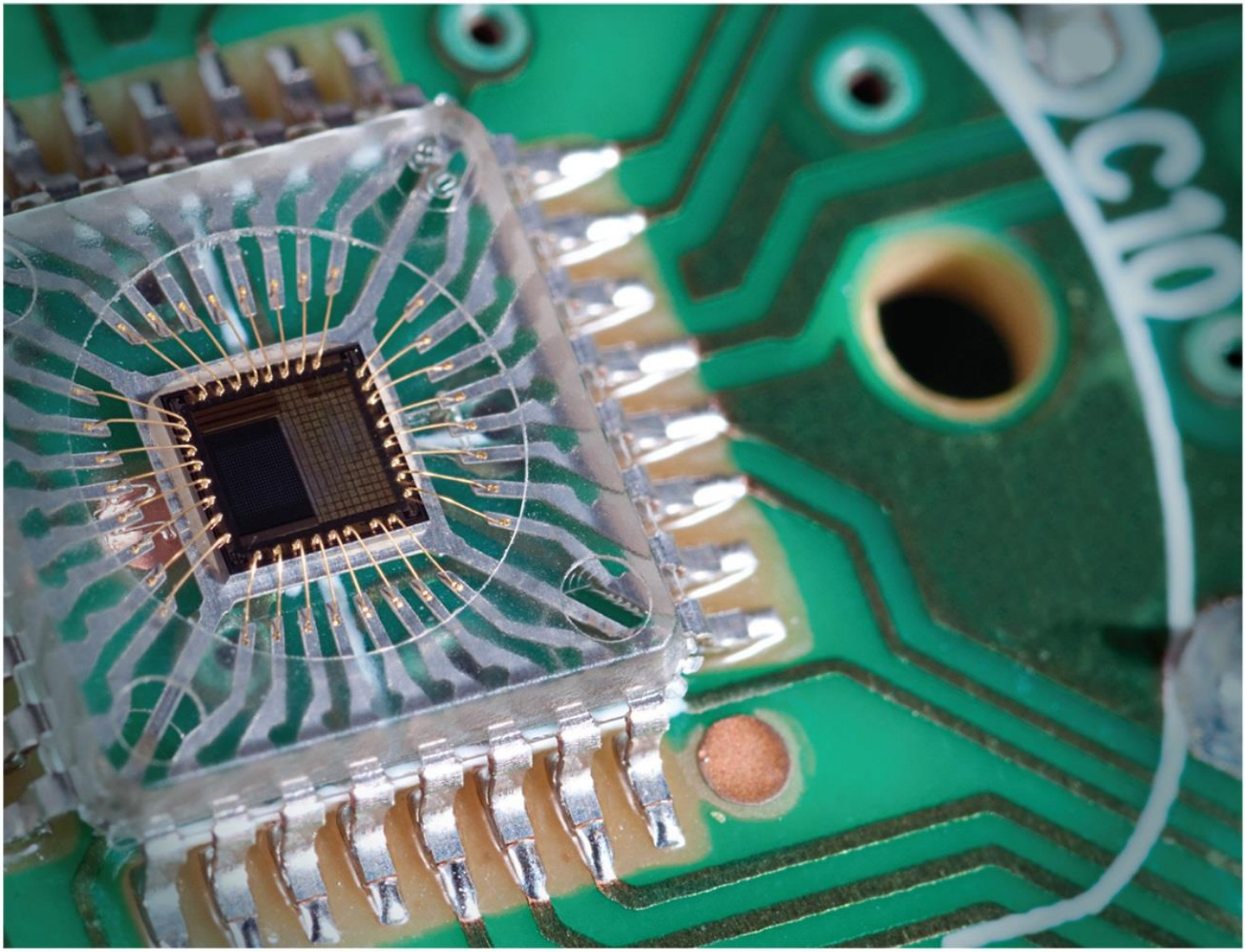


COCIR
GUIDE ON RoHS II DIRECTIVE

APRIL 2013

OBLIGATIONS FOR MEDICAL DEVICES

COCIR

SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

DISCLAIMER

This document reflects the best knowledge of industry experts across Europe and the state-of-the-art at the moment of publication. COCIR cannot be held responsible of any damage caused by the interpretations provided in this guide. Valid interpretation of Community legislation is the exclusive competence of the European Court of Justice. COCIR also recommends to producers when applying this document and its principles to always refer to the national legislation of the Member State in question.

FOREWORD

A USEFUL TOOL FOR OUR MEMBERS TO COMPLY WITH RoHS II

COCIR members have always played a driving role in developing the future of healthcare technology both in Europe and worldwide. For many years, COCIR has been proactive in green technologies and is at the forefront of green initiatives by proactively embedding environmental objectives throughout their products' lifecycles.

The objective of this guide is to provide Healthcare Industry with a brief reference to identify the key obligations arising from the inclusion of medical devices in the RoHS II Directive scope.

This guide also provides links to other external resources to help readers to easily access all the relevant documentation and information to allow a smooth implementation of RoHS requirements within their own company processes to ensure conformity by the defined deadlines.

According to Members' interest COCIR will evaluate the publication of a separate FAQs document by summer 2013.

Nicole Denjoy

COCIR Secretary General

TABLE OF CONTENT

1. INTRODUCTION

The RoHS Directive (2002/95/EC) on the Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment restricts the use of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenylethers in certain electrical and electronic equipment since 1st July 2006.

The RoHS Directive has now been replaced by RoHS II, Directive 2011/65/EU which was adopted on 27 May 2011 and published in the Official Journal of the EU on 1st July 2011. Member States had to transpose RoHS II into national legislation by 2nd January 2013.

RoHS II Directive maintains the same substances subject to restriction of RoHS I but extends them to medical devices which are placed on the market from 22nd July 2014 and to in vitro diagnostic medical devices which are placed on the market from 22nd July 2016.

Starting from 22nd July 2014 medical devices cannot be placed on the EU market (made available for the first time) if one or more of the banned substances are present in concentration higher than the maximum concentration values (MCM) in homogeneous materials.

Specific applications of the banned substances are exempted as specified in Annex III and IV of the Directive. Annex III lists exemptions for all EEE, while Annex IV lists exemptions that are specific for medical devices and monitoring & control instruments. In addition COCIR submitted to the EC in 2011/2012 12 new requests for exemptions that, once approved, will be published in Annex IV. This is expected to happen during 2013.

The European Commission published in December 2012 a guidance document (FAQs) on RoHS II providing additional interpretations and guidance. Nonetheless COCIR believes the FAQs document does not provide enough clarity on some important issues for the medical devices sextor:

- Application of article 2.2 to medical devices
- Exclusion of large scale fixed installations

The application of article 2.2 is actually under discussion in the EU Commission and will be dealt with during the RoHS II scope review that is scheduled to start in 2014.

More detailed information about the ROHS II Directive can be found on the ORGALIME “A practical Guide to understanding the specific obligations of Directive 2011/65/EU” that is available for download at the ORGALIME website: http://publications.orgalime.org/index.php/publications/en/

2. ENFORCEMENT DATE

Medical devices cannot be placed on the market after 22 July 2014 and in vitro diagnostic devices after 22 July 2016 if they contain one or more of the banned substances above the allowable concentrations, unless those substances are used in applications for which an exemption has been granted.

