

1st Questionnaire Exemption 31a (renewal request)

Exemption for „Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. “

Abbreviations and Definitions

BBP	Benzyl butyl phthalate
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
DEHP	Bis (ethylhexyl) phthalate
DBP	Dibutyl phthalate
DiBP	Di-isobutyl phthalate
EEE	Electrical and electronic equipment
MD	Medical devices
OEM	Original equipment manufacturer
PCB	Printed circuit boards
PVC	Polyvinylchloride
RRSM	Repair, refurbishment, servicing and maintenance

Background

The Oeko-Institut and Fraunhofer IZM have been appointed within a framework contract¹ for the evaluation of applications for the renewal of exemptions currently listed in Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) has submitted a request for a renewal of the above mentioned exemption, which has been subject to a first evaluation. The information COCIR has referred has been reviewed and as a result we have identified that there is some information missing. Against this background the questions below are intended to clarify some aspects concerning the request at hand.

¹ The contract is implemented through Framework Contract No. FWC ENV.A.2/FRA/2015/0008 of 27/03/2015, led by Oeko-Institut e.V.

Questions

1. COCIR requests the above exemption as an amendment of Ex. 31a and proposes to combine it with the existing Ex. 31a, which addresses lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in refurbished equipment. Please propose a combined exemption formulation or clarify if it is your intention to request a separate exemption, which could be added under item 31 of annex IV of the Directive.”

RoHS does not have a procedure for amending an existing exemption, so this should be considered a new exemption request. On the other hand, COCIR sees advantages in merging two very similar exemptions (this one and 31a) into a single one:

- Both exemptions are necessary to ensure repair and refurbishment activities at the point they can be considered as one
- In the future, renewing a single exemption would require less efforts both from industry and the European Commission.

In case the European Commission and the EC RoHS Delegated Acts Expert Group would agree about the merge, and in case the renewal request for exemption 31a that will be submitted in time for the deadline will be approved, the following seems a suitable wording.

“Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate, Benzyl butyl phthalate, Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer”

2. Estimations provided by COCIR in the application are understood to be based on refurbishment practices of imaging equipment (e.g., MRI, CT, X-RAY, ultrasound are specified), yet the request is made for medical equipment in general, including among others in vitro diagnostic MD. Please provide an estimation as to the following parameters for other than imaging MD equipment. This can also be estimated as a factor of the given volumes for imaging equipment:
 - a. Total market volume of refurbished equipment in tonnes in the EU/globally;
 - b. Estimated amount of RoHS restricted phthalates contained in such equipment (i.e. that would benefit from the exemption).

To COCIR’s knowledge, only medical imaging devices, IVDs and patient monitoring equipment are products under the scope of category 8 that are refurbished today in the EU. Other medical devices tend to be too small and of too low value to be refurbished. Moreover a closed loop is not likely for these small or low-value products, therefore excluding them from this exemption. The closed loop criteria mostly restricts, for now, this exemption to just medical imaging, IVDs and some patient monitoring equipment.

Nonetheless the EU agenda has a strong focus on circular economy and life time extension, reusability, refurbishment and remanufacturing are pivotal points of this agenda.

Refurbishment/remanufacturing practices are slowly getting more common for other medical devices. If such new practices are not covered in this exemption, the risk is that any effort in this sense by companies will be made void. It is not a reasonable expectation that in the future a company will engage in requesting a new exemption for a new refurbishment business that cannot be launched before such exemption is granted.

