecafluoro-N-(2-(phosphonatooxy)ethyl)octanesulphonamidate	67969-69-1	USB connectors .
PTFE and FEP	9002-84-0, 25067-11-2	Catheters used during imaging as well as other medical procedures
FKM Type 2 which contains VDF, TFE, HFP	-	Flexible sheath of transoesophageal ultrasound medical device (see section 3 on substitution issues).
Homo-polymer of vinylidene fluoride (VDF) and hexafluoropropylene (HFP)	9011-17-0,	O-rings, seals, gaskets and patient contact rubber parts.
Sulfo-, 1,4-bis(3,3,4,4,5,5,6,6,6-nonafluorohexyl)ester, sodium salt and Poly(oxy-1,2-ethanediyl), α-methyl-ω-[[3,4,4,4-tetrafluoro-2-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-1,3-bis(trifluoromethyl)-1-buten-1-yl]oxy]-	54549-95-0, 83731-88-8	Surfactants and antistatic agents used on X-ray films.
sulfo-, 1,4-bis(3,3,4,4,5,5,6,6,6-nonafluorohexyl)ester, sodium salt, Sodium 2,3-bis(3,3,4,4,5,5,6,6,6-nonafluorohexyloxycarbonyl)propane-1-sulfonate and 1-[2-(Trifluoromethyl)quinazolin-4(1H)-ylidene]-4-(2,4,4-trimethylpentan-2-yl)semicarbazide (also contains a PFHxA substance	54549-95-0, 402913-85-3, 243843-53-0	Surfactant, antistatic agent and development accelerator used on dry imaging film.
Fluoroethylene/vinyl ether (solvent soluble polymer)	-	Used on imaging plates that are used in place of X-ray film to digitize X-ray image.
Perfluoroalkyl group-containing oligomer	-	Dispersing aid (surfactant) to improve the dispersibility of the conductive layer on digital flat panel detectors based on gadolinium oxysulfide scintillators.

Full name of PFAS	CAS number	Uses
Unidentified PFAS	-	Filter membranes for anesthesia gases.
Nafion (sulfonated tetrafluoroethylene based fluoropolymer-copolymer)	66796-30-3	Tubes used for humidity balancing in anesthesia devices.
Unidentified heat exchange fluids (e.g. produced by Galden, DuPont, 3M and others)	-	Heat exchanger fluid are inert fluids that are used to provide cooling in ultrasound probes.

2.2 Electrical components

Some types of electrical and electronic components contain fluoropolymers in the form of insulated wires, adhesives, and other parts. This is required because these components are surface mount soldered onto circuit boards by heating them inside ovens at over 240°C and most alternative polymers cannot withstand this temperature. COCIR will need to rely on electrical component manufacturers to substitute PFAS in components such as surface mount relays, transformers, inductors, connectors, various types of valves, sensors, etc. The electronics industry has stated that this will take at least five years and up to 13.5 years to complete. It is likely that some components will become obsolete, and this is especially likely for those parts made in only small numbers or if substitution proves to be technically impossible. This would mean that there will not be drop-in replacements for some types of components available to COCIR members and so their only option will be to redesign circuit boards and equipment (but this cannot start until obsolescence is confirmed by the component supplier). This is regarded as a significant change requiring Medical Devices Regulation (MDR) approval which will take many years after the component supplier announces the obsolescence. Under these circumstances, it is more likely that the medical product will become obsolete and therefore discontinued, impacting the availability of medical devices.

2.3 Fluoropolymer insulated cables

Most PFAS uses, in terms of quantity, in medical imaging and radiotherapy equipment are as fluoropolymer cable insulation. For example:

Table 2. Examples of fluoropolymer insulation used for cables in medical imaging and radiotherapy equipment.

PFAS polymers	End-use equipment	Comments
FEP, ETFE, PFA	Robotic arms of angiography systems	Main cable assembly typically with more than 20 individual cables. Needs to be very flexible and capable of rapid flexing when robotic arm moves.
PTFE	MRI	Cables must be suitable at very low temperature with good flexibility and low thermal conductivity, have a low dielectric

PFAS polymers	End-use equipment	Comments
		constant so does not distort images and be an excellent insulator for high voltages.
PTFE and polyamide/ Polydioctylfluorene copolymer(PA POF)	Angiography systems, main cable assembly and is also used for cooling hoses	Required to have low friction as cables slide against each other with minimal wear and have superior bending performance.
PTFE (components) and PFA/PTFE (cable insulation)	MRI body and transmit coil. Used in cables and components for coils	Must have a low dielectric constant so that it does not absorb much energy from electromagnetic fields and also have a high dielectric strength to prevent insulation breakdown in the high power radio-frequency (RF) field.
Various, including PTFE	X-ray equipment, including direct radiography (DR) detectors, X-ray tubes, collimators, generators, film cassettes and CR "Computed Radiography" cassettes. Also, digitisers that convert phosphor screen images into digital information.	Many components of all types of X-ray imaging equipment rely on parts (e.g. cables, circuit boards, etc.) that contain PFAS. Without PFAS, no X-ray imaging equipment could be sold in the EU and repairs will not be possible if replacement parts contain PFAS.
ETFE, PTFE	Radiography system	Cable assembly for patient table with more than 15 cables. Insulation must be thin (to fit into a confined space), low friction to avoid wear, very flexible and be fire retardant.
FEP, ETFE, PFA	Ultrasound imaging	Up to 256 thin flexible insulated wires to connect to multi-array probes. Fluoropolymer insulation can be as thin as 0.1mm but alternatives are all thicker.
PFA	Ultrasound probe cable	Cable insulation must have a very low dielectric constant, PFAS have the lowest of all polymers.
PTFE, PFA	MRI, ultrasound and X-Ray generating modules	These require electrically insulated transformers, tubes, cables that are immersed in transformer oil and so must be oil resistant. They must also have a low dielectric constant similar to the oil for electric field mitigation. A high breakdown voltage is also required.
PTFE, FEP, ETFE	MRI, CT, X-ray and ultrasound cables and connectors	Must provide very good electrical insulation at high frequencies and so have a combination of essential performance requirements including low dielectric constant of 2.1 to 2.3, dissipation factor of

PFAS polymers	End-use equipment	Comments
		about 0.0002, rated temperature of 100°C or higher, and electrical length (phase) variation is -100 PPM/°C or less.
Various fluoropolymers (PTFE, PVDF, FEP, PFA), side-chain fluorinated polymers (Fluorinated (meth)acrylate polymers, fluorinated urethane polymers, Fluorinated oxetane polymers) and perfluoropolyethers	Radiotherapy equipment, PFAS is used in cables to connect different sub-systems of the equipment	Cables include high voltage power as well as low voltage signals and communication. Cables also need to be flexible to bend to allow for the gantry to rotate 360 deg. Flexibility plays an important role in routing the cables around the machine. Thinner cables result in smaller bending radius. Performance of PFAS cables is superior to all substitutes, due to less stress and strain on the cables owing to lower bending radius, in highly dense sub-systems where bending radius is of a prime concern. Cables with PTFE as a dielectric performs well as they result in lower signal losses owing to better signal transmission. Polymers must also be fire retardant and suitable for a wide temperature range. Cables will be exposed to ionizing radiation for long periods and must not degrade.

Fluoropolymer insulated cables are used in many types of imaging equipment due to its unique combination of properties which include:

- They are inherently flame resistant, so flame retardants do not need to be added to the polymer.
- Excellent flexibility which is important when making connection to moving parts such as patient tables in MRI, CT, etc., and connections to X-ray sources and detectors.
- They maintain flexibility and stability over a very wide temperature range, for example, fluorinated ethylene propylene (FEP) can be used at temperatures well below -200°C to over +200°C. Some areas close to the superconducting magnet inside MRI scanners can reach very low temperatures, with some instances below -200°C.
- Cables with fluoropolymer insulation are suitable for very high frequency signals, which is essential for transmitting huge amounts of data generated by MRI, PET, and CT scans. With MRI, they must be able to do this within powerful magnetic and electric fields.
- Fluoropolymers are biocompatible according to ISO 10993, which means that they can be placed in physical contact with patients' skin. Most potential alternatives have not been certified as biocompatible.
- Low friction resistance is essential in cable assemblies where wires need to slide against each other. Friction causes wear and shortens the equipment's useful lifetime. Severe wear can cause a short circuit causing the equipment to malfunction which can be fatal

for patients. For example, radiotherapy systems need to accurately control the dose of radiation which is supplied to patients according to a strict schedule. A fault could mean that patients cannot be treated.

- Low dielectric constant is important in MRI because patients need to be exposed to high Radiofrequency (RF) fields. If the cable's dielectric constant is not low, currents are generated and dissipates the RF field, which degrades the MRI image.
- High dielectric strength is important for MRI where cables are exposed to high power electric fields. If the insulation has too low dielectric strength, it will break down causing the equipment to fail.

Other essential performance properties include suitability for heat, chemical and UV sterilisation.

Further illustrative example uses of fluoropolymer cables in medical devices include:

- Cables used to connect to MRI coils which are devices used to scan parts of patients and are connected to the MRI scanner. These cables must have a negligible impact on the image quality. MRI scanners detect hydrogen atoms in materials within patients' bodies and so hydrogen atoms in the materials of cable connections could affect image quality and so must be minimised by careful selection of materials. Fluoropolymers have a very low hydrogen atom content being based on -CF2- groups in polymer chains whereas all non-PFAS polymers are based on -CH2- groups. Substitution for PFAS will therefore be very difficult.
- Insulation made with PFAS polymers can be very thin and very flexible; this is essential for making electrical connections to types of ultrasound probes that use arrays of piezoelectric elements which require up to 256 thin individual wires to connect to the ultrasound probe array. Each element is very small with many elements arranged in a small area. The wires must be very thin and flexible to allow the medical technician to move the probe precisely to where it is needed. Also, the PFAS insulation used is biocompatible according to ISO 10993. Very few other polymers are biocompatible, and all other polymers used for wire insulation are thicker and most are less flexible. These requirements are also essential for connections to robotic arms of X-ray equipment and in other types of medical device where movement occurs.