A medical device is defined as: 'a medical device within the meaning of point (a) of Article 1(2) of Directive 93/42/EEC and which is also EEE' while in vitro diagnostic medical device means an in vitro diagnostic medical device within the meaning of point (b) of Article 1(2) of Directive 98/79/EC;

3. BANNED SUBSTANCE

The substances restricted by RoHS II and the related Maximum Concentration Values (MCVs) are the following:

Substance	**MCVs**
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %

The actual concentration value in % has to be calculated by dividing the weight of the substance by the weight of the homogeneous material that contains the substance. The following definition of "homogeneous material" is provided by Article 3(20):

> ***Article 3(20)***
> *'homogeneous material' means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.*

Guidance on how to comply, in particular with reference to surface coating should be published by the European Commission. The report commissioned to ERA Technology on this important aspect is available at the following link:
https://docs.google.com/a/biois.com/viewer?a=v&pid=sites&srcid=YmlvaXMuY29tfHJvaHN8Z3g6NjMzNDczZTYxZGE3YWFlYw

4. EXCLUSIONS FROM THE SCOPE

RoHS II applies to all EEE with some exclusion. The exclusions which could affect the medical sector are:

"Large-scale fixed installations"

RoHS II Directive provides a definition of "large scale fixed installation" which unfortunately does not clearly communicate the term "large scale". The European Commission provided some additional criteria in the FAQs document which can be helpful for most medical devices but still leaves some openness for interpretation. Appendix XX presents a decision tree useful to help companies to qualify their equipment as LSFI or not. It makes use of the criteria stated in the RoHS II text and of the criteria presented in the EC FAQs document. Appendix III analyse the application of the LSFI definition to 4 medical installations (particle therapy, magnetoencephalography, radiopharmaceutical production and radiation therapy)

"Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment";

This exclusion is very useful to understand that all medical devices and accessory equipment destined to be part of a fixed installation that could qualify as "large scale" are excluded by RoHS II.

"Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis".

This exclusion can be applied, in COCIR view, to medical devices developed only for research and development (e.g. magnetic resonance equipment with 7 Tesla or higher magnetic field strength.)

5. SPECIFIC DISPOSITIONS FOR SPARE PART

Article 3(27) of the Recast RoHS Directive defines a "spare part" as:

Article 3(27)
"Spare part" means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.

Articles 4(4) and 4(5) of the Recast RoHS Directive exclude spare parts from RoHS requirements in the following cases:
Spare parts, for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

- *EEE placed on the market before 1st July 2006;*
- *medical devices placed on the market before 22nd July 2014;*
- *in vitro diagnostic medical devices placed on the market before 22nd July 2016;*
- *EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned (see Annex III and Annex IV of the RoHS Directive for details of exemptions and dates).*

The key date for the above exclusions is therefore the date at which the initial EEE was "placed on the market" - not the date when it was repaired, nor the date when the spare part was "placed on the market".

6. REPAIRED/REFURBISHED MEDICAL DEVICES (MD)

Medical devices that were placed on the market before the entry into force of RoHS restrictions, once repaired, upgraded or refurbished do not need to be RoHS compliant and to have a new CE marking or DoC as long as it is made available as 'used', 'pre-owned' or 'refurbished', etc.

A repaired, upgraded or refurbished MD can only be made available as a "new" EEE if it complies with RoHS II and all applicable RoHS II requirements as of that date. Making available a used MD as "new" is equivalent to placing it on the market.

Note: Equipment placed on the market outside EU for the 1st time cannot be imported and placed on the EU market as 2nd hand or refurbished, after July 2014, unless it is RoHS compliant.

7. NEW LEGISLATIVE FRAMEWORK AND CE MARKING

RoHS II Directive has been aligned with the New Legislative Framework (revising the New Approach) consisting of Regulation (EC) 765/2008 and Decision 768/2008/EC. Therefore it contains formal requirements regarding CE marking, conformity assessment and other obligations of economic operators.

Starting from the application of substance restrictions, 22nd July 2014 for medical devices and 22nd July 2016 for IVD, manufacturers of medical devices should develop new technical documentation and new declarations of conformity including RoHS information.

The main source for interpretation of the New Approach is the "Guide to the implementation of directives based on the New Approach and the global Approach" also known as the "Blue Guide". This guide can be downloaded at the following link:
http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/ Should recognize that the Blue Guide is under revision.

7.1. CONFORMITY ASSESSMENT AND TECHNICAL DOCUMENTATION

Article 7 references Module A of Annex II to Decision 768/2008/EC, "internal production control" under the sole responsibility of the manufacturer, without the involvement of any third party. This procedure requires the manufacturer to issue a Declaration of conformity (DoC) and to draw up a technical documentation that should contain, wherever applicable:

- general description of the product
- conceptual design and manufacturing drawings and schemes, with necessary explanations
- harmonized standards applied and/or relevant technical specifications
- test reports

The above mentioned documentation should allow control authorities to verify the conformity of the product to RoHS II requirements.

In general it can be said that the detail level of the technical documentation depends on the risk presented by the restricted substances to be contained in certain materials or components. In most cases the declarations collected from suppliers or contractual agreements/technical specifications would be sufficient.

Chemical tests and test reports are normally not required unless for components/parts/material for which a high risk of non-conformity is involved, due to the nature of the product, or the low reliability of the supplier or other considerations.

The CENELEC standard EN 50581 *"Technical documentation for the assessment of electrical and*

electronic products with respect to the restriction of hazardous substances" helps manufacturers to define the appropriate content of the technical documentation and to put in place procedures and a systems that can be integrated in existing quality or environmental management systems.

In addition, the following IEC standards exist and provide useful guidance relating to material restrictions:

- IEC TR 62476 "Guidance for evaluation of products with respect to substance-use restrictions in electrical and electronic products"
- IEC/PAS 62596 "Electrotechnical products - Determination of restricted substances – Sampling procedure – Guidelines"
- EN 62321 "Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)"
- IEC 62474 "Material declaration for Products of and for the Electrotechnical Industry"

Another useful tool to help in preparing the technical documentation required by RoHS is BomCheck, a web based application adreesed to the supply chain to declare the content of chemicals.
https://www.bomcheck.net/

ENVIRON prepared a Guidance available at the following link:
https://www.bomcheck.net/assets/docs/Guide%20to%20Using%20BOMcheck%20and%20EN%20505081%20to%20Comply%20with%20RoHS2%20Technical%20Documentation%20Requirements.pdf

7.2. EU DECLARATION OF CONFORMITY

The EU Declaration of Conformity must be issued for products falling into RoHS II scope and has to be held by the manufacturer at disposal of authorities upon request.

For products not covered directly by the RoHS II Directive but which have to comply with substance restrictions, such as components, a RoHS DoC cannot be issued. Any statement or declaration regarding conformity of components to RoHS requirements is a voluntary declaration which can be regulated by contractual agreement but should not be confused with a DoC.