- a. COCIR does not have an estimation per ton of other sectors. It is reasonable to expect that other sectors will provide relevant data during the public consultation phase, for instance IVDs.
 - b. We estimated an amount of less than 2 tonnes of phthalates, that is provided in the exemption request Q5.3. If there is 1000 tonnes of refurbished medical equipment (all types) out of a total of 3200 tonnes (these figures are from page 18 of exemption request), then the maximum phthalate content of refurbished equipment is less than 625kg. One manufacturer reported that out of 50.000 purchased parts only 50 of them had been flagged as containing one of the four phthalates (the others had been declared by the suppliers as not containing such phthalates). However it is not possible to tell if the conforming parts had been compliant from the beginning or if they had been redesigned by the first/second/third or fourth tier supplier at some point of time. Therefore they cannot be reused without the requested exemption. This issue of not knowing the substances which had been used in the past cannot be solved by material testing or by requesting the suppliers to provide this information. Testing for RoHS substances is mostly a destructive test and would need to be carried out for each and every part separately, because it is not possible to determine which parts are coming from the same batch. Requesting information from the suppliers is also not possible because oftentimes 5-10 years later no business-relationship is existing anymore and/or the suppliers would also need to query their former supply-chain for that type of information.
3. In the technical description to the exemption request you declare that this exemption is relevant to EEE in the scope of category 8; “*medical devices such as MRI, CT, PET, SPECT, ultrasound imaging, patient monitors, In vitro-diagnostic medical devices*”. However in section 1.a (page 2) you only marked category 9 (i.e. monitoring and control instruments) from the list of relevant EEE. Does this mean that your request for renewal of Ex. 31a is also to apply to category 9 EEE? If this is the case, please provide information to support the necessity of the exemption for such equipment.

Following some contacts with a company which manufactures electron microscopes, COCIR also decided to mark category 9. COCIR does not represent category 9 equipment manufacturers so cannot provide information to support the necessity of the exemption for such equipment. This information should be provided by category 9 manufacturers during the public consultation phase, if they confirm that they want this exemption to apply to category 9.

4. You provide an estimation of less than 2 tonnes per year for RoHS substances (DEHP, DBP, DiBP and BBP) present in EEE waste. This is based on an average of 0.1% of the total of recovered and reused parts, which refers to “about 2200 tonnes of parts and 1000

tonnes of equipment (total 3200 tonnes) are refurbished and then reused in the EU annually". In the technical description of the application you declare a content of substance in homogeneous material (% weight) between 1 and 50%, why do you base the above mentioned estimation on an average 0.1% of the total of recovered parts? Please clarify the logical steps behind this calculation.

As COCIR stated in the dossier, it is impossible to know the content of phthalates or their concentration when the equipment was produced as there were no restrictions for in place. The total weight of the recovered parts mentioned in the dossier, refers to parts made of steel, aluminium, electronics and plastics. The 1% to 50% concentration range refers to the concentration in plastics containing phthalates (not all plastic). Therefore the 1-50% should be applied only to a small percentage of the total weight of the recovered parts, nominally "plastic likely to contain phthalates". COCIR estimated, based on expert opinion, that phthalates in "plastic likely to contain phthalates" can amount to a 0,1% of the weight of parts of medical imaging devices, that are, for the most part, made by heavy metals and alloys.

5. In your application you mentioned that there is no net change in the amount of RoHS substances (DEHP, DBP, DiBP and BBP) entering the EU, given that after 21 July 2021 *"the amounts entering will be similar to the amounts leaving"*. Please provide more information about the refurbished MD parts market along with current data and future projections of the flows of these parts from and into the EU to clarify this statement.

It is impossible to have an estimation of the fluxes of parts and equipment in a global market, as there has never been a need to put in place such a complex reporting system. The statement just reflects reality. Reused parts of medical devices likely to containing phthalates are used worldwide. Their "concentration" is homogeneous, as there is no reason to believe that such parts concentrate in certain countries or regions. Parts are recovered from all the world, refurbished in a few locations, and shipped anywhere in the world where there is a medical device to be repaired. The "concentration" parts likely to contain phthalates is therefore constant and homogeneous in the EU and globally. The "concentration" of such parts has already started to decrease as phthalates have been gradually phased out to meet the 2021 deadline and to meet national initiatives on green public purchasing. The fact that no exemptions for phthalates, except 2 very specific cases submitted by COCIR and a COCIR Member, have been submitted, proves that phthalates were being already substituted wherever possible well before 2018.

COCIR can even assert that the concentration of phthalates containing parts is decreasing in the EU faster than in other regions for the following reason. According to EU legislation, medical devices placed on the market outside the EU, cannot be reimported, refurbished and sold in EU (this is a topic we already had chances to discuss with the European Commission and Oeko-Institute). Therefore, all the medical devices likely to containing phthalates, produced in EU and shipped outside are not allowed to be re-sold in the EU after refurbishment. COCIR expects that the region with the lowest concentration of medical devices likely to contain phthalates and their parts is the European Union.