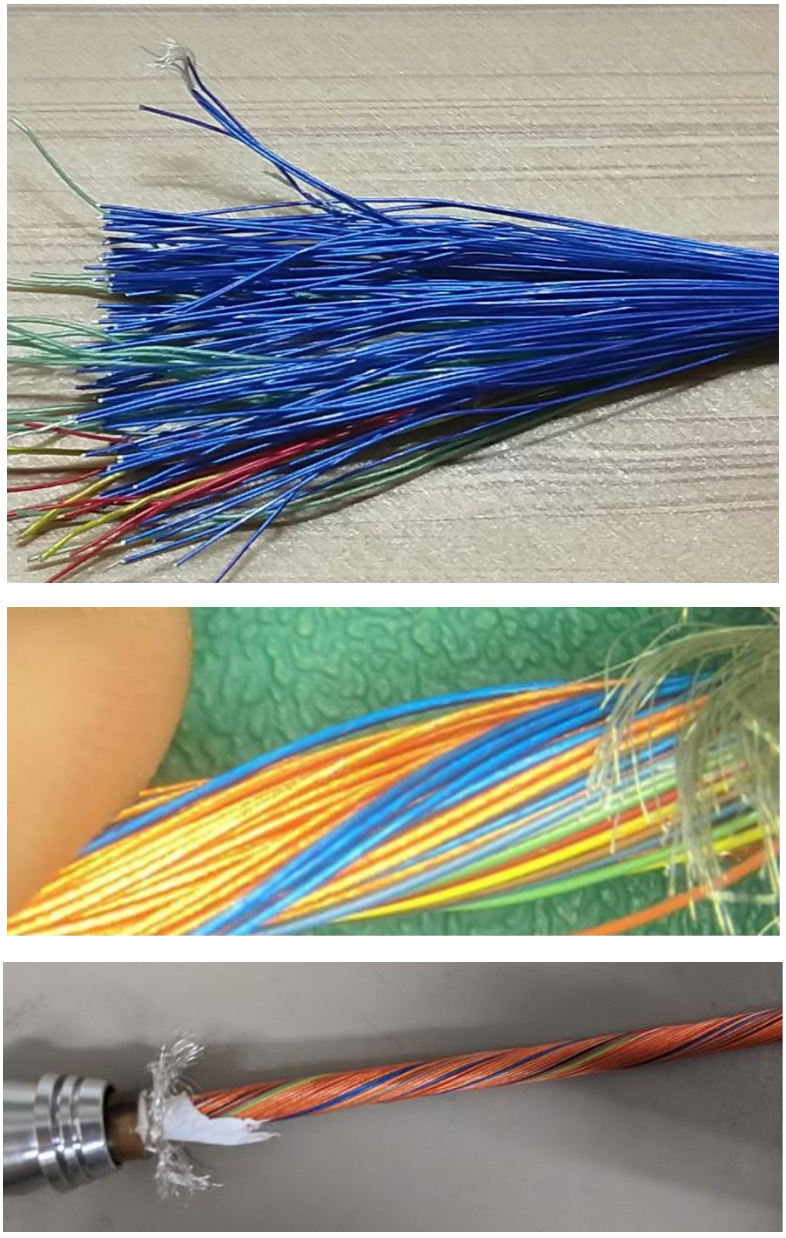


Figure 1. Examples of multi-strand cables for connection to ultrasound probes (source COCIR)

- The polymer must not generate static electricity when two parts rub against each other. This is especially important for MRI as static discharge will affect the image which could prevent accurate diagnosis. Static electricity discharge is undesirable for all medical imaging devices as this may cause patients to move which distorts images and the "spikes" can also affect images. This is also important for radiotherapy where patients must not move so that only the tumour is irradiated. Silicone and polyester are especially susceptible to static generation, but other polymers are also prone to this and so need to be avoided. Fluoropolymers do not cause static issues.

It is also worthwhile noting that medical devices also use special cable assemblies of complex designs that need to function in unusual conditions. For example, certain cables

in CT need to operate at very high frequency and high power.

Source: COCIR

Figure 2: Representation of the complex internal structure of a high power cable

- Many cables used in radiotherapy equipment are exposed to ionising radiation. These cables have multiple essential requirements as listed in Table 2 including radiation tolerance. At present, there are no known substitutes. Degradation due to radiation is difficult to accelerate realistically and so testing of potential substitutes will take many years.

There are some cables used in Magnetic Resonance (MR) devices that will experience extremely low temperatures and severe stresses while they also need to be safe in high magnetic fields. They are required to be extensively tested in MR environment to ensure image quality is not affected:

- MR signal: All materials used in or near the imaging volume of MRI scanners are required not to exceed a certain level of electromagnetic response in the frequency range of interest for MR imaging during and after exposure to electromagnetic excitation by MR transmit signals.
- Electrostatic spikes: Any material used within the MRI exam room has to be evaluated for potential build-up of electrostatic energy that could discharge during imaging to an extent, hampering MR imaging (spikes).

Although there may sometimes be alternatives, these will only rarely be a suitable as a drop-in replacement and material reformulation and equipment redesign will usually be needed. In many cases, no suitable drop-in alternative material is likely to be identified, then substitution may be achieved only via redesign of the medical device so that the PFAS material can be avoided, and this will take much more time and will require re-approval by an EU Notified Body. In these instances, a derogation from the restriction would be essential for the continued supply of these devices to EU hospitals and clinics, or alternatively exclusion from the restriction altogether by derogation, so that the medical devices sector has the necessary time to develop alternatives for these applications.

2.4 Integrated circuits

Integrated circuits (IC) are widely used by all of the electronics industry. PFAS chemicals and materials are used to manufacture, test and package these components but most of

the ICs themselves do not contain PFAS. Therefore, many of the types of ICs that are manufactured in the EU are likely to become obsolete, even with a long derogation. It is not worthwhile for IC manufacturers to revalidate new PFAS-free processes for older types of IC as this would be too costly. Therefore, usually IC manufacturers would continue to sell older designs of components until this is no longer possible, such as when a derogation expires. These old designs of IC would then be replaced with new designs that have functional differences so are not drop in replacements. Also, IC manufacturers do not announce future obsolescence early to prevent loss of sales of these older components. Medical device manufacturers are not able to start work on redesign until they know which ICs will become obsolete and new designs are available. The many types of ICs that are currently manufactured in Austria, Ireland, France, Germany, Hungary, Italy, Czech Republic, Finland, Sweden, Belgium, and the Netherlands would be affected.

Medical device manufacturers will therefore need to redesign circuit boards when any current ICs become obsolete and the new alternative does not have the same characteristics. One COCIR member company has reported that one MRI scanner contains 600 separate printed circuit boards all of which contain ICs. It typically takes one design engineer one year to redesign one circuit board. If many ICs become obsolete and many circuits need to be redesigned, this can take many years due to the limited number of design engineers who are capable of doing this work. In addition, after redesign, the MRI scanner must be tested and re-approved by an EU Notified Body before it can be sold in the EU, which takes many years. Another COCIR member reports that when one important IC was made obsolete, it took nearly 5 years before a redesigned product could be sold in the EU and at a cost of €5million. The timescales for substitution will be an issue for COCIR's members. One COCIR member has estimated that the cost of ICs being replaced by the semiconductor industry due to a PFAS restriction could be € 400 million for 5 years, with the next generation of medical devices being delayed by 3 to 4 years. The EU semiconductor industry is likely to need a derogation of at least 13.5 years, after which new designs of IC may become available. Only when these ICs are obtained by COCIR members can they redesign, test, and obtain re-approval of medical devices which can take another 10+ years making a total of over 23 years after EIF for all types of products.

Additionally, changes in electronic components, such as different IC die attach formulations, will need extensive life testing to ensure the medical equipment is safe and reliable for the duration of their long life (requirement by the EU Medical Device Regulation). Many components are used in harsh environments that produce excessive mechanical and thermal stresses, such as high G-forces in CT gantries, extreme temperatures near superconducting electromagnets, extremely high magnetic fields in MRI and exposure to ionizing radiation in radiotherapy equipment.

2.5 Lubricants

Several types of PFAS are used in lubricants, with PTFE being one of the more commonly used. One critical use that has been identified so far, is the use in automatic injectors that are used to inject minute quantities of contrast agents into patients for most imaging procedures, such as CT, MRI, PET, or fluoroscopy examinations. Another use is in a grease that is used to assemble fluoropolymer seals and gaskets in anaesthesia equipment. Greases that contain PTFE or other PFAS polymers are used to lubricate moving parts of medical devices and are intended to give many years of service with minimal maintenance. They are also used in production machinery. PFAS polymers have, as shown above in section

2.3 the lowest coefficient of friction of any polymers and so are the best long-lifetime polymer lubricants. Fluoropolymers are regarded as having superior chemical and moisture resistance than other types such as molybdenum disulphide and graphite. In applications where PFAS lubricants are currently used, research and testing will be required to determine which PFAS-free substitute offers adequate lubricant and how long the lubrication is maintained before maintenance is required. It is conceivable that for some uses, equipment redesign may be the only option that may or may not succeed. Some of those applications may require an extension beyond the 13.5 years derogation requested by COCIR because, at present, there seems to be no alternative able to satisfy minimum performance requirements for current technologies.

2.6 Elastomers

Medical imaging and radiotherapy equipment uses PFAS elastomers because these give superior performance and longer lifetimes in the applications where they are used. The main types used are FKM rubbers as defined by ASTM International standard D1418 and ISO standard 1629 which includes vinylidene fluoride (VDF) and hexafluoropropylene (HFP) copolymers, also known as Viton (or FKM). Several other types that contain other fluoropolymers are also used for chemical resistance, flexibility at low temperature or for high temperature chemical resistance. There are several PFAS-free elastomers, but each has different properties and limitations and where a PFAS elastomer is currently used, it is unlikely that a suitable drop-in replacement will exist and so significant testing and probably also redesign will be needed for each of the current uses of PFAS elastomers.

2.7 Medicinal products

Some imaging procedures using ultrasound, X-ray, PET, and SPECT require the use of contrast agents which are types of diagnostic medicinal products. These contrast agents are used to visualise tumours, blood vessels or parts of internal organs. Active substances defined as PFAS within the scope of the restriction proposal have been provided with a time-unlimited derogation, However, these and non-PFAS active substances are manufactured in the EEA using PFAS chemicals which would be in scope of REACH and so a PFAS restriction would prevent the manufacture of contrast agents in EEA factories, which would in turn be forced to close or relocate to outside of EEA territory. The contrast agents could also not be imported into the EU because they need to be contained in packaging that contains PFAS. For example, PFAS are used in the seals of these containers to prevent leaks which is important for PET contrast agents as they become radioactive material following radiolabelling performed on the site of usage at healthcare providers. As the contrast agents are injected into patients, they must not be contaminated by the packaging materials. Most types of polymers contain additives that can leach out into the contrast agents and so cannot be used. PFAS polymers are used because they can form perfect seals and do not contain additives that could cause contamination. Changing packaging of medicinal products is not straightforward as this must be tested for realistically long periods (to reflect transport conditions and storage times) and approved before it can be used. A successful testing and validating change procedure would also require the submission or update of registered marked authorisations provided to the medicinal product in every jurisdiction where the medicinal product is intended placed on the market and is a process which may take 2 to 4 years. This is also an issue for the packaging of any other types of pharmaceuticals such as anaesthetics, disinfectants and

drugs that are used during imaging and radiotherapy procedures and manufacturers need sufficient time to identify suitable substitute materials, carry out testing and gain approvals.

Millions of procedures are carried out each year in Europe using contrast agents. COCIR estimates that 20 million procedures using contrast agents are carried out each year for X-ray/CT in the EU and many more procedures for MRI, PET, and ultrasound. Production of contrast agents is a specialised and complex process and global production only just meets demand so that any disruption to the availability of contrast agents will prevent medical procedures using X-ray, MRI, etc., from being carried out in the EU. For example, during the COVID pandemic, one Chinese factory was closed causing significant global shortages in 2022[2]. Significant quantities of contrast agents are manufactured in the EU so if EU factories are unable to operate because of a PFAS restriction, global shortages would result and many millions of medical diagnostic and treatment procedures that use these substances could not be carried out.

3 SUBSTITUTION ISSUES

It is important to note that COCIR's members manufacture medical devices and are users of cables, mouldings, components and sub-assemblies and they will have to rely on their suppliers to develop suitable substitutes. Ideally, substitutes should be drop-in replacements with identical performance, however, this is very unlikely to be possible for PFAS. Regulatory re-approval will be needed before a re-designed medical device or one with a substitute material having different performance characteristics can be sold in the EU. COCIR's members options are to ask suppliers to develop alternatives that meet the required performance specifications, i.e. be identical drop-in replacements or if this is impossible, which COCIR believe will usually be the case, complete re-design of medical devices will be necessary and this takes a long time, as discussed in Part I and summarised below in section 5. Redesign could succeed in certain cases, but degradation of clinical performances or decreased reliability and worse safety risks would not be acceptable and would prevent inferior substitute designs from being sold in the EU. Therefore, derogations may need to be granted for extended period of times, until more suitable alternatives are developed.