In most cases products are covered by more than one Directive. The NLF states that one single DoC covering all relevant Directives has to be issued. For medical devices this provision has not yet been incorporated in the MDD and is not reflected in RoHS II. Therefore, for now, the manufacturer has the choice to issue a single combined Declaration of Conformity or to provide a separate declaration for each relevant directive.

7.3. CE MARKING

The NLF requires only one CE marking to be added to products. RoHS II requirements regarding CE marking do not affect CE marking requirements with regard to other directives applying to the product itself.

For medical devices requiring a CE marking with the numerical suffix identifying the notify body, such as medical devices class IIb, and IIa, no additional CE marking is required.
In case of class III medical devices, the documentation to be submitted to Notified Bodies is not required to contain any references to manufacturer procedures or tests to ensure RoHS compliance.

To avoid that the use of this CE mark can be interpreted as the Notified body also assessed the manufacturer processes to ensure RoHS compliance, it is advisable to add a statement in the DoC explaining that RoHS compliance is ensured under the sole responsibility of the manufacturer.

7.4 PLACING ON THE MARKET

RoHS II Directive applies to medical devices placed on the market after 22 July 2014. The concept of being "placed on the market" has been subject to many discussions and many interpretations. The following documents have been analysed:

- Blue Guide to the implementation of directives based on the New Approach and the Global Approach (http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/)
- Interpretative document of the Commission's services: placing on the market of medical devices (November 2010)
- Regulation (EC) No 765/2008
- Proposal for a regulation on market surveillance of products COM(2013)75

Regulation 765/2008 provides the following definitions:

'placing on the market' *shall mean the first making available of a product on the Community market"*

*'**making available on the market'** shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge"*

Medical Devices produced in Europe

The interpretation of the terms "making available" and "placing on the market" indicates that the mere termination of the manufacture is not sufficient for a product to be considered placed on the market. It must have entered into the distribution chain.

The Guide to the implementation of directives based on the New Approach and the Global Approach ("Blue Guide") states that the placing on the market takes place when the product is transferred from the stage of manufacture with the intention of distribution or use on the Community market.

The transfer can consist in a physical hand-over and/or be based on a legal transaction. It can relate to the ownership, the possession or any other right transferred from the manufacturer to a distributor or to the end user. A transfer of a product is considered to have taken place, e.g., when it is sold, leased, given as a gift, rent out or hired. Where a manufacture operates an own distinct distribution chain, the transfer can also occur to that distribution chain.

In certain circumstances, a device which physically is still in the manufacturer's warehouse can be considered as placed on the market. For example, this may be the case where the ownership or another right of a certain product has already been transferred to either a distributor or the end user but the product is still stored by the manufacturer on their behalf. A case-by-case assessment is required and the manufacturer would have to be able to demonstrate that the product is singled out for being distributed.

Medical Devices Imported in Europe

Imported products must at least be released for free circulation by custom in the internal market before they can be considered as being placed on the EU market (see Articles 27-29 of Regulation (EC) No 765/2008). In particular paragraphs 1 and 2 of Article 29 of Regulation 765/2008 state that products which present a serious risk or which are not compliant with harmonised EU legislation, and which therefore shall not be placed on the EU market, shall not be released for free circulation. The question is whether the placing on the market is deemed to coincide with the release for free circulation. An importer is defined as the person established within the EU who places a product from a third country on the EU market. The importer can either be the authorised representative or another third person, who may belong to the non-EU manufacturer's own distribution network.

If the transfer of the finished device from the manufacturer (or a distributor) established outside the EU to the importer takes place prior to or during the customs procedure, its release for free circulation will also be the moment of its placing on the market.

Under certain circumstances, however, the placing on the market of an imported medical device does not coincide with its release for free circulation, namely in cases where that product has not yet been transferred from the stage of manufacture to the distribution stage.

COCIR Suggestion

Considering the complexity of the issue and the different business models and sales practices, COCIR suggests, as the safest interpretation, to consider that a product is placed on the market when it leaves the factory and ownership is transferred to the sales-organization/client or when EU customs clearance is granted and ownership is transferred to the sales-organization/client.

8. COCIR REQUESTED EXEMPTIONS

COCIR requested, between September 2011 and March 2012, twelve new exemptions to be added to Annex IV:

1st Batch

1. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers; (recommended validity – 31 December 2019)
2. Lead in solders used on PCBs for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards
3. Lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions (recommended validity – July 2012)
4. Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment (recommended validity – July 2012)
5. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation (recommended validity – July 2021)
6. Cadmium in phosphor coatings:
    a. in image intensifiers for Xray images (31 December 2019)
    b. in spare parts for x-ray systems placed on the EU market before 1 Jan 2020 (1 January 2020)
7. Lead in
    - solders on printed circuit boards,
    - termination coatings of electrical and electronic components and coatings of printed circuit boards
    - solders for connecting wires and cables,
    - solders connecting transducers and sensors

    that are used durably at a temperature below -20°C under normal operating and storage conditions.
    (recommended validity – July 2021)
8. Lead in:
    - solders
    - termination coatings of electrical and electronic components and printed circuit boards
    - connections of electrical wires, shields and enclosed connectors

    which are used:
    a) in magnetic fields within the sphere of 1 m radius around the isocenter of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere.
    b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy
    (recommended validity – 30 June 2020)
9. Lead in alloys as a superconductor and thermal conductor in devices that depend on superconductivity for their operation (request submitted by TMC - supporting evidence provided by COCIR)

2nd Batch

1. Hexavalent chromium in alkali dispensers used to create photocathodes
   - in X-ray image intensifiers until 31 December 2019
   - and in spare parts for X-ray systems placed on the EU market before 1 Jan 2020

2. Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer.

3. Lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment (recommended validity – 31 December 2019)

4. Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices others than portable emergency defibrillators:
   - used in Class IIa – mobile medical devices – 30 June 2016
   - used in Class IIb – mobile medical devices – 31 December 2020
   Where mobile medical devices are defined as medical devices which are designed and approved by a notified body, according to Directive 93/42/EEC, to be hand carried, or to be transported on own wheels, on a cart or trolley or in a vehicle, aircraft or vessel during and/or between operations.

The approval procedure could require up to 18 months, therefore the first batch of 8 exemptions is expected to be published on the O.J. middle 2013 and the 2nd one end 2013.

8.1. EXEMPTION OF LEAD IN SHIELDING AND COLLIMATORS

Exemption 5 in RoHS II, Annex III exempts the use of lead in shielding for medical devices. Shielding has to be understood as any kind of application using lead to stop, absorb or collimate x-rays or ionising radiation in general. Therefore any application of lead as “shielding” in the more general sense is covered by the exemption.

Appendix I present a report commissioned by COCIR to ERA Technology which fully support COCIR conclusions for the application of the exemption to collimators.