6. According to COCIR's status report for 2016², your estimation about the total amount of recovered parts and equipment annually in the EU2 is based on an internal survey of 4 companies involved in refurbishment activities.
- a. Given that COCIR has currently more than 40 members, do you consider this estimation (3200 tonnes) to still be relevant and to reflect the current situation in the EU for RRSN activities/market?
 - b. Please specify how many of COCIR's members are currently involved in refurbishment activities; if relevant please clarify how many are involved as OEMs and how many are involved as suppliers, etc.

a) & b) There are only 4 COCIR Members, all OEMs, active in refurbishment, and another one with some activities. Such companies cover 99% of the market for the types of equipment that are refurbished, if not 100%. Other companies are involved in repair but not on refurbishment as such. The market has not changed significantly since 2016, therefore the estimation of 2016 is still relevant. There are also 3rd party refurbishers in EU (not OEM) that operates at local level, but their market share is not known to COCIR.

By describing different scenarios for the possibility to use recovered parts for RRSN of medical devices, you declare that *“As only about one third of new medical devices are sold in the EU, this means that two thirds of recovered parts could not be used to RRSN medical devices that have been placed on the EU market after 21 July 2021 without this exemption”*. Please provide complementary information about the global MD market data to support this statement.

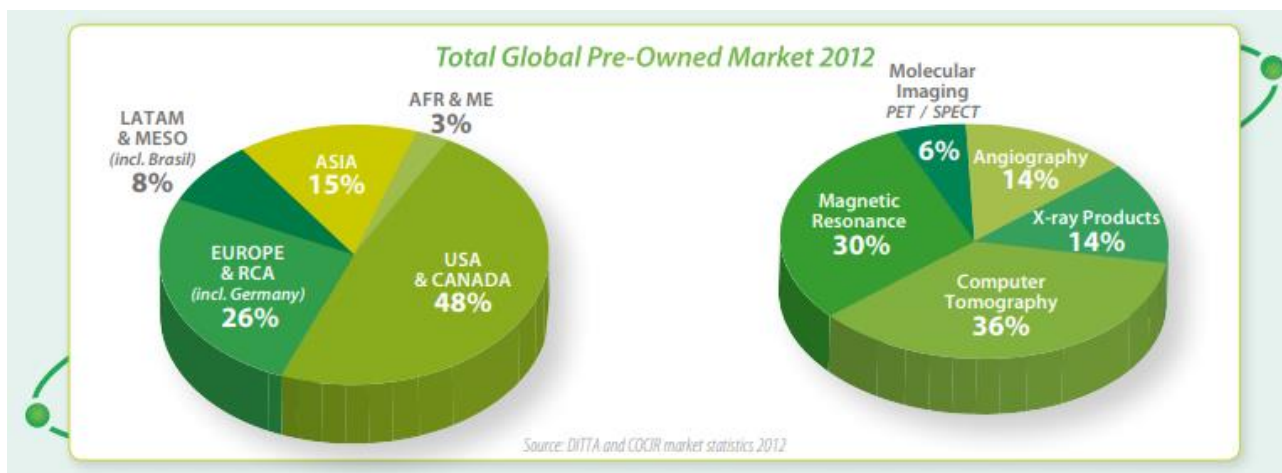
COCIR collects data about the market of medical imaging devices globally, with the exclusion of North America and part of Africa. For a series of complex reasons (e.g. different definitions are used) the data is not-comparable in a straightforward way. As a result it is not possible to have a complete overview of the global market as North American data is not available to COCIR. According to our best estimations, the EU market account for a 30% of the global market. This is confirmed by the following statement reported on the COCIR website:

The **global market** for medical equipment is worth **€110 billion** (source: [European Commission](#)) with around €28 billion in Europe, and of this **€20 billion for COCIR member companies**.

A global survey conducted in 2012 by MITA (Medical Imaging Technology Alliance), the COCIR-like association in USA, estimated similar values also for the market of refurbishment equipment. Such market data has been used in 2015 for brochures on the “Contribution of refurbishment to circular economy”.