PFAS are reported by COCIR members to be widely used in medical devices and therefore many materials and components will need to be changed. In many cases, substitution will be initially carried out by the component manufacturer. Once these alternatives are available, medical device manufacturers will then need to assess the alternative to ensure it meets the necessary technical and safety requirements. Only when the substitutes have been identified, replaced, evaluated, proven to be suitable and no less reliable, accurate or effective and safe can they be used in a medical device and be approved for sale in the EU.

3.1 Cable insulation substitution issues

Each use of fluoropolymer cables has a unique range of essential requirements. MRI for example is a very demanding environment as some cables are exposed to very powerful magnetic and electric fields and some also need to operate at very low temperature. At present there is no known substitute wire insulation material that has all of the essential

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10155429/

performance criteria, so substitution will depend on either entirely new polymers being developed, as there are no suitable drop-in replacements for use in medical devices available now, or complete redesign, which will be difficult and time consuming and may not always be technically possible.

Table 3 below compares examples of commonly used cable insulation materials with some of the fluoropolymers used in medical devices. Note that these are typical values as the actual values vary depending on the additives used, such as fillers, flame retardants and pigments as well as water absorption % and the test conditions.

Table 3. Comparison of properties of commonly used cable insulation materials.[3]

Polymer		Dynamic friction coefficient	Lowest usable temperature (°C)	Dielectric constant at 1MHz	Breakdown voltage kV/mm	Water absorbtion
PFAS	PTFE	0.1	-60 to -268	2.1	25	0.01%
	FEP	0.1	-268	2.1	20	0.01%
PFAS-free	XLPE	0.26	-30	2.4	50	0.03%
	PA	0.3	Ca. -30	4.0	25	2.0%
	PVC	0.3	-55	4.0	10	0.4%
	Polyimide (DuPont datasheet)	0.48	<-200	3.4	-	Ca. 2%

- A low dynamic friction coefficient is important when cables need to slide against each other without sticking or causing wear. Fluoropolymers have the lowest friction coefficient.
- A low usable temperature is essential for use in MRI scanners close to the superconducting magnet. Most types of polymers become hard and brittle and will degrade when any vibration or movement occurs, which is a feature of MRI scans.
- Low dielectric constant and high breakdown voltage are requirements for MRI applications as the cables are exposed to powerful magnetic and electric fields. Fluoropolymers have the lowest dielectric constant of any polymer and so provide the best high frequency data transmission performance.
- Low water absorption is beneficial where steam or chemical sterilisation is used to avoid significant dimensional changes (i.e. swelling). Water absorption can also affect the electrical properties of the insulation.

[3] Various sources of data including https://www.lube-media.com/wp-content/uploads/2017/11/Lube-Tech106-PolymerTribology.pdf and https://myelectrical.com/notes/entryid/178/cable-insulation-properties

Flexibility is another important characteristic especially for robotic arms and connections to moving parts. Flexibility depends on the materials' hardness, stiffness and bend radius but is not defined by one single parameter. Good bending fatigue performance of the polymer is also essential for a long lifetime without failures. Usually, manufacturers need to test materials under realistic conditions to identify suitable materials.

Some commonly used cable insulation is clearly unsuitable as it is too stiff, such as halogen-free cross-linked polypropylene (XLPP) which contains a high proportion of mineral flame retardant that makes it very inflexible. Some of the softer, more flexible materials, such as silicone, have poor wear resistance and silicones can generate static electricity which causes electrical faults. One COCIR member has assessed PFAS-free hoses for angiography systems. PFAS gives a long lifetime and excellent bend radius with minimal wear at a high bending speed of movement. Fabric hoses have been tested as a possible substitute but had inferior wear properties and bend radius and so would fail much sooner than PFAS hoses. This is unacceptable to hospitals as it means that the angiography equipment would need to be repaired more frequently and will be out of use for significant periods of time so that seriously ill patients could not be treated. Angiography is commonly used for operations during emergency surgery meaning that a system failure, or its unavailability could be fatal.

Low temperature: The only flexible cable insulation materials that are rated for below -200°C are fluoropolymers and polyimide (e.g. Kapton) insulation. Polyimide is however very different to fluoropolymers and historically has been the cause of failures in military and civil aircraft[4]. Also, it has a relatively high thermal conductivity, especially at low temperatures (0.8W/mK at ambient) unlike fluoropolymers (0.3W/mK at ambient) which is a serious disadvantage for MRI. Polyimide also has a relatively high dynamic friction coefficient so is not a drop-in replacement.

Combination of requirements: Substitution is complicated because each application has its own combination of essential requirements so that a single suitable substitute for all uses will not exist. For many uses, as discussed above in section2.3, a low susceptibility to static build up is important. Some parts need to be sterilised by heat, chemicals, or UV without damage and where contact with patients' skin occurs, the material must be tested and approved for biocompatibility. This means that manufacturers are limited to medical grades of polymers where skin contact may occur. COCIR expects that there will not be suitable drop-in replacements for current uses of fluoropolymers as no PFAS-free materials will have the same combination of essential requirements. It is likely that if a PFAS-free polymer were feasible, it would already be in used where they are suitable as PFAS-free polymers are usually much lower cost than PFAS polymers. COCIR's members expect that the only way to replace PFAS polymers would be by re-design of their medical devices. As explained elsewhere in this submission, redesign, where possible, will take much longer than if drop-in replacements were available.

3.2 Flame retardant plastics

Fluoropolymers are inherently flame resistant and so flame retardant additives are not required unlike with most other types of polymer. All of the medical devices covered by this

[4] https://lectromec.com/should-polyimide-insulated-wire-by-trusted/

submission are required by the MDR to comply with EU safety standards and these include a requirement that plastic parts that are associated with electrical circuits are flame resistant. Resistance to burning is very important because up to 500,000 fires are caused by electrical faults in Europe annually[5] and this would be much worse without fire resistant plastics.

Polycarbonate (PC), ABS (acrylonitrile butadiene styrene) and PC/ABS are used in medical devices because these plastics are tough and not easily damaged by, for example impacts from hard objects or by being dropped. Impacts can easily occur in emergency situations. Common uses are in housings and transparent covers to prevent patients and hospital staff from coming into contact with live electricity. The most commonly used flame retardant for PC and PC/ABS, and sometimes also in ABS, that does not degrade the mechanical properties or appearance is potassium nonafluorobutane sulphonate, which is suitable in transparent and coloured materials. This flame retardant also prevents drips of flaming liquid from occurring in fires, which are a main cause of fires spreading. Most alternatives have been reported to be unsuitable[6] but recent research with polydimethylsiloxanes is showing promising results.

Medical devices are not made solely for the EU and each model is sold globally and so must comply with legislation in the EU, USA, China, Japan, and all other countries where they are marketed. Therefore, plastics must meet the UL V0 fire retardancy standard which is required in the USA. Only PC and PC/ABS containing potassium nonafluorobutane sulphonate can meet the UL V0 requirements and also be effective with thin sheet (0.8 – 1 mm). Currently, no PFAS-free substitutes exists that can meet all of these requirements.

COCIR members want to avoid regrettable substitutions. One possible substitute for PC/ABS is bisphenol A diphosphate[7]. According to reference 6, this has technical performance disadvantages but also, being based on bisphenol A, it may degrade into this substance which is an endocrine disrupting substance.

Research by COCIR's members' suppliers to identify suitable alternatives will need to be carried out. Samples of PFAS-free flame-resistant polymer need to first be obtained and parts extruded for testing. Some materials may prove to be unsuitable, but if any meet COCIR's members' specifications, they can be assessed and tested in medical devices. Re-approvals will also be required. The timescale is uncertain because at present, COCIR's members have not yet identified all of the PFAS-polymer parts that require substitution and also obtaining samples of suitable substitutes has not yet been possible.

The applicable safety standard for flame resistance is IEC 60601-1 for medical devices. In relation to fire and flammability, IEC 60601-1 specifies the maximum permissible temperatures of devices under certain conditions, such as whether there is skin contact or whether contact is likely. In general, fires or escaping flames, which can also lead to excessive temperatures, must be avoided. This standard has requirements placed on medical electrical equipment, for example, in oxygen-enriched environments (i.e. where

[5] https://www.eaton.com/content/dam/eaton/markets/residential/fire-safety/documents/Eaton-Fire-Safety-season-infographic-EN.pdf

[6] https://www.sciencedirect.com/science/article/abs/pii/S1359836822002530

[7] https://www.3dxtech.com/wp-content/uploads/2021/06/FR_PCABS_SDS_v1.0.pdf

patients receive oxygen) or the fire resistance of housings. This standard also formulates special requirements with regard to accompanying documents, power supply, housing structure and isolating device.

For electrical and electronic medical devices, the common harmonised EU standards are:

- EN50575 (Electrical cables permanently installed, and subject to the Construction Products Regulation (CPR)) EN 50575 is a regulation which brings together common classification, criteria, and monitoring requirements to form seven 'Euroclasses'. These classes have fire performance assessment processes based on EN 60332-1-2, EN 50399 and EN ISO 1716. There are additional tests for Smoke Production, Flaming Droplets and Acidity.
- EN 60950-1 Information technology equipment
- EN 60065 Audio, video, and similar electronic apparatus
- EN 60335-1 Household and similar electrical appliances

The tests used for meeting the fire safety requirements of electrical and electronic equipment to EN 60950-1 and EN 60065 are the flammability tests to IEC/EN 60695-11-10 (UL94) (HB-V2-V1-V0) and IEC/EN 60695-11-20 (UL94) (5VA-5VB) and in addition the needle flame test to EN 60695-11-5.

The tests used for appliances to EN 60335-1 are the glow wire tests to:

- 60695-2-10 Glow-wire apparatus
- 60695-2-11 Glow-wire flammability test for end products (GWT)
- 60695-2-12 Glow-wire flammability index test for materials (GWFI)
- 60695-2-13 Glow-wire temperature test for materials (GWIT)

For cables, there are a series of 'Euroclasses' for the cable, which determine how and where it can be used. This is assessed on the outcomes of the following test methods:

- EN ISO 1716 A method for the determination of the gross heat of combustion (QPCS) of products at constant volume in a bomb calorimeter
- EN 50399 Burning behaviour of bunched cables
- EN60332-1-2 Fire test on a single cable

Because COCIR's members products are sold internationally, compliance with other standards are also required to ensure fire safety:

- UL94 Flammability tests of plastic materials for parts in devices and applications
- UL 1581 Reference standard for electrical wires, cables, and flexible cords
- UL 1694 Standard for Tests for Flammability of Small Polymeric Component Materials

- UL 2556 Wire and cable test methods

UL 60601-1 (previously UL 2601-1) is the U.S. national standard for safety testing electrical medical devices. The standard is based on IEC 60601-1 with U.S. national differences. These differences are the broadest and most detailed of all the national deviations to IEC 60601-1, and include implications on flame resistance. The differences arise for a variety of reasons (see Table II), including UL requirements for recognized components dealing with fire, shock, and safety hazards. These differences address components that do not have a harmonized IEC component standard. The deviations are identified in UL 60601-1 as "DC national differences".