9. FAQS - GUIDANCE DOCUMENTS FROM INSTITUTIONS

9.1. EUROPEAN COMMISSION GUIDANCE

The European Commission developed a first “Frequently asked questions” guidance document on WEEE and RoHS in 2005. It can be downloaded at the following link:
http://ec.europa.eu/environment/waste/weee/pdf/faq_weee.pdf

This document which remained valid until 3 January 2013 (deadline for the transposition of the RoHS II Directive and repeal of RoHS I) has been recently updated for RoHS II while a new version will be published separately for WEEE. This new version is still a draft and subject to public consultation until 14 September.

The document is available here:
http://ec.europa.eu/environment/waste/rohs_eee/events_rohs3_en.htm

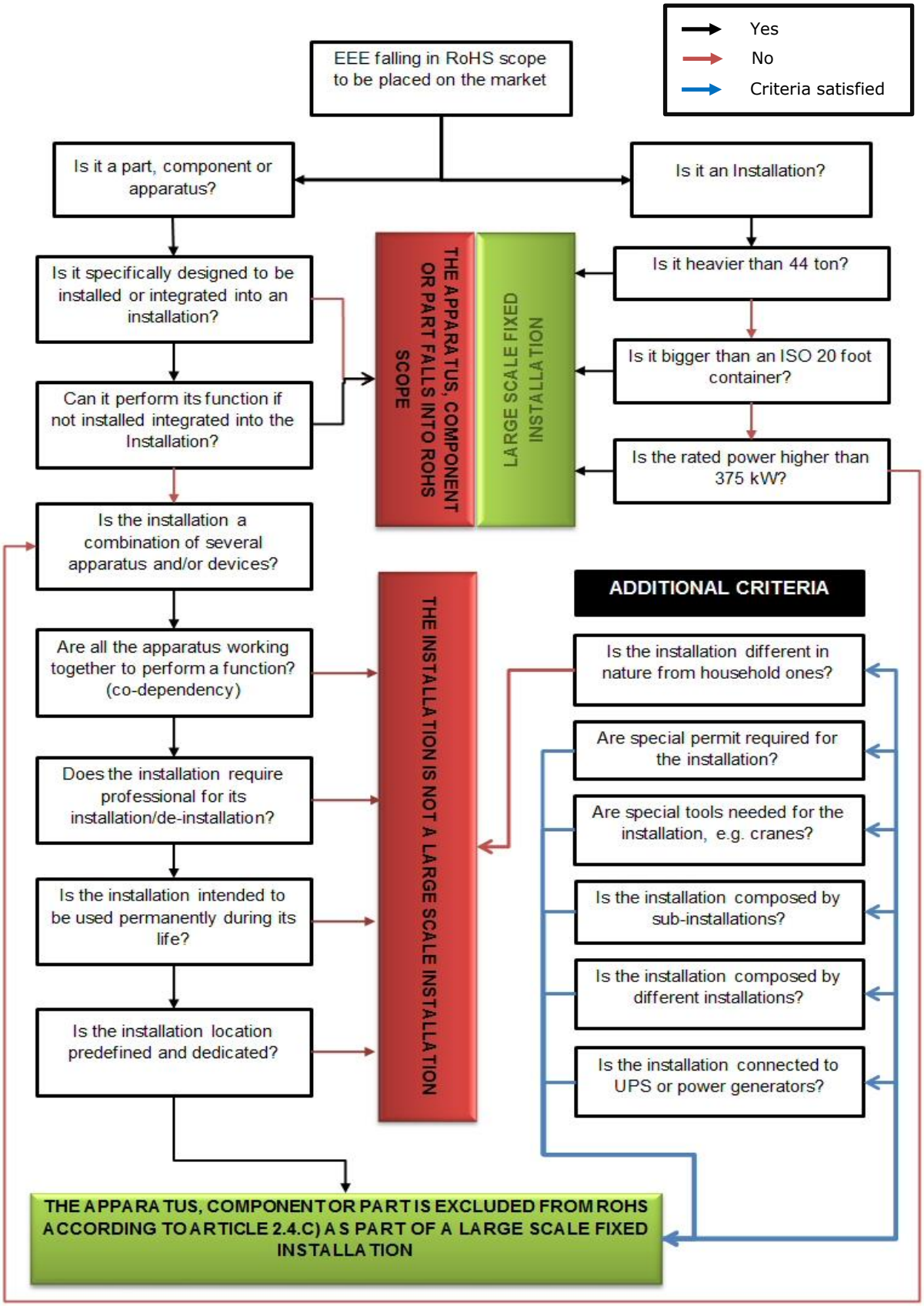
The new RoHS II FAQ document could provide useful information. Nonetheless COCIR suggests using it cautiously as some provided interpretation, in industry view, are not fully in line with the legal framework of new approach and the RoHS II text itself.

9.2. UK GUIDANCE

The UK department for business and industry (BIS) published a website dedicated to RoHS. A new guidance on RoHS II is available for download:
http://www.bis.gov.uk/nmo/enforcement/rohs-home/FAQs#Rohs

APPENDIX I

ROHS II – LARGE SCALE FIXED INSTALLATION DECISION TREE



APPENDIX II

Applicability of RoHS exemption 5 of Annex VI to collimators
ERA Project No. 043123033

See hereafter

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Applicability of RoHS exemption 5 of Annex VI to collimators

ERA Project No. 043123033

Background

In 2006, ERA carried out a review for the European Commission on the possibility of inclusion of categories 8 and 9 in the scope of the RoHS directive. As a part of this review, exemptions from the six RoHS substance restrictions were considered and as a result Annex IV was included in the recast directive 2011/65/EU. Item 5 of this Annex is "lead in shielding for ionising radiation". This is a fairly broad scope exemption which is described in ERA's report to the Commission[1]. Radiation shielding is used to block ionising radiation to protect patients and other people that might be exposed such as hospital workers. It is also used to protect electrical equipment that is used near radiation sources and to block unwanted scattered radiation. Radiation sources include X-radiation for imaging, a variety of ionising radiation types that are used for radiotherapy and radiation from radio-isotopes that are used for nuclear medicine and are detected by techniques such as positron emission tomography (PET). In all of these applications, shielding materials are used as a physical barrier to block radiation.

Two of the uses of lead in medical devices are as collimators for ionising radiation and in anti-scatter devices which are a type of collimator. The ERA report described some of the uses of lead as shielding including its use in some types of collimators. This guidance explains how exemption 5 of Annex IV is applicable to collimators.

Definitions of collimators and shielding

Wiki[2] defines collimators as

> "… a device that narrows a beam of particles or waves. To "narrow" can mean either to cause the directions of motion to become more aligned in a specific direction (i.e., collimated or parallel) or to cause the spatial cross section of the beam to become smaller".