<https://www.globalditta.org/activities/good-refurbishment-practice.html>

² COCIR Self Regulatory Initiative for medical imaging equipment, status report for 2016, http://www.cocir.org/fileadmin/6_Initiatives_SRI/SRI_Status_Report/COCIR_SRI_Status_Report_2016_final_12092017.pdf



In 2018 a new survey was conducted by DITTA (The Global Association of medical imaging, radiotherapy, radiopharmaceutical production and healthcare IT industry). Refurbishment accounted for global revenue of approximately 865 million Euros in 2017. Approximately 70% of all refurbished medical imaging devices are sold in the U.S. (46%) and the European Union (24%).

- In the elaboration on the health impacts in the event that a renewal is not granted (section 6), you emphasize how the lower price of refurbished parts reflects on the ability of hospitals to provide adequate health care. Here you state that *“Today we already see that the demand for refurbished equipment exceeds the numbers that are available”*. Please justify this statement with EU specific data about market developments and trends for refurbished parts.

There are no market trends or market data available that can justify the statement. It is companies' experience. As an indication, COCIR provides here an average estimation by companies about the waiting time for an hospital to get an average refurbished equipment after the order.

For a refurbishment equipment:

- The waiting time for customers to receive their refurbished devices is usually between 8 to 16 weeks. Normally a waiting time of 12 weeks is considered “long” so companies discuss with clients in such cases as they may prefer to buy a new one or upgrade an existing one.
- Some refurbished device products can only be offer on request as companies have to specifically look for a used system to buy it back for refurbishment, as it is not available. In such a case it can also take longer than 4 months.
- Many products are not offered as refurbished as manufacturers know that they cannot any longer offer such specific devices as refurbished because of too long waiting times then they completely remove it from the list of systems offered.
- There are some refurbished devices that cannot be offered in the EU as they are mainly sold as new outside Europe.

A survey run by COCIR in 2018 for a meeting with DG GROW, highlighted that 8 months were required for an hospital to receive a refurbished high-end CT scanner. The refurbishment process requires two weeks on average. The additional time (7 months) is due to the lack of equipment to refurbish compared to the demand.

By comparison, an hospital can get a new devices in half the time, from 3 to 8 weeks.

The infographics attached at the end of this document, just released by COCIR, on the Age Profile of the installed base of medical imaging devices, highlight a dramatic situation regarding the obsolescence of the installed base. Refurbishment is a key element of the strategy to allow EU hospitals to renew their equipment in an affordable way.

8. When referring to the existing closed-loop system for EEE waste of MD, you mention that OEMs do not collect equipment of other manufacturers, with the implication that equipment that cannot be refurbished is treated as waste. Could you provide data regarding the annual amounts of equipment treated as waste in comparison to the amounts of refurbished equipment (information provided for refurbished parts and equipment contributing to the described closed-loop³)? This would help illustrate the size of material flows entering, circulating in and exiting (input, output) the RRSM system.

The closed loop take back system referred to in RoHS does not relate to waste equipment but to used equipment. Waste cannot be reused or refurbished. Waste equipment in the EU are disposed according to the WEEE Directive.

Used medical devices not handed over to OEMs for waste disposal: unfortunately, this is data which COCIR does not have as hospitals do not always profit from the possibility offered by the WEEE Directive and handle the waste equipment disposal mostly by themselves. Medical devices have a considerable value as waste due to the content of recyclable metals (steel, lead, copper, aluminium). For this reason, hospitals can sell equipment directly to brokers or recyclers rather than returning it to the OEM. COCIR believes that the disposal, also in this case, happens anyway under the umbrella of the WEEE Directive and quantities are reported to the national registries. Unfortunately, quantities are reported under the very general “Category 8”, therefore it is not possible to know how many tons of medical imaging devices are returned to recycling. Since 2018 the situation is even worse, as waste medical devices are now reported under two categories “large appliances” and “small appliances” making even more impossible to determine the waste flows.

Used medical devices handed over to OEMs: COCIR companies collect WEEE and report the quantities to national registries. Unfortunately, following the letter of the WEEE Directive, medical imaging devices are reported together with other medical devices, therefore it is impossible even to know how many tons (not units) of medical imaging devices have been collected. The WEEE Directive is focused on total tonnes without any provision allowing to increase granularity of reporting.