The international base standard, IEC 60601-1, does not call out requirements for flammability for polymeric materials. However, the U.S. national deviation in UL 60601-1 refers to the "Standard for Polymeric Materials—Use in Electrical Equipment Evaluations," UL 746C which describes polymeric materials in detail. The general flammability testing requirements in the US are UL 94 – Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances. The U.S. national differences in UL 60601-1 require a minimum flame rating of UL 94V-2 for transportable equipment and UL 94V-0 for fixed or stationary equipment. If the fire enclosure is sourced by circuits limited to less than 15 W, flammability requirements are not required.

For existing equipment, currently in service and being manufactured, parts as originally designed and validated for use, will need to continue to be available throughout the life of the equipment to maintain the existing validation for the equipment. Cost of revalidation of existing equipment for new parts (i.e. of a different design owing to substitution of a substance) is normally too high, and not justifiable, resulting in reduction in life of the medical equipment in service, which adds cost and disruption to currently extremely stretched MRI, CT, and other services.

3.3 Dry bearings and gear wheels

Medical devices are designed for continuous use for many years with minimal need for preventive maintenance as patients cannot be diagnosed or treated while maintenance is carried out. Many types of medical imaging and radiotherapy devices have bearings and gear wheels to allow parts to move easily and smoothly, such as robotic arms and rotating parts of MRI and CT. Fluoropolymers, such as PTFE are often the technically optimal choice for these applications as fluid lubricants (oil or grease) are not needed due to the very low coefficient of friction of fluoropolymers. As shown above in Table 3, fluoropolymers have the lowest friction coefficient of 0.1 or lower, whereas all other polymers have higher values. Polyethylene is one of the lowest friction options of the PFAS-free polymers with a coefficient of at least 0.2, which is at least double that of fluoropolymers[8]. One publication[9] states that PTFE has the lowest static friction coefficient of any polymer (from stationary to moving) of 0.05. Bearings and gear wheels are designed to last the lifetime of the medical device and if liquid lubricants can be avoided, this reduces the need for downtimes for

[8] More details are outlined within http://www.appstate.edu/~clementsjs/polymerproperties/$p$lastics_$f$riction$5f$w$ear.pdf

[9] https://www.researchgate.net/figure/Comparison-of-Teflon-friction-coefficients-at-normal-pressures-of-129-and-387-kPa_fig3_241035366#:~:text=The%20coefficient%20of%20friction%20for,also%20nearly%20equal%20%5B16%5D.

maintenance. Bearings and gear wheels will suffer from wear, but this can be minimised by the choice of materials and design. If medical device manufacturers have to find substitutes for PTFE, then their choices are limited:

- PFAS-free polymers – all are likely to wear more rapidly as they have higher friction coefficients. Increased friction generates heat which could cause over-heating resulting in seizure which will destroy the bearing or gears.
- Leaded copper alloys – these can be used without lubricants or with only small amounts that last a long time, but lead is not permitted in medical devices by the RoHS Directive.
- Metal parts with lubricating grease or oil – This would require a total redesign and extensive testing to determine:

    a) The design needs to stop start frequently. It is a highly challenging to ensure lubrication when parts are frequently stationary because lubricant flows away from the bearing surfaces while the equipment is not moving. As a result, there may be no lubricant present for a short period when movement starts, and this will increase the wear rate and any wear particles will disperse into the lubricating grease or oil causing it to be less effective.
    b) A suitable maintenance schedule that gives an acceptable lifetime without an increased maintenance frequency.
    c) How to avoid oil and grease contamination in the hospital.
    d) If the design has a suitably long lifetime of at least 15 years and ideally longer.

Substitutes to PFAS are therefore all inferior, which is why PTFE was originally chosen. It will therefore be difficult to identify materials and designs that give reliability and performance that are acceptable to medical device Notified bodies who will be asked to approve the new designs.

3.4 Ultrasound TEE probe bending neck sheath

One essential use of PFAS polymers is for flexible sheaths that cover the mechanical linkages and electric cable bundles in the articulatable region of Transesphageal Echocardiography (TEE) ultrasound transducers that are inserted into the oesophagus, via the larynx, of patients to obtain real-time images, doppler based blood flow and functional assessment measurements of the human heart. These covers have many essential requirements as follows:

- Electrical insulation to meet Body-Floating (BF) rating (as defined by EN 60601-1).
- Mechanically flexible. The transducer must be positioned in a manner relevant to the heart to acquire images and doppler traces to assess cardiac disease. The transducer must maintain positive contact with the oesophageal wall or fundus in the transgastric position such that acoustic energy can flow from and back to the transducer. Any changes in acoustic impedance in the acoustic path, such as imaging through air, will be deleterious on the ability for the transducer to image.

  The position of the transducer and contact forces are maintained by a control mechanism that is located proximally to the transducer tip in a manner similar to a gastroendoscope. High flexibility with low control wheel resistance of the flexible region

of the transducer is paramount so that the physician performing the TEE study uses tactile feel of the distal tip to determine the appropriate amount of force to position and maintain good acoustic contact while not applying excessive force that could cause oesophageal trauma or injury. The flexibility of the bending neck sheath is a primary factor in determining the tactile response to the overall transducer.

- Low friction resistance. As stated above (in Table 3), PFAS polymers have the lowest friction coefficient.
- Highly resistant to cut through from patient's teeth and surgical instruments (they are often pre-cleaned with instruments such as hypodermic needles, scissors, or scalpels).
- Biocompatible. The transducer including the sheath is inserted into patients' bodies and so must not leach out chemicals that are harmful or might cause sensitisation. This includes substances that are either additives in the polymer or have been absorbed during sterilisation cleaning. This eliminates the use of most PFAS-free polymers as water absorption of most are much higher than PFAS (as shown in Table 3).
- Must be resistant to a wide variety of cleaning, disinfection and sterilization agents including enzymatic cleaners, glutaraldehyde, ortho-phthalaldehyde (OPA), peracetic acid, and Ultraviolet light (UV-C), often in automated cleaning systems that operate at high temperature (e.g. up to 120°C).
- Durable enough to last for the intended multi-use life of a TEE transducer.

All COCIR members who produce this type of device have to use PFAS polymers for this type of application. One of these manufacturers has searched for a suitable PFAS-free substitute but has found that there are no PFAS-free polymers that match all of the above list of essential requirements. Substitution is therefore currently impossible.

3.5 Dry X-ray imaging films

Many hospitals in the EU use dry imaging film for X-ray examinations. These films rely on PFAS to obtain the required high-quality images. Without these films, hospitals with X-ray equipment that use these films will not be able to obtain X-ray images of their patients if PFAS is restricted without a derogation. Films are produced with several PFAS as described in Table 1 and are needed to provide all of the following essential properties:

- Surface tension control of coating liquid as a coating aid,
- Stabilization of dispersion of hydrophobic functional materials as an emulsion dispersant,
- Adjusting the charge of the coating film and suppressing static as a conductive material,
- Providing smoothness on the surface of sensitive materials as a lubricating material,
- Adds antifouling property to the surface as a surface modifier.

X-ray film manufacturers have not been able to identify PFAS-free substitutes that provide all of the above properties.

4 QUANTITIES OF PFAS USED IN MEDICAL IMAGING AND RADIOTHERAPY PRODUCTS

Determination of the quantity of PFAS used in medical imaging and radiography equipment requires knowledge of all uses. As yet this assessment is still not complete and is not expected to be available for at least one year and may take at least 3 years to complete.

Under the assumption that everything that could be PFAS was considered as PFAS, in Part I COCIR estimated 300g of PFAS fluoropolymers is used in big scanners such as CT, MRI, PET etc. and Linear Particle Accelerators (LINACS). As demonstrated below, with new information, COCIR has been able to recalculate the quantity more accurately. Only small amounts are used in devices such as Ultrasound and in most types of X-ray imaging devices, whereas large angiography systems with robotic arms and MRI, where PFAS is used in large cable assemblies, contain larger amounts of PFAS. The initial estimate given in Part I resulted in a total comprised between 3 and **10.6 tons** of PFAS used in the sector in Europe every year, with most being in the form of fluoropolymers.

Considering the quantitates reported in the restriction proposal, in Part I we stated that COCIR accounts for a **0,0012% of the total manufacture and uses** of PFAS in Europe and **0,02% of the use in the medical devices sector (using the worst-case scenario).**

Further research by COCIR members is being carried out to determine the quantities of PFAS in their products, but as explained in section 2, this is not yet complete. However, some COCIR members have determined that some products contain more than the initial 300g estimate and some types contain much less. The most PFAS in a medical imaging device is about 10kg (special case of very large cable assemblies) whereas the least is probably less than 10 grams. The types of equipment that contain the largest quantity of PFAS are the largest and most complex types which are sold in relatively small numbers whereas the smaller simpler products with much less PFAS tend to have much larger sales. Therefore, the total quantity of PFAS in new products sold in the EU annually has been estimated as follows:

- Assume that CT, MRI, PET, and the most complex types of X-ray equipment contain on average 5kg PFAS.
- Assume that other types of X-ray and ultrasound equipment contain about 100g and 10 grams of PFAS respectively.
- Annual sales of medical imaging and radiography equipment have been estimated by COCIR using published data and confidential data from its members.

Based on the above assumptions, the total annual amount of PFAS per year is now estimated to be about **26.3 tonnes** or **0.003%** of all PFAS used in the EU[10].

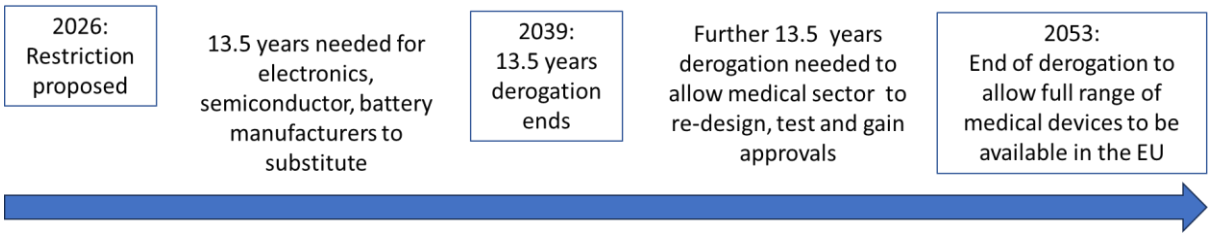
5 ESTIMATED TRANSITION TIME TO PFAS-FREE ALTERNATIVES

COCIR members believe, based on the methodology and analysis provided in Part I that a derogation for medical imaging and radiotherapy devices is required and the minimum

[10] COCIR has used the estimated total quantity of 837,000 tonnes of PFAS provided in the Annex XV report.

technical period is 13.5 years. However, in addition, this would be acceptable only if there is a mechanism put in place in the derogation text for a mandatory review by the European Commission of the derogations with clear timelines and with the possibility of extensions for some applications where evidence is provided to justify an extension of the expiry date. COCIR members know that substitution is currently not possible for many of their current uses due to the lack of PFAS free parts and components. As such they are not able to start working on PFAS replacement. It seems certain that after 13.5 years COCIR will be aware of certain applications for PFAS that an additional derogation period will be needed to allow the continued sale of medical devices. This mechanism, such as a review followed by amending the REACH Regulation, must result in new derogations in force before the 13.5 year after EIF period expires.