Other definitions include:

[1] *See page 180. Report can be downloaded from http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf*
[2] *http://en.wikipedia.org/wiki/Collimator*

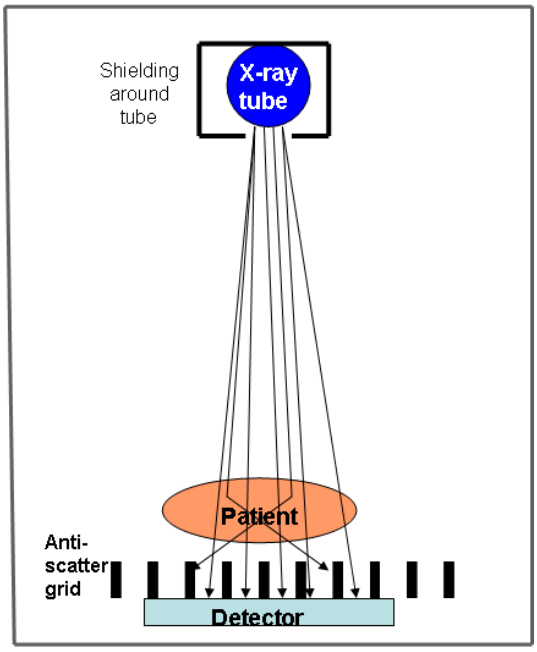
- A device that turns incoming radiation into parallel beams
- Any device for limiting the size and angle of spread of a beam of radiation or particles

Shielding (for ionising radiation) is defined for example as:

- Physical barriers designed to provide protection from the effects of ionizing radiation
- A protective device or structure
- To protect or defend with or as if with a shield
- To cover up or conceal

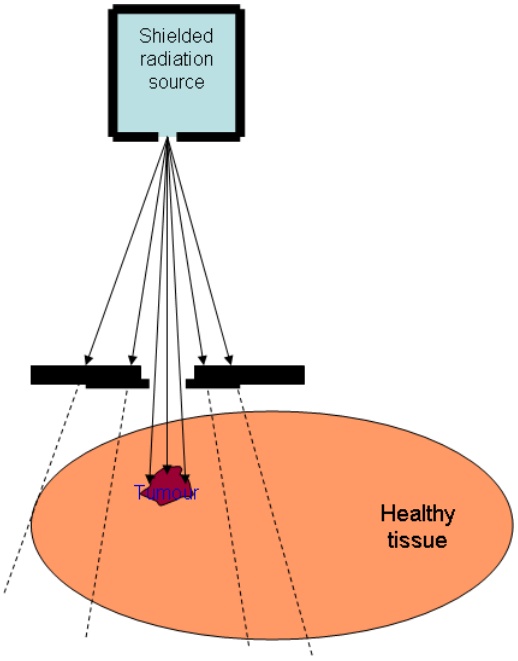
Collimator designs and functions

Collimators are used for a variety of purposes including to improve image quality and to target radiation onto cancerous tumours without harming surrounding healthy tissue.
When a part of the human body is imaged using X-rays, some of the radiation from the X-ray tube is scattered by nearby materials, these unwanted scattered X-rays can pass through the imaging area in different directions to those that are directly from the X-ray source. Scattered X-rays make the image less clear and so need to be removed by using an anti-scatter device or collimator.
An example for a medical application is anti-scatter devices that have complex grid structures made with lead which acts as a physical barrier to ionising radiation in certain directions. The purpose of the anti-scatter device is to allow radiation to pass through only in one direction. The anti-scatter device collimates an X-ray source to make it more uni-directional by acting as a shield that blocks radiation from undesirable directions as shown below:

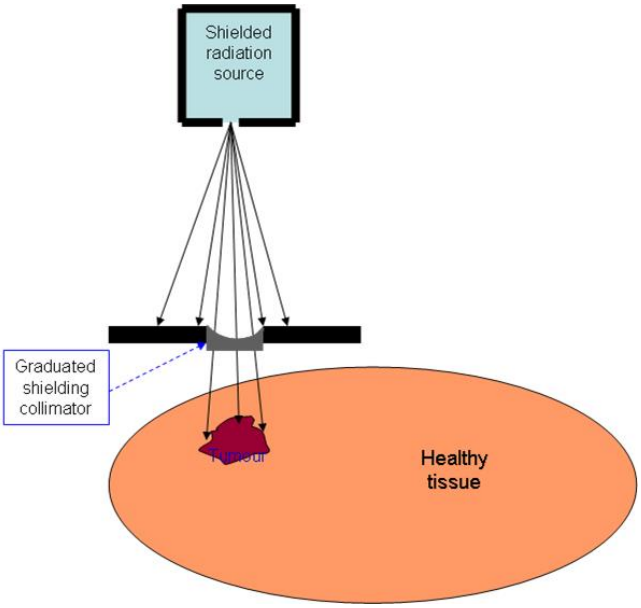


In the above example, radiation shielding is also used to protect the patient, electrical

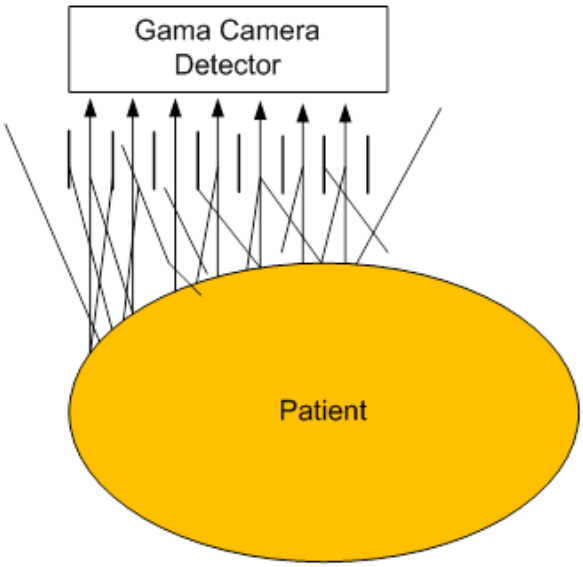
circuits and the detectors from scattered radiation and from radiation emitted from the tube in other directions.
Cancerous tumours are destroyed by beams of collimated ionising radiation. These beams need to be as unidirectional as possible and the area of exposure is be precisely controlled by collimators to prevent damage to surrounding healthy tissue. These devices are essentially an assembly of lead plates that are moved to positions, acting as a physical barrier (i.e. a shield) to prevent radiation reaching healthy tissue that surrounds the tumour. A typical collimator arrangement is illustrated below:



Another type of collimator used for radiation therapy is to adjust the radiation intensity across the region being exposed. This is achieved by using a radiation shielding material such as lead to block a proportion of the radiation. Graduated shielding collimators made of lead are used to “filter” the radiation beam, basically to modify the intensity of the beam. Typically this is done by a flattening filter, which ensures that the beam is uniform across the treatment area and a shaped piece of lead may be used to modify the beam intensity. Another example is the wedge filter; this produces a beam with a deliberate gradient (when plotted it forms a wedge-shape) and it allows the clinician to apply this varying beam intensity to particular anatomical structures which require such a gradient. An example is illustrat elow:



Collimators are also used in nuclear medicine to ensure that radiation emitted from the patient travels only in one direction to the detector so that a clear image is created by a gamma camera:



Scope of exemption 5 of Annex IV

The ERA "category 8 / 9" report describes a variety of applications where lead is used as a physical barrier to block ionising radiation. Examples include thick sections to protect patients and staff in hospitals and workers who use industrial X-ray imaging equipment. The shielding may be optically transparent (high lead-content glass) so that hospital staff can see patients while they are being imaged; or flexible shielding (e.g.) aprons, that can be worn by staff and patients. The report also describes applications where lead is used to improve the quality of images. These include:

- As grid structures – e.g. as anti-scatter devices
- In capillary plates used for X-ray collimation
- With equipment for radiation measurement – shielding is required to block stray radiation

The intention of exemption 5 of Annex IV is to allow the use of lead as a physical barrier, i.e. shielding for ionising radiation; this includes its use to protect humans from harmful radiation and control of the direction of ionising radiation to improve image quality and patients' treatment.