COCIR is engaged in an exercise trying to determine the waste medical devices sent to recycling by analysing the variations of the installed base over the years and the number of new medical devices placed on the market every year. Such an estimation would not be available soon.

³ COCIR has estimated that about 2200 tonnes of parts and 1000 tonnes of equipment (total 3200 tonnes) are refurbished and then reused in the EU annually.

9. In order to justify the impact of new parts manufacture in comparison with RRSM of parts in MD you have referred to the results of a full life cycle assessment conducted and published in connection to this exemption application. This publication reports that 95% of MRI can be refurbished, 85% of CT and 65% of X-ray systems and shows that all impacts from refurbished systems are smaller than for new systems. You present the size of impacts in percentages of refurbished systems in comparison with a new system for three impact categories. Please provide the original unpublished work that supports these results⁴.



Gabi Zamplaret -
JCLEPRO-S-17-0941C

10. One part of the environmental impacts of the LCA results presented refers to PVC, used as cable insulation of cable assemblies and to make electrical connections in complex subassemblies and to transducers. You report that 50% of these can be reused.
- a. Given that the technical feasibility for the replacement of these cables with phthalate-free containing materials currently exists, please confirm whether your justification for the reuse of these cables is solely based on the possible avoided impact of material used in the manufacture of new parts.
 - b. Please specify in this case if cables are reused wherever possible or only in cases where the complete assembly can be used, i.e. also saving the impact of disassembling and reassembling the assembly.

The decision of reusing cables or cables/assemblies depends on many factors and is evaluated on a case by case basis by expert technicians or engineers. Refurbishers will as a first priority reuse whole cable assemblies including connectors if possible, but if any parts are damaged, then parts of the assembly may be used. We are not speaking of automated series production, but about complex equipment which are disassembled and examined one by one, with the objective to restore their performances and safety and to reuse as much as possible to save costs for companies but in particular for hospitals. In the more general context of circular economy and companies' environmental policies, as reflected in the EU agenda and the general waste hierarchy, reuse is considered the best contribution to environmental protection and circular economy. This is why companies in the medical device industry have been improving reuse and design for reuse in the past 20 years. 50% of reuse of cable assemblies, while an estimation, is the proof of the commitment of the sector to implement circular economy and to reduce the use of virgin materials whenever possible.

It is also important to note that the increased cost of using new cables assemblies instead of recovered ones would impact the affordability of refurbished equipment. As already stated before, the key to refurbished equipment is their lower price compared to a new one (same dynamic as for used/second-hand cars). If companies would not be allowed to keep the cost down for the user, there will be no more refurbishment in the future.

⁴ Specified as: *Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners, Gabriel I Zlamparet et.al. Unpublished work that can be provided to the European Commission*

To a certain extent this is also true for repair. The ability of a company to provide fast and cheap repairs is a very competitive factor that ultimately affects healthcare provider ability to have functioning machines for their patients.

11. In the application you display a calculation of selected EU impacts on repair, maintenance and servicing of medical devices in the EU without this exemption. This is based on an assumption that “90% of parts are PCBs (30% 1 or 2 layer, 30% is surface mount devices and 30% ICs) and the rest is PCB cables (50% PVC and 50% copper wire), using the VHK ecodesign impact data”. Do you have industry data that supports the VHK estimations or that would clarify the possible degree of error regarding these percentages for the contribution of each part type to the overall amount of recovered parts for RRSM activities?

This is intended only as an illustrative example. Clearly the composition of medical devices varies considerably. In fact the ratio of parts makes no difference to the result, reuse is always preferable (environmentally) to manufacture of replacements. Reuse of parts, in the refurbishment process, is always performed in a way to ensure safety and effectiveness of the refurbished equipment.

12. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following in relation to all EEE placed on the EU market through this exemption (i.e., not just by COCIR members):
- a. Please confirm that the provided information related to the volume of EEE concerned (3200 tonnes of WEEE possibly generated through a forced substitution) and the respective amount of DEHP, DBP, DiBP and BBP to be avoided⁵, can be used to estimate the relevant values for a 5/7 year period should the exemption not be granted (please see also question 5 in this respect). If relevant, please provide information as to possible increase or decrease trends expected in the years to come that may affect the volumes.