One major issue for medical device manufacturers is that before they can start the redesign process described above, suitable PFAS-free components and materials will need to be developed and commercially available. COCIR is aware that the electronics and semiconductors industries, as well as the industries for many other types of components (such as batteries) need a considerable time period to develop substitutes and will be requesting derogations of 13.5 years or longer. This is likely to mean that COCIR's members will be forced to follow the timescale shown below:



The above is a worst-case scenario as medical device manufacturers will start looking for substitutes as soon as the final version of the PFAS restriction is confirmed. However, COCIR believes that for most medical imaging and radiotherapy products, the above timescale is reasonable and will be needed for many types of products. It will be essential that further, more specific derogations can be requested and adopted where substitution proves not to be possible. As a result, it is essential that the EU carry out a review before the suggested initial 13.5-year derogations end (early enough to amend the legislation before derogation expiry). Such that they are able to determine the time needed to complete substitutions and to amend the legislation. This will allow these newly identified additional derogations to be adopted before the initial derogations expire.

Alternatively, inclusion of medical devices in the scope of the restriction could be postponed until all types of substitute components and materials have been developed and are freely available, although sufficient time will still be needed for redesign, testing and approvals.

6 SOCIO ECONOMIC IMPACT ASSESSMENT - IMPACT ON AVAILABILITY OF MEDICAL DEVICES AND HEALTHCARE IN THE EU

Hospitals use the most suitable imaging technique to diagnose and treat patients. Some diagnostic and treatment procedures have been developed using one specific type of

medical imaging device and this includes many types of ultrasound imaging equipment as well as MRI, PET, CT, etc. Therefore, if, for example, a hospital's ultrasound machine that is used for these types of medical procedure were to fail, due to a part that contains PFAS, after PFAS is restricted without a derogation, the hospital could not repair or replace their machine. This loss of a device will not only affect patients who need this device to be used for their treatment, but also the hospital staff who use it, who may lose their jobs.

The proposed restriction of PFAS in the EU would, without the derogations requested in this submission, have severe negative effects which will include the following:

- Harm and potentially deaths of EU patients from a lack of availability of medical devices.
- Increased costs for EU hospitals and clinics.
- Loss of competitiveness for EU manufacturers and refurbishers of medical devices.
- Loss of EU jobs.

Each of these are described below.

6.1 Extension of the MRI calculation to other imaging modalities

The calculations for MRI in Part I, which were based on EU sales of MRI and numbers of scans carried out, can be performed for Computer Tomography (CT) and X-ray Angiography as COCIR has been collecting sales numbers of such modalities in units (not just market value) and data about density of the installed base. For other modalities such as PET and SPECT, ultrasound, general radiology, mammography, or fluoroscopy COCIR is not able to perform similar simulations, although we do not expect results to be dissimilar.

If PFAS is banned as proposed but without a derogation for medical imaging and radiotherapy equipment, as requested in this submission, all COCIR members have stated that they **will not be able to sell at least 95% of their products** in the EU until new re-designed products have been developed, tested, and approved. This will include radiotherapy, MRI, CT, PET, SPECT, all types of X-ray and ultrasound imaging. With no sales possible, EU hospitals and clinics will be affected in several ways:

- They will not be able to buy new or refurbished products to be able to treat existing and new patients. Hospitals in all EU states have growing waiting lists and so need to increase the number of available medical imaging and radiotherapy equipment that they have available, especially radiotherapy, MRI, PET and SPECT and CT. Lack of availability will have a negative impact on EU patients.
- Hospitals will not be able to replace older equipment with new state-of-the art models. Typically, MRI, CT, etc., are replaced by hospitals after about 10 years because the performance of new designs gives superior diagnosis and treatment with better outcomes for patients. As a result, they will be forced to use their older equipment for longer than is desirable, and this will have a negative impact on patients' treatment. Leasing or the loan of equipment would also not be permitted by a REACH PFAS restriction.

- As with all electrical products, medical devices sometimes fail and need to be repaired. Some parts wear out and faults sometimes develop, especially when the equipment is relatively old and nearing the end of its normal lifetime. If a part needs to be replaced by one that contains PFAS or is made in the EU with PFAS, this will not be possible and so the medical device could not be repaired. Repairs are the first choice of hospitals who cannot afford to replace all of their defective equipment. As no new equipment will be available, the net results will be a decrease in the number of medical imaging and radiotherapy products in hospitals available to treat patients.

The impact of the proposed restriction will vary depending on the type of medical device. Newer advanced technologies such as radiotherapy, MRI, PET and SPECT and CT are required at higher volumes in EU hospitals in order to treat an ever-growing list of patients, reduce waiting lists and improve patient outcomes, but manufacturers will not be able to supply these products. Older types of medical device, such as most types of X-ray imaging and ultrasound will normally be expected to be replaced when they become too old to be reliable or because their performance cannot match newer models. However, some new devices will also be required as demand for treatment continues to increase in the EU. It is difficult to estimate the future impact from the proposed restriction on patients as future sales are affected by all of the above factors, as well as economic factors. It is also not known whether there is spare capacity in some EU States. This seems to be unlikely, as waiting lists are growing throughout the EU, although a lack of medical technicians may also be a limitation.

Considering that CT, ultrasound, and X-ray devices are even more numerous in Europe than MRI, with far more examinations per year. It is hard to estimate if the impact of reduced availability of equipment can be partially supplemented by a higher use of the existing installed base. Unfortunately, recent data on waiting times for diagnostic examinations in Europe is pointing to a fairly different picture, where existing equipment is already being used at maximum capacity and so any decrease in availability will have a negative effect on EU patients' health.

Despite the uncertainties described in Part I of this submission, COCIR has attempted to estimate the possible future impact of the proposed restriction on the provision of treatment using the types of medical imaging device manufactured by its members, using two calculation methods.

Method 1

Using method 1, the impact is shown below as the number of diagnoses / treatments that may not be carried out between 2026 and 2040 if no PFAS derogation is granted. This is estimated using the MRI calculations shown above and data from NHS England[11] on the numbers of diagnostic procedures carried out in England in 2019 (the last year before COVID 19)[12]. This data shows that there were 44.9 million examinations in 2019 for a

[11] This data is used here because NHS England publishes detailed data on the numbers of examinations of each type that are carried out each year. Although the UK is no longer in the EU, it is likely that the ratio of types of examination are not very different to the EU average (No EU data of this type appears to be available).

[12] https://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2020/10/Annual-Statistical-Release-2019-20-PDF-1.4MB.pdf

population of 56.3 million.

- Standard X-ray (excludes CT) 51.7%
- Diagnostic ultrasound 22.9%
- CT 13.4%
- MRI 8.5%
- PET and SPECT 0.55%

The percentages across the EU will not be identical to England but are likely to be similar. Also, the EU's population in 2019 was 448 million at the end of 2019.

Table 4. Method 1: Total number of diagnostic procedures that could not be carried out in the EU between 2026 and 2040 if there is no PFAS derogation.

Modality	**Assumed proportion of examinations, based on NHS England data**	**Patients treated per year by one device**	**Total number of procedures that would not be carried out without a PFAS derogation over 15 years (2016 to 2040)**
MRI	8.5%	4000 – 6000(a)	474 million to 710 million (from section 4.3 of Part I)
CT	13.4%	6000 – 17000(a)	1,121 to 3,171 million
PET / SPECT	0.55%	2000 – 2500(a)	15 to 19 million
Other X-ray	51.7%	2800(b)	2,015 to 2,018 million
Ultrasound	22.9%	1000(c)	319 million
Total			**3.95 to 6.24 billion**

a = Data from COCIR members

b = Estimate assuming 1 examination takes 1 hour, used 6 days/ week and 9 hours per day

c = Estimate from the European Society of Radiology group of ultrasound in Europe[13]

Using this estimation method, the total number of examinations that may not be carried out in the EU during the period 2026 to 2040 due to hospitals not being able to buy new or replace their medical imaging equipment is 3.95 to 6.24 billion or **263 to 415 million per year** on average during this period.

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3731462/

Method 2

As these totals are surprisingly large, an alternative method has been used for comparison. This method determines the number of examinations that cannot be carried out due to medical imaging equipment reaching end-of-life but cannot be replaced. In 2026, we assume the stocks will be similar to the current quantity. In 2027, and each subsequent year until 2038, it is assumed that 5% of the stock will reach its end-of-life[14]. This is a lifetime of 20 years, which is longer than most hospitals use of medical devices This is because equipment is likely to develop faults that cannot be repaired due to an inability to supply parts containing PFAS or there are no parts available for such old machines. If we use only the minimum number of examinations that are typically achieved by each medical device per year from Table 4, the calculated numbers are as follows (with three example years plus totals assuming 5% disposal per year and a comparison with 3% and 7.5%):

Table 5. Method 2: Estimates of the numbers of examinations that cannot be carried out 2027 to 2038 due to a PFAS restriction with no derogations.

Modality	Number if 5% reach end-of-life each year (millions)				3% disposal per year	7.5% disposal per year
	2027	2033	2038	Total 2027 to 2038	2027 – 2038 (million)	2027 – 2038 (million)
MRI	2.08	14.6	22.9	152	91	228
CT	2.25	15.8	24.8	164	98	246
PET / SPECT	0.1	0.7	1.1	7.3	4.4	11
Other X-ray	6.7	46.7	73.4	487	292	731
Ultrasound	12	84	132	876	526	1126
Total (million)	**23.1**	**162**	**254**	**1687**	**1012**	**2361**

Stocks of MRI, CT, PET, and SPECT are data published by EUROSTAT[15]. Stocks of other X-ray equipment is estimated from COCIR's confidential data and stocks of ultrasound machines

[14] Most medical imaging devices are designed to be used for at least 15 years. For this calculation COCIR has assumed that older equipment will be less reliable so that by 20 years on average, a significant proportion will develop unrepairable faults (as spare parts with PFAS cannot be used).

[15] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_resource_statistics_-_technical_resources_and_medical_technology

is based on an assumption that on average EU hospitals each have 10 machines[16] and there are 15,000 public hospitals in the EU[17] plus another 9000 private hospitals.

The results with method 2 are smaller than method 1 but method 2 assumes the minimum number of examinations carried out per year by each machine, and it assumes a disposal rate that is lower than is currently carried out where the lifetime of most machines is about 15 years including by second users. Method 2 also excludes purchase of new machines that would increase the EU stock, which would be very significant for MRI, CT, and PET/SPECT, but less significant for X-ray and ultrasound. COCIR therefore expects the true total to be somewhere between those of the two methods so will be in the range:

- Ca. 1 to 6 billion examinations over 15 years, or
- Ca. **90 million** (based on 5% disposal per year) to **400 million examinations per year** on average during the 15-year period.

Whatever the exact calculated impact of this restriction, if there is no derogation, the number of patients who will be examined by these techniques each year will decrease very significantly. These numbers will not recover until new PFAS-free models are developed and approved for sale in the EU. Note that these numbers do not include medical procedures that cannot be carried out due to a shortage of contrast agents as described in section 2.7.

The impact on radiotherapy is described below in section **Error! Reference source not found.**.