Collimators as ionising radiation shielding

Ionising radiation is generated by a variety of high energy sources emerging in many directions. Ionising radiation usually travels in a straight line, so any that travels in directions other than that intended needs to be blocked by radiation shielding and high atomic mass materials, such as lead are used.
When ionising radiation strikes an atom, three things can occur:

- It passes through unaffected (more likely with light elements)
- Its direction is deflected (scattering) or
- It is absorbed (more likely with the heaviest elements)

Effective shielding material should absorb the incident radiation as scattering is not desirable as this causes radiation to travel in other undesirable directions. Lead used in collimators will be exempted from the RoHS substance restriction if the function of this lead is to be "shielding for ionising radiation". Shielding is a physical barrier that blocks ionising radiation by absorbing it and the function of lead in collimators is to act as the shield or physical barrier to unwanted ionising radiation. The function of the lead in collimators is to absorb any ionising radiation travelling in an undesirable direction and so it is used as a shielding material to block unwanted radiation. The lead shielding ensures that radiation emerging from the collimation device is in only the required direction and from the correct location. The use of graduated collimators for radiotherapy is slightly different in that the shielding material blocks only a proportion of the radiation, allowing the rest to pass.

Conclusions

Any material that effectively absorbs ionising radiation can be used as "shielding", so where lead is used to act as a physical barrier to ionising radiation, it can rely on exemption 5 of Annex IV of Directive 2011/65/EU. Lead is used in collimators and in anti-scatter devices to absorb ionising radiation that is travelling in an undesirable direction and so this lead is used as shielding for ionising radiation. Therefore its use in collimators, in anti-scatter devices and in radiation filters would be exempt from the RoHS substance restrictions due to exemption 5 of Annex IV.

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APPENDIX III

Applicability of RoHS definition of large-scale fixed installation to certain medical installations:

- Radiopharmaceutical production
- Particle therapy
- Magnetoencephalography
- Radiation therapy

TABLE OF CONTENTS

INTERPRETATION OF ROHS EXCLUSION FOR LSFI APPLIED TO MEDICAL EQUIPMENT

COCIR

COCIR represent the Radiological, Electromedical and Healthcare IT Industry in Europe. COCIR member companies manufacture amongst others medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery, and biopharmaceutical manufacturing technologies. They also help clinicians around the world to develop new ways to predict, diagnose, inform and treat diseases.

OBJECTIVE OF THIS PAPER

This document is intended to be a COCIR internal document, providing a common view of COCIR Companies on the interpretation of the exclusion of LSFI and its application to certain medical devices. It is also supposed to provide a detailed analysis and arguments that could be used by COCIR Companies in case of discussion with border or control authorities regarding the conformity of medical devices to RoHS.

This document assesses whether certain medical technologies, namely:

1. Radiopharmaceutical Production System
2. Particle Therapy Equipment
4. Radiation Therapy System
5. Magnetoencephalography

fall under the scope of the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) or are explicitly excluded according to definitions and criteria.

RoHS SCOPE

According to Art. 2, 1, the RoHS Directive applies to electrical and electronic equipment falling under the categories set out in Annex I.
Art. 2, 4. (d) and (e) specifically exclude “large scale stationary industrial tools” and “large scale fixed installations” as well as all their components and parts.

CONCLUSION

The four medical equipment assessed in this document (Radiopharma installation, Particle Therapy, Angiography X-ray and Radiation Therapy) are explicitly excluded from the scope of the RoHS Directive as they clearly meet the definition of “large scale fixed installations” according to Art. 3,(4).

2. LEGAL ANALYSIS: ELEMENTS TO UNDERSTAND THE LSFI EXCLUSION

The WEEE and RoHS recast Directives introduce the new exclusion for "large scale fixed installations". This new exclusion is stricter than the one applied so far for "fixed installations". Therefore to interpret this new exclusion it is important to provide some solid interpretation to the words "large scale", in particular, to "large scale combination" considering the text of the exclusion:

*"large-scale fixed installation means a **large-scale combination** of several types of apparatus and, where applicable, other devices, which are assembled and installed by professionals, intended to be used permanently in a pre-defined and dedicated location, and de-installed by professionals;"*

The term apparatus according to Art. 2 ,1 (b) of the EMC Directive means:

> *"any finished appliance or combination thereof made commercially available as a single functional unit, intended for the end user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance".*

This definition includes the following aspects, which are also relevant for the purposes of the RoHS exemption: "finished appliance or combination thereof", "commercially available as a single functional unit", "intended for the end-user".

"Finished appliance" is defined as *"any device or unit that delivers a function and has its own enclosure"* (EMC Guide, p. 18).

The term "large size" is not self-explanatory and nor defined in the RoHS Directive. In order to establish the meaning, referencing to other Directives e.g. 2004/108/EC (EMC Directive) or 2002/96/EC (WEEE I Directive) as well as to elements of the legislative co-decision procedure RoHS II and WEEE II could be useful.

EMC Directive
Defines the term fixed installation in Art. 2, 1 (c):

> *"a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location"*

WEEE Directive

The only "precedent" for the term "large scale" would be the term "large scale stationary industrial tool" in Annex IA of Directive 2002/96/EC (WEEE Directive). According to Annex IA, "large scale stationary industrial tools" are exempt from WEEE-Category 6, which covers "electrical and electronic tools". The WEEE Directive, however, does not define the term either. Only the "Frequently Asked Questions" on RoHS and WEEE, published by the European Commission in 2005,[3] describe large scale stationary industrial tools as:

> *"machines or systems, consisting of a combination of equipment, systems, finished products and/or components, each of which is designed to be used in industry only, permanently fixed and installed by professionals at a given place in an industrial machinery or in an industrial building to perform a specific task.*
> *Not intended to be placed on the market as a single functional or commercial unit."*

This definition, which is not legally binding, does not contain specific minimum requirements for the size of a stationary industrial tool. The absence of such specific requirements may serve as an initial indication that equipment might be considered "large scale" if it meets the other requirements

[3] *http://ec.europa.eu/environment/waste/weee/pdf/faq_weee.pdf.*

spelled out in the definition, without having to meet an additional minimum size requirement.

Further, there is no indication why a "large scale" industrial tool would not also qualify as a "large scale" fixed installation. As admitted in the current version of the European Commission FAQs for RoHS II, LSFI and LSSIT often overlap.