COCIR can confirm that 3200 tonnes per year over the next 5 – 7 years is likely to be refurbished. The amount of contained phthalates is less certain, firstly as the value of up to 2 tonnes is only a very approximate estimate and the true value may be much less. Over the next 7 years the amount of restricted phthalates will decrease as none will be used in new medical devices from July 2021 except where permitted by exemptions.

- b. Please estimate possible impacts on employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – health services providers, manufacture, supply chain, retail, etc.

We did not mention impact on employment, even if it can be assumed that the refurbishment businesses will be affected in their operations and processes. Employment may not be affected significantly as refurbished equipment will continue to be sold outside of the EU, but EU hospitals will be forced to buy more new equipment, which should balance out any effects on employment. The main consequences of not having the exemption granted have been detailed in the dossier

⁵ COCIR estimates less than 2 tonnes per year for RoHS present in EEE waste. This is based on an average of 0.1% of the total of recovered and reused parts.

and in the answers so far. We think the impact on employment is negligible compared to all the others, in particular the impact on the access to medical devices in EU.

- c. Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers, health service providers, patients).

It is not possible to estimate such costs. As COCIR explaining in the paper, repairing phthalates free equipment will be more difficult immediately after 2021 as warehouses of spare parts will be filled with likely-phthalates-containing parts. New parts will have to be used, with a higher costs for hospitals already from 2022 (after the expiration of the 1 year warranty) and likely longer times that will reflect on patient treatment. These costs cannot be estimated. What is even more relevant for COCIR is that the production of new parts will involve a higher environmental impact, as shown in the dossier, while reusing old parts is the way-to-go for a fully functioning circular economy.

Refurbishment is different. It will be impossible for many years to refurbished phthalates-free devices as there will not be spare parts available for refurbishment of devices coming back after 2021. All stocks will be of likely-containing-phthalates parts.

The impact for healthcare could be estimated by multiplying the number of expected sales of refurbished equipment for the average cost of a new equipment, instead of the cost of a refurbished one (as such products will not be available). COCIR cannot estimate the development of the refurbishment market between 2021-2026. A big question mark is represented by this exemption being approved or not.

There are many researches and reports online that could provide such figures. For instance:

<https://www.marketwatch.com/press-release/refurbished-medical-devices-market-industry-size-growth-analysis-and-forecast-of-2025-2018-12-13>

<https://globenewswire.com/news-release/2018/11/19/1653854/0/en/Global-Refurbished-Medical-Devices-Market-2019-2023-Key-Players-are-Block-Imaging-Canon-General-Electric-Koninklijke-Philips-and-Siemens-Healthineers.html>

Anyway refurbished equipment costs normally 10-50% less than purchasing a new one. Considering the already worsening age profile of the installed base, this will be another incentive for hospitals to keep the old equipment, providing a low-quality service to EU patients:

https://www.cocir.org/uploads/media/16052_COC_AGE_PROFILE_web_01.pdf

Please note that answers to these questions are to be published as part of the available information relevant for the stakeholder consultation to be carried out as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.



OBSOLESCENT MEDICAL IMAGING TECHNOLOGY IS UNDERMINING PATIENT SAFETY

COMPUTED TOMOGRAPHY (CT)



21%

Over one fifth of the CT installed base in Europe is now **MORE THAN 10 YEARS OLD.**

2,900

Around 2900 CT units in Europe are obsolete, challenging to maintain and repair, inadequate for conducting some procedures; **REPLACEMENT is ESSENTIAL.**



The majority of these CT units are in: **ITALY, GERMANY, SPAIN, POLAND, UK, GREECE, PORTUGAL and FRANCE.**