6.1.1 Limitations of the methodology

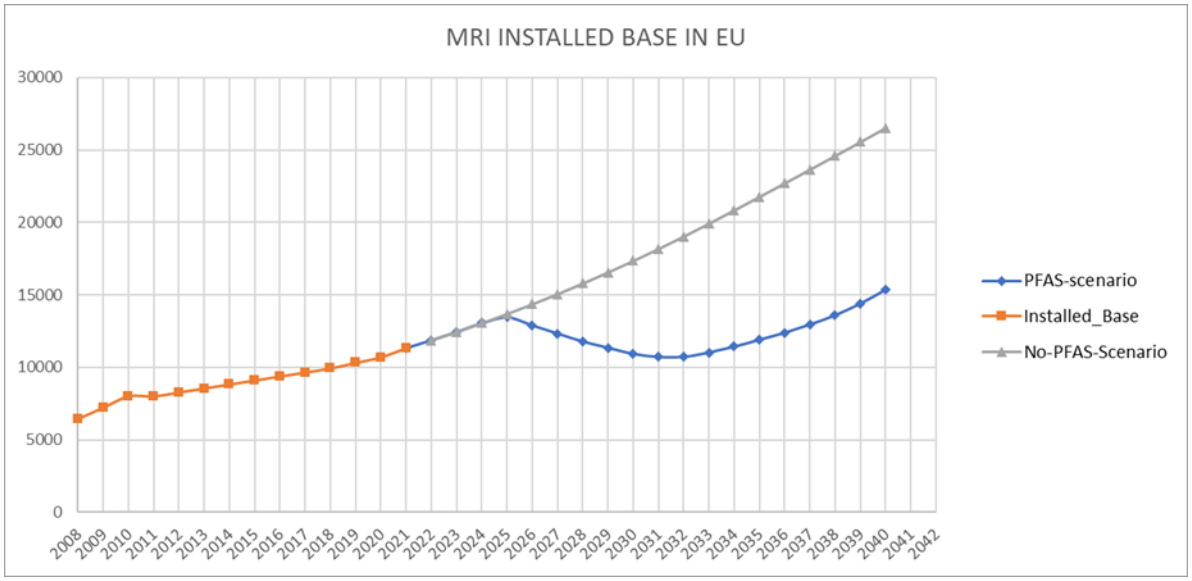
The forecast of MRI sales and the expected development of the installed base are based on expert opinions and simple linear extrapolations. It is possible that sales, and in particular the installed base (the number of medical imaging devices that are installed in EU hospitals), will stabilize at a certain point due to the finite number of hospitals and clinics in the EU (at around 24K hospitals each with one MRI installed[18], (figure 4-4 of our Part I submission is reproduced below). The actual number of installed MRI may however not level off if current research into prostrate cancer screening using MRI[19] is successful and is adopted in the EU as this will require many more MRI. MRI screening for prostrate will not however be possible if MRI cannot be sold in the EU due to a PFAS restriction.

[16] Estimated from data in https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3731462/

[17] http://www.hope.be/wp-content/uploads/2015/11/79_2009_OTHER_Hospitals-in-27-Member-States-of-the-European-Union-eng.pdf

[18] https://www.statista.com/forecasts/1166223/hospital-count-forecast-in-europe

[19] https://www.bbc.co.uk/news/health-66507893



However, older MRI will become obsolete /malfunction and need to be replaced by new or refurbished MRI scanners and this would not be possible if MRI sales are prevented by a PFAS restriction that is adopted without a derogation for medical imaging and radiotherapy equipment.

Publicly available data about usage of imaging equipment reports the number of examinations in EU, and not the number of patients. We assumed that "1 examination" = "1 patient" which is probably an overestimation with some patients needing more than one examination. The NHS England data used for method 1 is also for examinations, not the numbers of patients and some patients will experience multiple examinations during a year.

We also assumed equipment will be used at full capacity despite the increase in the installed base, in particular in the business-as-usual scenario. The assumption seems to be justified at least for the coming years, but it is hard to estimate how the situation of healthcare could be the closer we get to 2040.

The correlation between cancer mortality and equipment density is very weak, due to the many influencing factors that affect survival and the limited variability in density in the EU. However, qualitatively, it is known that cancer outcomes are improved by early diagnosis and treatment and so any effect that delays diagnosis, will inevitably negatively affect mortality**Error! Bookmark not defined.**.

One other important assumption is that most types of medical imaging equipment will be PFAS-free and approved for sale in the EU within 13.5 years after EIF. This may be over-optimistic as COCIR's members do not currently know of suitable substitutes for most current applications. If this work takes longer, more patients will be affected by a shortage of equipment, there will be longer delays and so logically, more cancer deaths could occur.

6.1.2 Conclusions

As already explained, COCIR notes that these estimations are based on broad and rough

assumptions and that the real impact could be one or more orders of magnitude lower. Nonetheless it is certain that:

- The restriction will negatively affect access to healthcare, in particular imaging diagnostics and radiotherapy.
- Several million, probably hundreds of millions of patients will be negatively affected depending on the time granted for a derogation considering all imaging modalities together.
- The longer the time allowed for companies to transition to PFAS free solutions, the lower will be the predicted impact on patients in the EU.
- The artificially induced scarcity of medical imaging and RT devices will exacerbate the already serious problems healthcare systems are facing in the EU with excessively long waiting times that translate into inferior healthcare and a higher excess death rate.

Considering the recent MDR experience, described in Part I, and the current difficulties being experienced by national healthcare systems, COCIR believes that a 13.5 year derogation period **plus** a review that considers additional specific derogations could be the best solution as it will ensure the phase out of PFAS where technically possible with the most limited impact on access to healthcare and on the health of patients.

6.2 Impact on competitiveness of EU manufacturers

There are at least 17 manufacturers of medical imaging and radiotherapy products globally although most only make some types of these products. For MRI, there are at least 7, of which three manufacture in the EU. The table below gives the minimum number[20] of global manufacturers for each type of medical device and how many of these manufacture products in the EU. Some of these manufacturers are not COCIR members so there is uncertainty of where some companies manufacture.

Table 6. Numbers of manufacturers of medical devices and the number who manufacture in the EU.

Type of medical device	Minimum number of global manufacturers	Number of EU manufacturers
MRI	9	3
CT	6	2
X-ray	11	4
Ultrasound	>10	At least 3
PET and SPECT	6	1 - 2

[20] These are the numbers that COCIR is aware of, however, in some cases there may be more.

Type of medical device	Minimum number of global manufacturers	Number of EU manufacturers
Radiotherapy	8	3
Particle therapy	2+	1

If the PFAS restriction is adopted without a derogation for medical imaging and radiotherapy equipment, none of these medical devices can be manufactured or refurbished in the EU. Sales of machines will also not be permitted in the EU but new and refurbished machines that are manufactured outside of the EU can continue to be sold to countries without PFAS restrictions. This will put manufacturers who produce products within the EU at a very significant competitive disadvantage compared with their non-EU competitors. EU manufacturers will not be able to manufacture any products, so will have nothing to supply to non-EU customers whereas their non-EU competitors who produce products outside of the EU can continue to operate normally outside of the EU.

	EU based manufacturers	Manufacturers located outside of the EU
Hospitals in the EU	No production possible	Production is possible but no sales to EU hospitals permitted as products contain PFAS.
Hospitals outside of the EU	No sales as production in the EU is not possible	Production is possible and sales will be permitted as no restrictions exist.

Figure 3. Effect of PFAS restriction on EU based manufacturers competitiveness

COCIR's members estimate that PFAS-free products will not be available to sell for at least 8 - 10 years in which time, they will have almost no income from the EU market, so there is a significant risk of bankruptcy.

6.3 Loss of EU jobs

COCIR members have determined that all medical imaging and radiotherapy products contain PFAS and so cannot be manufactured in the EU once these substances are restricted. If there is no derogation to allow time for redesign, testing and approvals, the employees in EU factories who manufacture the current range of products as well as those that refurbish in the EU will become redundant. Other job roles will also become redundant such as sales, marketing warehouse staff, etc., as well as jobs at EU suppliers if no products can be made or sold in the EU. COCIR has not been able to determine an accurate total number of job losses from its members or their suppliers but has estimated that this will affect at least 100,000 EU employees (excluding component suppliers). For example, one COCIR member that manufactures medical imaging and radiotherapy equipment in the EU has stated that there would be over 3000 job losses from one medical imaging product

type which could not be made in the EU plus many more losses from manufacturing MRI and other types of equipment. At least seven companies manufacture medical imaging and radiotherapy equipment in factories in the EU. Several companies refurbish medical devices in the EU, but this will not be possible if PFAS is restricted without a derogation. COCIR estimates that this would result in many hundreds of EU job losses.

The total EU job loss may be as high as 160,000 jobs as MedTech Europe estimate that there are 800,000 medical device workers[21] in the EU, of which 20% are involved in medical imaging and radiotherapy equipment.

Job losses by hospital staff could also occur. It is unclear how many job losses would occur as currently there is a severe shortage of many types of medical staff in the EU, but if medical imaging devices at hospitals fail and can't be replaced, the staff that use them may no longer have a job. This would affect jobs such as radiologists, sonographers, cardiologists, anesthesiologist, and potentially other roles. COCIR estimates that in total, there could eventually be more than 1000 medical staff job losses if PFAS is restricted without a derogation.

6.4 Costs incurred by manufacturers

COCIR has surveyed its members to determine the expected costs of this proposed legislation. Costs will include:

1) Redesign, testing and approvals of medical imaging and radiotherapy equipment,
2) Lost sales by EU manufacturers for their non-EU markets (as described in section 6.2),
3) Costs from disposal of components and parts that cannot be used, and
4) Suppliers costs.

The cost of all medical imaging and radiotherapy equipment redesign, testing and approvals is very uncertain because all current uses of PFAS have not yet been identified and the difficulty of substitution is not yet known.

One example of likely costs is for the cable assembly of angiography robotic arms. This is predicted to take two experienced engineers five years at a cost of €1.5 million which relates to only one part of the angiography system. Another example is the cable assembly to low temperature superconducting magnets of MRI scanners. This is a very demanding environment and so it is expected that at least four full-time trained and experienced engineers will require 10 years, at a cost of €6 million. PFAS is used in many other parts of MRI so the total cost for each model will be very large and at least many tens of millions of euros. COCIR has estimated the minimum costs of redesign, testing and approvals of medical imaging and radiotherapy equipment manufacturers as follows.

Two scenarios can be considered:

1. No derogation is granted so manufacturers would need to redesign all products simultaneously. This is not a viable option as medical device manufacturers do not

[21] MedTech Europe https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf

have sufficient numbers of trained and experienced engineers to do this. This would therefore take at least ten years, but with no income from the EU market to fund this work, many EU companies would be forced to cease trading.

2. With a derogation, granting manufacturers at least 13.5 years to redesign all products. Medical devices are periodically redesigned to improve their performance, diagnostic capability, to improve treatment or to reduce treatment costs. This is normally carried out one product at a time. With sufficient time allowed to substitute PFAS without stopping EU sales, PFAS substitution would be an additional task within the product redesign process and so the cost of PFAS substitution would be less than option 1 as testing and approvals would be carried out in the normal course of innovation.

COCIR has previously calculated the cost[22] of substitution of hazardous substances in medical imaging and radiotherapy equipment that were required by the EU RoHS Directive. The actual cost that was incurred by COCIR's members between 2010 and 2021 totaled **€800 million for substitution of ten substances**. The substitution of nine of these ten substances was straightforward and in most cases the costs were mainly due to one substance, lead, especially as solder. In reality, the true cost was much higher as many products had to be redesigned because suppliers made essential components such as integrated circuits obsolete, due to RoHS, but these redesign costs were not included in the above total.