RoHS and WEEE Recast

The legislative procedures of the RoHS and WEEE Recast suggest that no specific criteria exist for the minimum size of a "large scale fixed installation".

(i) Initial definition of "large scale fixed installation"
The initial Commission proposal for a recast of the existing RoHS Directive[4] did not contain an exemption for "large scale fixed installations". The inclusion of such exemption was proposed by the European Parliament[5]. Initially, the Parliament suggested the following definition:

"a particular combination of several types of apparatus and, where applicable, other devices, assembled and installed permanently at a predefined location. It shall not include electrical an electronic components which may, during the lifespan of the installation concerned, be replaced from time to time and which can also fulfil their function without being part of that installation".

Accordingly, the definition initially put forward by the European Parliament emphasized that the exemption for fixed installations should be limited to devices which are (a) installed permanently at a predefined location and (b) are not necessarily a part of an installation but could function independently. No further requirement as the minimum "largeness" of a fixed installation was put forward.

(ii) Examples for large-scale fixed installations
In position papers on both the RoHS Recast and the WEEE Recast, the Council of the European Union explained that the term "fixed installation":

"covers also nonindustrial commercial fixed installations (like large cooling rooms or large kitchens in restaurants) and fixed installations in hospitals, schools or public buildings".[6]

The examples provided by the Council (large cooling rooms, large kitchens, fixed installations in hospitals, schools or public buildings) show two things: Firstly, fixed installations in hospitals are covered by the term "fixed installation" and secondly, mid-sized installations qualify as "large". In light of the typical size of cooling rooms, kitchens, installations in schools and public buildings – many of which will be smaller than a medical imaging installation and easier to install and to remove from their current location, the argument can be made that with regard to its size most of medical imaging equipment fit well into the list of fixed installations provided by the Council.

(iii) Purpose of exempting large-scale fixed installations: Controlled waste stream
Further guidance can be obtained from the European Parliament legislative resolution of 3 February 2011 on WEEE Recast, which also contains an exemption for "large-scale fixed installations"[7]. The European Parliament's proposal for the WEEE Recast explains, in Recital 10, the rationale why large-scale fixed installations should be excluded from the scope of the WEEE Directive:

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[4] *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0809:FIN:EN:PDF.*
[5] *See the Parliament's draft proposal of 15 June 2010: http://www.europarl.europa.eu/sides /getDoc.do?type=REPORT&mode=XML&reference=A7-2010-0196&language=EN#title1, Amendments 23 and 42.*
[6] *http://register.consilium.europa.eu/pdf/en/10/st12/st12300.en10.pdf*
http://www.europa-nu.nl/9353000/1 /j4nvgs5kjg27kof_j9vvikqpopjt8zm/vifg629pm6zg
[7] See Amendments 2, 13 and 19, http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0037&language=EN&ring=A7-2010-0229.

"Large-scale fixed installations, inter alia, should be excluded from the scope of this Directive because they are permanently installed and operated at a particular location, are assembled and disassembled by specialist personnel ***and therefore represent a controlled waste stream****"* (emphasis added).

Accordingly, the underlying rationale of making an exemption for large-scale fixed installations in WEEE Recast is that the waste stream of such fixed installations is already controlled. The same rationale applies with regard to RoHS. Both, RoHS and WEEE, share the legislative goal to control waste streams. If waste containing restricted substances is already controlled – as is the case for large-scale fixed installations – there is no need to include such installations in the scope of RoHS and WEEE.

(iv) European Commission FAQs

The EC updated the Guidance document of RoHS Directive published in 2006 (Frequently Asked Questions on WEEE and RoHS Directive). In this new version of FAQs on RoHS II the EC proposes some criteria to help manufacturers to understand how to apply the LSFI exclusion to their products. Unfortunately some of the proposed criteria are arbitrary and extremely difficult to apply or verify. That is going to increase legal uncertainties and may cause complex discussions with control authorities.

Some of the conclusions of the FAQs document are anyway worth to be mentioned here:

1. *Due to the nature of both exclusions [LSFI and LSSIT], in case of doubt, decisions are to be taken on a case-by-case basis.*
2. *As for the industrial context for professional installation and de-installation, scenarios such as the need for special assembling equipment, required permits, if the commissioning is a professional engineering exercise, specialised training, considerable installation time etc. can be indicator.*
3. *"Large-scale" can be used […….omissis……] It also relates to tool or installation complexity, and to the effort needed for installing, operating, maintaining and de-installing a tool or an installation.*
4. *If the installation exceeds the minimum requirements for* ***one*** *of the following criteria, it can be considered large-scale:*
    - *If, when installing or de-installing the installation, it is too large to be moved in an ISO 20 foot container because the total sum of its parts as transported is larger than 5,71m x 2,35m x 2,39m, then it can be considered large-scale.*
    - *The maximum weight of many road trucks is 44 tonnes. Thus if, when installing or de-installing the installation, it is too heavy to be moved by a 44 tonne road truck, because the total sum of its parts as transported weighs more than the truck's load capacity, it can be considered large-scale.*
    - *If heavy-duty cranes are needed for installation or de-installation, the installation can be considered large-scale.*
    - *An installation that does not fit within a normal industrial environment, without the environment needing structural modification, can be considered large-scale. Examples for modifications are modified access areas, strengthened foundations etc.*
    - *If an installation has a rated output greater than 375 kW, it can be considered large-scale.*

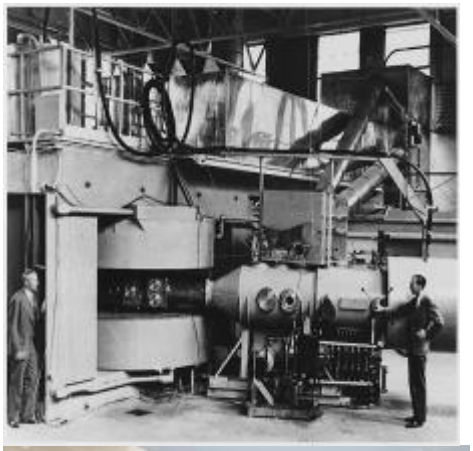
The dimensional criteria listed above in point 4 can be useful to provide some indication. In case such criteria are not met, or cannot be applied, decision has to be taken on a case-by-case basis taking into account complexity of the installation and other elements such as the ones highlighted in point 1 to 3.

3. RADIOPHARMACEUTICAL PRODUCTION INSTALLATION

3.1. DESCRIPTION

Radiopharmaceuticals (also called radiotracers) are medicinal formulations containing radioisotopes which are safe for administration in humans for diagnosis or for therapy. Specific radiopharmaceuticals are used e.g. for imaging organ function and disease states. All of this falls in the area of nuclear medicine.
A Radiopharmaceutical Production Installation in essence consists of a cyclotron (a type of particle accelerator) which allows the production of the radiotracer. A cyclotron is an electrically powered machine which produces a beam of charged particles that can be used for medical, industrial and research processes. As the name suggests, a cyclotron accelerates charged particles in a spiral path, which allows for a much longer acceleration path than a straight line accelerator.