2008

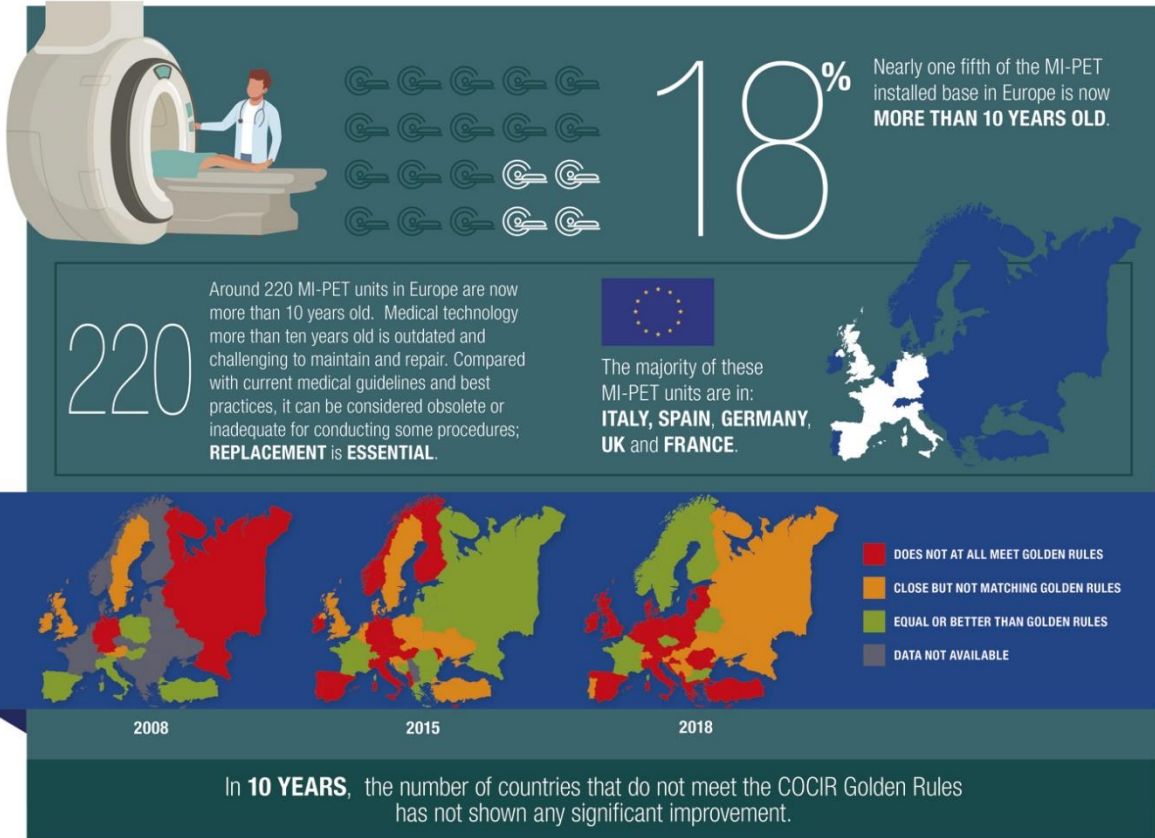
2015

2018

In **10 YEARS**, the number of countries that do not meet the COCIR Golden Rules is over **3 TIMES** more.



OBSOLEScent MEDICAL IMAGING TECHNOLOGY IS UNDERMINING PATIENT SAFETY
**MOLECULAR IMAGING
 POSITRON EMISSION TOMOGRAPHY (MI-PET)**





OBSOLESCENT MEDICAL IMAGING TECHNOLOGY IS UNDERMINING PATIENT SAFETY

MAGNETIC RESONANCE IMAGING (MRI)



21%

Over one fifth of the MRI installed base in Europe is now **MORE THAN 10 YEARS OLD.**

2,100

Around 2100 MRI units in Europe are now more than 10 years old. Medical technology more than ten years old is outdated and challenging to maintain and repair. Compared with current medical guidelines and best practices, it can be considered obsolete or inadequate for conducting some procedures; **REPLACEMENT is ESSENTIAL.**



The majority of these MRI units are in: **GERMANY, SPAIN, ITALY, UK and GREECE.**





OBSOLESCENT MEDICAL IMAGING TECHNOLOGY IS UNDERMINING PATIENT SAFETY

X-RAY ANGIOGRAPHY / INTERVENTIONAL