The cost for PFAS substitution is expected to be much higher because there are many PFAS substances and uses and there are technical difficulties as explained above in section 3. It is also likely that many components will become obsolete requiring redesign of products. Some COCIR members have estimated the costs for substitution of PFAS in a few selected uses and these costs range from €3.6 million to replace a cable assembly, to €16 million for substitution of certain MRI cables. The likely cost to COCIR's members therefore for PFAS substitution is much higher than for RoHS is likely to exceed **several billions euros** at least.

With a 13.5 year derogation, work on substitution would be possible as EU manufacturers will be able to continue to operate and fund this work. Without a derogation, most will have no revenue and so will have to cease trading.

Recently a COCIR company estimated the cost of substitution of a lead-free chip set in a specific modality due to the decision of discontinuing the product (while medical devices were still excluded from the scope of RoHS) as €400 million taking 3 to 4 years as it involved full redesign of most of the PCBs. Such costs could not be estimated by COCIR in the study run in 2015[22] and as such increased the expected total cost significantly.

Companies that manufacturer medical imaging equipment in EU factories will not be permitted to make or sell these products (see Figure 3). This will affect sales to both the global non-EU and EU markets for at least 8 years and these companies with EU factories will have reduced sales for up to 15 years estimated **at about €10 billion** per year[23].

[22] Unpublished confidential COCIR report. This is available on request.

[23] COCIR has estimated this approximate total from revenue figures in company annual reports and COCIR's estimates of the proportion of production sites that are located in the EU. This total is for medical imaging and radiotherapy only that is manufactured in the EU.

Based on previous experience with RoHS and REACH substance restrictions, the value of components that become waste can be as much as **€100 million or more**, depending on the transition time and ability to supply these as spare parts.

Suppliers' costs are not known to COCIR but are expected to be, in total, very large. Some smaller suppliers are likely to cease trading. There is no doubt that component and sub-assembly suppliers will have very large costs for substitution and testing, but COCIR is not able to estimate this cost. Previous experience of EU substance restrictions such as the RoHS Directive have shown that costs can be extremely large, although this depends on the difficulty of substitution. One study found that the RoHS Directive cost the electronics industry **$32 billion**[24] and this was for only the original 6 substances; the proposed PFAS restriction will ban many thousands of substances, so the overall cost is expected to be magnitudes larger.

7 PFAS EMISSIONS FROM USE PHASE OF MEDICAL DEVICES

The forms of PFAS used in medical imaging and radiotherapy equipment are mostly polymeric, or as non-volatile additives in polymers, lubricants, or adhesives. Medical imaging and radiotherapy equipment operates at ambient temperature in hospitals with a few non-relevant exceptions[25]. At and below ambient temperature, there will be no vapour emissions of PFAS during the use of the equipment and fluoropolymers will not decompose to form monomers[26].

Micro-particles of polymers can be generated when polymers are abraded and wear. However, most uses of equipment by COCIR's members do not involve abrasion or wear. In some of COCIR's members' applications bundles of fluoropolymer cables are used in several types of medical imaging to make electrical connections to moving parts (as well as hose connections) as described in section 2.3 In these applications, the fluoropolymers slide against each other but with very low contact force. Fluoropolymers are known to wear if the contact force is high and they slide against a material with a high coefficient of friction such as metal, but wear can be negligible with low force and two fluoropolymer cables or hose sliding against each other. Fluoropolymers are used because of their low coefficient of friction which minimises any wear when wires slide against each other as well as other properties. As described in section 2.3. COCIR members have designed their products to avoid wear so that replacement of wiring assemblies is not required during the lifetime of products. COCIR members examine used products when they are refurbished and they are not aware that any significant wear occurs. In addition, if any wear were to occur, most uses of fluoropolymer wire and hoses are inside enclosures so no particulates can escape. In conclusion, therefore, emissions of PFAS during the use phase are not believed to occur.

[24] https://www.eetimes.com/the-impact-of-rohs-now-and-in-the-future/#:~:text=Cost%20of%20implementation&text=(TFI)%20found%20that%20the%20RoHS,billion%20annually%20to%20maintain%20compliance .

[25] Some parts of MRI are very cold and X-ray tubes can become fairly hot, however no PFAS is used in or close to the hot parts of X-ray tubes.

[26] One publication reports no weight loss at ambient and up to 150°C indicating that no depolymerisation occurs. Abstract from https://www.sciencedirect.com/science/article/abs/pii/0141391093901111U

8 ENVIRONMENTAL IMPACT AT END-OF-LIFE AND WASTE CONSIDERATIONS

The medical devices produced by COCIR members are generally long-life items (about 20 years, and sometimes longer), with a good market for refurbishment and reuse of products. COCIR member companies use only very limited quantities of non-polymeric PFAS and these are mainly in the forms of flame retarded polymer parts, cured adhesives used in components and sub-assemblies. The majority of uses are of polymeric forms of PFAS used in their products. No uses by COCIR members of PFAS process chemicals have been identified. Small amounts of PFAS additives are used in lubricants although these are probably PTFE.

8.1 PFAS emissions

Most PFAS emissions are understood by COCIR to occur during the manufacture of these substances and their use to manufacture polymers and other chemicals. From a survey of COCIR members and their immediate suppliers, it has been established that most of their uses of PFAS are as solid polymeric forms (see section 2), mainly in components, cables, and sub-assemblies. COCIR's members do not use gaseous or liquid forms of PFAS and all of the solid forms used are not volatile and do not emit vapors at the temperatures at which they are used. At the end of life of COCIR's members' equipment, PFAS is likely to cause relatively small or negligible quantities of emissions compared to the initial PFAS production phases. COCIR believes that it will be extremely unlikely, (as discussed in section 7) that any emissions will occur from the continued use of existing equipment, repair using already manufactured spare parts and disposal at end of life by recycling in the EU and in any event, recycling of existing equipment and parts will happen with or without a PFAS restriction. PFAS emissions during these lifecycle phases would be negligible in comparison with PFAS production emissions and they will quite probably be undetectable.

COCIR has no quantitative data on emissions, but PFAS polymers and other substances are known to be thermally very stable, due to the strength of the C-F bond. PFAS materials are not normally heated during medical equipment production[27] or use. COCIR is aware that medical imaging and radiotherapy equipment is recycled, usually in the EU and only by licensed EU recyclers.

8.2 Impact of spare part availability on environmental fate of equipment and risks from manufacturing releases

COCIR members do not make chemical forms of PFAS, and COCIR's survey of its members has found that they are mainly users only of parts that contain PFAS. COCIR member companies intend to substitute for PFAS as soon as possible. The issue of spare parts is, however, important. As explained above, spare parts are essential for repair of existing medical devices to enable EU hospitals and clinics to continue to treat patients. It is essential that spare parts are readily available to ensure that the equipment can quickly be repaired and used because while it is not functioning, patients cannot be treated, and delays can cause serious harm to EU patients.

[27] This is with the exception of soldering, however PFAS polymers are used because they are unaffected by soldering temperatures.

Spare parts include replacement circuit boards, sub-assemblies, and components and these are required by the EU MDR to be identical to the original parts that were used in the product when new. If the restriction as proposed is adopted, those parts that contain PFAS could not be supplied or used without a derogation. As explained above, equipment made by COCIR's members is often repaired using spare parts recovered from used equipment and these parts are also used to refurbish used equipment. Assuming that a derogation for medical imaging and radiotherapy equipment is granted, many of these parts and the equipment that will be refurbished will have already been manufactured before this restriction takes effect. As such there will be little additional PFAS production required and so only a small further impact on the environment or health from production of PFAS. Already produced parts will reach end of life either A) after they are reused to repair or refurbish equipment and this equipment reaches end of life or B) without a derogation, they will become waste earlier when PFAS is restricted. Typically, a medical imaging device may be refurbished once after being in use for at least 7 years. Recovered spare parts are likely to be reused only once. Any emissions from these spare parts will be the same irrespective of when they become waste, the only difference is the date when these parts reach end of life.

If new spare parts are needed that contain PFAS, this will only be because PFAS-free "drop-in" alternatives do not exist, cannot be made or are not available. These parts will be needed only to repair existing equipment without which patients cannot be treated and some may die.

8.3 Environmental fate of end-of-life product and associated spares

Disposal of equipment made by COCIR members is regulated by the Waste Electrical and Electronic Equipment (WEEE) Directive (2012/19/EU). COCIR's members' equipment is valuable metal-rich and so is always recycled to recover the metal content. Due to the heavy nature and high value of most of COCIR members' equipment, almost all is believed to be recycled within the EU and the recycling processes used are regulated by EU waste legislation, including the Industrial Emissions Directive (2010/75/EU).

According to several US studies on incineration of PFAS, at the high smelting process temperatures used for metal recovery from e-waste scrap, all PFAS would be completely destroyed so there would be none or negligible emissions at end of life, although EU recyclers are not obliged to monitor PFAS emissions. A US EPA study[28] shows that heating PFAS for two seconds at 1000°C is enough to completely destroy PFAS. E-waste is usually smelted for metal recovery, either to recover steel or copper. Secondary steel smelting is carried out at over 1600°C and copper smelters operate at least at 1200°C[29].

Further evidence that all PFAS are destroyed by high temperature incineration is available from several recent studies and a recent study shows that no harmful PFAS emissions occur with well-run incinerators.[30] COCIR's members' equipment does not contain volatile PFAS

[28] https://www.epa.gov/sites/default/files/2019-09/documents/technical_brief_pfas_incineration_ioaa_approved_final_july_2019.pdf .

[29] https://www.tf.uni-kiel.de/matwis/amat/iss/kap_a/backbone/ra_1_3.html

[30] Aleksando, K., Gehrmann, H-J., Hauser, M., Matzing, H., Pigeon, D., Stapf, D., Wexler, M. (2019). Waste Incineration of Polytetrafluoroethylene (PTFE) to Evaluate Potential Formation of per- and Poly-Fluorinated Alkyl Substances

such as hydrofluorocarbons and so these substances should not cause emissions during collection, storage, dismantling or sorting of scrap materials. Electrical equipment recycling is efficiently carried out in the EU and strongly regulated by EU legislation. COCIR members are aware that most of their medical devices are recycled within the EU when they reach end-of-life. EU metal smelters who recover metals from e-waste and operators of incinerators are already obliged to ensure that there are no emissions of polychlorinated biphenyls, dioxins, furans, and other toxic by-products occur and the high temperature process conditions that are required to achieve this may also completely destroy all types of PFAS.

8.4 Fate of end-of-life of waste cable and wire

Fluoropolymer insulated copper wire is recycled in the EU to recover the copper metal for reuse. First the insulation layer is removed to separate quite clean copper. Copper has a melting temperature of 1085°C and so at least 1100°C is needed to melt the wire and at this temperature, any fluoropolymer insulation residues will be destroyed. The removed fluoropolymer is incinerated at high temperature to destroy the PFAS. Publications indicate that it is likely that some CF_4 may be produced, which is not a PFAS as defined by the proposed regulation. Other emissions will be of CO_2, water vapor and simple hydrocarbons[31].

8.5 Minimization of release of PFAS from waste and end-of-life product

COCIR's members take back used equipment from their customers either for refurbishment and re-use or for disposal, a strategy that supports the circular economy. Collection of a high proportion of many types of medical imaging and radiotherapy equipment is currently achieved. As such COCIR's members can ensure that disposal is carried out in the EU according to the requirements of EU legislation, and therefore minimise emissions of harmful substances. Hospitals sometimes dispose of their own equipment and due to its high value as scrap, this is also recycled in the EU by licensed waste recyclers.

9 DISCUSSION AND CONCLUSIONS

COCIR members use PFAS in a wide variety of electrical and non-electrical applications in the EU. These materials cannot be easily substituted as they form an integral part of the medical device. Drop-in replacements do not exist, and inferior substitutes that might be regarded as "good enough" for use in low-risk consumer products are not permitted to be used in medical devices. Medical devices are subject to specific technical performance requirements and medical equipment standards mandated by EU legislation. As such they cannot be sold in the EU without Notified Body approval.

COCIR has surveyed its members to identify which PFAS are used. Many uses have been identified but this work is still on-going and COCIR's members have stated that this will take at least three years to complete. COCIR's members are users of PFAS polymers, polymers

(PFAS) in Flue Gas and Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, A. Krasimir et.al. Chemosphere 226 (2019) 898 – 906.

[31] https://www.ghd.com/en/about-us/examining-thermal-destruction-for-pfas-waste.aspx

that contain PFAS flame retardants, lubricants, elastomers, adhesives, and coating materials that contain PFAS. All of these uses of PFAS are of solid forms that are not volatile at the temperatures at which they are used. Initial investigations on substitution of these PFAS uses has already shown that drop-in replacements do not exist and for all current uses, any substitute material will be inferior and unsuitable. COCIR members have determined that their only option for at least 95% of their products and for most COCIR members, all of their products would be to stop all sales in the EU and redesign new products, unless a suitably long derogation is granted. This is necessary because the EU Medical Devices Regulation does not permit the sale of products that could be less safe for patients than previous designs of approved products.

The COCIR assessment of uses of PFAS suggests that substitution of most uses of PFAS may be possible in 13.5 years for:

- Medical imaging and radiotherapy equipment,
- Associated accessories, and
- Medical devices that are required to perform imaging and radiotherapy procedures.

However, it is likely that within this timescale, substitutes for some current uses of PFAS will not be found and so more time will be needed. Also, more time may be needed as medical device redesign is likely to be delayed by medical device manufacturers having to wait for other industry sectors such as electronics and semiconductors to carry out substitution first. COCIR understands that many of the suppliers' industry sectors are requesting derogations for 13.5 years, so that suitable substitute components will not be available to COCIR's members for use in their new designs for many years after EIF. Therefore, the requested review process foe extending derogations beyond 13.5 years will be essential.

The following elements, analysed in parts I and II of COCIR's submission support the request for the derogation duration:

Socio-economic impacts

Without a derogation for a sufficient number of years, COCIR expects that the technical impossibility to substitute all PFAS applications and redesign all models will cause serious impacts on the availability of medical devices with the following consequences:

1. At least 95% of current models of medical imaging and radiotherapy devices will have to be withdrawn from the EU market.
2. Devices being discontinued will have a consequential **reduction in access to healthcare for hundreds of millions of patients** from EIF to at least 2040.
3. The total reduction in the number of patient examinations is estimated to be in the range of about 1 to 6.2 billion over 15 years (until 2040), or on average 66 to 416 million per year.
4. The reduction in equipment density can possibly cause **tens of millions of cancer patients** over a 15 year period not to receive proper healthcare. This may reduce their chances for better outcome (see chapter **Error! Reference source not found.**) at least until 2040. A 13.5 year derogation could lower such numbers to a few thousands.
5. The impact on cancer patients is compounded by the recent surge in cancer cases,

reportedly by up to 40%, that will require an even larger availability of radiotherapy centres.

6. The already serious problem with waiting times for healthcare getting longer in the EU will be exacerbated and add to the negative impacts so far experienced.
7. The competitiveness of companies with factories located in the EU will be significantly harmed as, unlike their non-EU competitors with factories outside of the EU, they will not be able to manufacture and sell products to non-EU countries that do not have PFAS restrictions. COCIR estimates that stopping production in EU factories will cost the EU **about €10 billion per year** for at least eight years and probably permanently as it is likely that companies with EU factories will relocate to outside of the EU in order to supply their non-EU customers. This very large loss of income could force some EU manufacturers and their suppliers to cease trading.
8. The cost for substitution of PFAS, with a 13.5 year derogation has been estimated by COCIR as several billions of euros. Without a derogation, this work may not be possible as there will be no income from sales of medical imaging and radiotherapy equipment to fund it. COCIR is unable to predict these costs, but the cost to the electronics industry from the RoHS Directive was calculated to be **$32billion** for six substances, the cost for PFAS substitution could be larger.
9. As EU factories will not be able to manufacture products, there will be at least 100,000 job losses and up to 160,000 as a worst-case, although this figure excludes job losses by suppliers. In addition those EU companies that refurbish medical devices in the EU will be forced to stop and this will result in more EU job losses. There may even be job losses at hospitals if medical equipment ceases to be usable and cannot be repaired or replaced.

Technical aspects

1. Identifying all PFAS applications within a global supply chain of 5.000 to 11.000 suppliers and assess possible alternatives will require many years. Many alternatives cannot be tested until COCIR's suppliers are able to obtain production samples (not prototypes as these may be different). COCIR's members expect that this will take at least three years.
2. An initial review of potential substitutes for current PFAS uses such as cable assemblies in angiography systems, ultrasound probe cables or in MRI magnets shows that no alternative cable insulation material is available that has all of the essential properties and performance of fluoropolymers. It is very likely that no suitable drop-in alternatives exist for all types of medical imaging and radiotherapy equipment. The only option available to manufacturers if PFAS is banned without a derogation, is to stop sales in the EU and redesign their products, which will take many years.
3. As medical imaging and radiotherapy equipment is in scope of the Medical Devices Regulation, manufacturers are not permitted to make changes that result in an increased safety risk to patients such as if performance or reliability are negatively affected by substitution. The inferior but "good-enough" alternatives that may be considered acceptable for consumer products will therefore not be acceptable in medical devices.
4. PFAS-free components can be tested and integrated into new designs only once they are available. Many of the components will become available just before the expiry of applicable derogations (such as for semiconductor processing). If, for instance, a derogation of 13.5 years is granted for semiconductors, most likely

COCIR's members will not be able to start testing and designing before that expiration date. The design cycle of medical imaging devices is 5 to 7 years while for radiotherapy equipment is 9 to 11 years. Timescales are longer if many products need to be redesigned as the number of design engineers is limited.

5. Companies have limited specialised technicians and engineers while having a wide portfolio of applications. As already proven under RoHS, redesign takes requires significant time and resources. It is not possible to redesign many different models in parallel.
6. For certain applications there may not be alternatives providing the same clinical performances even in the expected timeframe, and therefore extension of derogations may be required as regulatory approval in the EU (or elsewhere) will not be granted for inferior products.
7. Despite using some of the best substance tracking tools, there are still likely to be unidentified uses which will not be discovered by companies until late in the substitution process. Even a 13.5-year derogation cannot shield companies and healthcare providers from the consequences of suppliers' mistakes.

Derogation needs for spare parts

A derogation is required for at least 13.5 years. In addition, the wording must allow for the reuse of spare parts for refurbishment and repair of devices placed on the market before the entry into force of the restriction for the sector:

1. The "repair as produced principle" is essential to allow continued servicing and repair of medical imaging and radiotherapy equipment in use at hospitals and clinics in the EU and also supports the EU's circular economy policy.
2. Refurbishment of medical devices requires spare parts to be available to refurbish used devices. As such, the restriction wording must allow for this practice to continue delivering affordable healthcare and benefits of suitable equipment. Some COCIR members manufacture spare parts for up to 10 years from the cessation of production of a type of device. Used parts may be recovered for reuse for even longer.
3. It has been already proven under RoHS, for exemption 31a and 47[32] that the reuse of spare parts is always better from an environmental perspective than generating waste and manufacturing a new one (which may use critical raw materials or other SoCs).

At the end of the derogation period, it seems likely that some uses could be identified for which alternatives will not be available, or where the alternatives would be regrettable substitutions. In these cases, a mechanism to review newly identified derogations that will be needed as well as to extend still required extant derogations would be essential. Also, more time may be needed as COCIR members will have to wait for suppliers to develop suitable substitutes (during the derogation period) before the medical devices can be redesigned.

[32] More details of 31a are available from https://rohs.exemptions.oeko.info/exemption-consultations/2019-consultation-1/annex-iv-ex-31a

10 RECOMMENDATIONS

COCIR recommends derogating medical imaging and radiotherapy devices: for 13.5 years. A review clause should also be included, supposing that 3 to 3.5-years.. are sufficient for the evaluation of newly requested derogations and amendment of the REACH Regulation before the original derogations expire.

1. ***By way of derogation, paragraphs 1 and 2 shall not apply to PFAS for the use in medical imaging and radiotherapy devices, their accessories and other medical devices required in a modern imaging suite or radiotherapy procedures and designed to work in such environments such as contrast injectors, patient monitoring, and other ancillary equipment that are needed to use these types of medical devices, until 13.5 years after EIF.***

Justification: A derogation for 13.5 years after EIF is needed to allow continued supply of medical imaging and radiotherapy (including proton therapy) equipment as well as ancillary equipment that is needed to use these medical devices.

2. ***Paragraphs 1 and 2 shall not apply to PFAS for the use in new spare parts to repair, service, updating of functionalities or upgrading of capacity or refurbishment of medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging or radiotherapy suite, placed on the market before 13.5 years after EIF.***

Justification: A derogation is also needed for spare parts to repair existing products in hospitals and clinics, for 13.5 years after EIF. The above wording is based on wording used in the RoHS Directive that allows the use of spare parts that contain RoHS substances:

3. ***Paragraphs 1 and 2 shall not apply to medical imaging, radiotherapy devices, their accessories and other medical devices required in a modern imaging suite or radiotherapy procedures, placed on the market for the first time before EIF+13.5.***

Justification: The above wording is required for medical imaging and radiotherapy equipment (capital investment equipment for healthcare providers) so that it can continue to be sold, transferred, leased, donated between hospitals, taken back, and refurbished to increase safety and performance for the useful life of the equipment. Such reuse should be supported under EU circularity principles.

4. ***Paragraphs 1 and 2 shall not apply to PFAS in spare parts recovered from and used for the repair, reuse, updating of functionalities or upgrading of capacity or the refurbishment of medical imaging devices, radiotherapy devices and other medical devices, provided that the reuse takes place in auditable closed-loop business-to-business return system and that each reuse of parts is notified to the customer.***

Justification: A time unlimited derogation is needed to allow circular economy activities such as refurbishment and reuse of recovered spare parts can continue benefitting EU hospitals, ensuring fast and cheaper repairs and shorter downtimes.

5. ***The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector, their accessories and other***

medical devices required in a modern imaging or radiotherapy suite and submit proposals for amending the regulation, by 10 years after EIF years to assess the need to maintain the derogation for specific applications for which no alternatives are yet available. The European Commission shall review the application of the restriction to the medical imaging and radiotherapy sector by [10 years after EIF] to assess the need to maintain the derogation or add new derogations for specific applications for which no alternatives are yet available and to publish proposed amendments to the Regulation.

Justification: Wording needs to be included to ensure that the PFAS restriction and its derogations are reviewed after, for example 10 years after EIF to allow the continued use of PFAS for any uses that are discovered to have no possible substitute materials or designs. Enough time is needed for the EU to assess requests for derogations and amend the legislation to allow them before the initial 13.5 year period expires.

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