Resulting risks derived from the usage of Radiopharmaceutical Production Installations are radiation and chemical/biological purity of the produced radioisotopes. These risks are well defined and it may be assumed are well controllable and controlled in state-of-the-art production facilities. Synthesis equipment (chemistry module) for the formulation of numerous radiopharmaceuticals, used for medical imaging purposes, is in part integrated into the cyclotron or may be custom build in near-by laboratories at the production site.



Major components of a Radiopharmaceutical Production Installation or isotope production installation are:
- Cyclotron
- Ion source
- Beam extractors and diagnostics
- Beam lines
- Vacuum and radio frequency systems
- Stationary and movable shields
- Control and heat exchange cabinets
- Synthesis equipment (chemistry module)

3.2. USES

Radiopharmaceutical Production Installation produces proton beams which are used to manufacture short-lived positron-emitting radioisotopes used in medical diagnosis. Radioisotopes decay by either positron emission or electron capture. Depending of this, the isotope is used in combination with Positron emission tomography (PET) and Single Photon Emission Computed Tomography (SPECT). The latter utilizes the gamma rays associated with electron capture. These two types of imaging techniques rely on cyclotron-produced radioisotopes.

3.3. LEGAL ANALYSIS

3.3.1. ROHS Scope

According to Art. 2, 1. of the RoHS Directive 2011/65/EU, it applies to electrical and electronic equipment ("EEE") falling under the categories set out in Annex I. Annex I comprises, amongst other equipment, category 6 (Electrical and electronic tools) and category 8 (Medical Devices).

Production equipment for radioactive tracers is generally speaking not covered by Directive 93/42/EEC concerning medical devices (MDD), thus not qualifying as a medical device. Only cyclotrons directly connected to the imaging equipment (e.g. PET scanners, PET-CT, PET-MR and other positron sensitive nuclear-medicine imaging equipment) may qualify as medical device.

In consequence, a Radiopharmaceutical Production Installation falls under category 6 (Electrical and electronic tools).

2.3.2 Large Scale Fixed Installations

A Radiopharmaceutical Production Installation does not fall into the RoHS scope as it has to be qualified as "large scale fixed installations".

The term large scale fixed installation is defined in the ROHS Directive Art. 3, (4) as follows:

"large scale fixed installation" means a large size combination of several types of apparatus and, where applicable, other devices, which are assembled, installed by professionals and intended to be used permanently in a pre-defined and dedicated location, and to be de-installed by professionals;

Radiopharmaceutical Production Installations have to fit the definition criteria to be considered large scale fixed installations:

a) To be a large size combination of several types of apparatus and other devices.
b) To be assembled and installed by professionals.
c) To be intended to be used permanently in a predefined and dedicated location.
d) To be de-installed by professionals.

With regards to a)
A radiopharmaceutical installation is a combination of several types of apparatus and other devices as explained above, such as:

- Cyclotron
- Ion source
- Beam extractors and diagnostics
- Beam lines
- Targets
- Vacuum and radio frequency systems
- Stationary and movable shields
- Control and heat exchange cabinets
- Synthesis equipment (chemistry module)

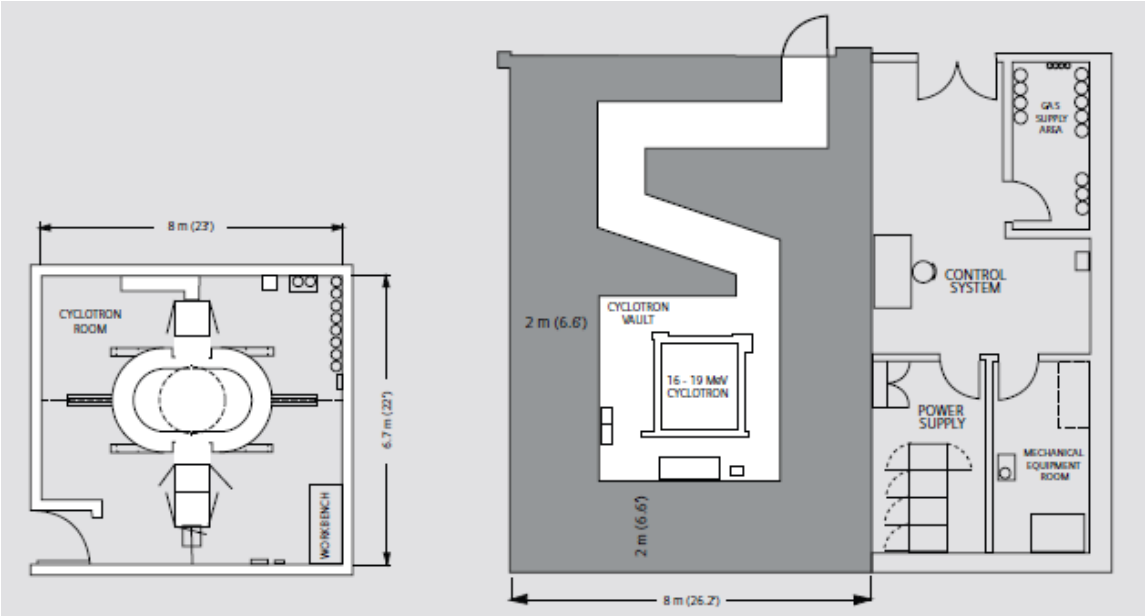
The analysis of criteria at points b), c) and d) also shows un-equivocally that the radiopharmaceutical production installation is a Large Scale Fixed Installation.

With regards to b), c) and d)
A radiopharmaceutical installation is set up in accordance to the individual needs of the customer and his radiopharmaceutical production goals. It has tailor made elements and is build up individually at a predefined and dedicated location.

Just the cyclotron total weigh can excess 50 tons, requiring special capacity cranes for the installation process. The room dimension for an unshielded cyclotron is about 50m³ and for a shielded cyclotron about 150m³. Furthermore, the radiopharmaceutical production system requires

the installation of a series of rooms designed and approved by a physicist to ensure no radiation inadvertent release or radioactivity escape.

In addition to the room for the cyclotron, a hot lab (special equipment with radiation shielding to allow for the extraction and use of the generated radioisotopes) and a quality control laboratory are required. Below is an example of how the total installation site might look. On the left, the cyclotron room, on the right, the complete radiopharmaceutical production installation, including the cyclotron room.



The cyclotron system may be delivered with an integrated radiation shield and is intended to be put in a controlled area for the task of radiopharmaceutical production. Even if the level of radiation around the cyclotron system is low, the installation of a cyclotron system in close proximity to a public area has to be planned with professionals in the field of radiation protection. The areas where the radioisotopes are prepared and used, the scanner room, blood lab and areas for quality control are usually identified as radiation areas and are restricted for the purpose of the protection of individuals from exposure to radiation.
The cyclotron system takes a professional team up to 5 weeks to install, calibrate, and test.

European Commission RoHS2 Guidance document (FAQs)
At least, two of the conditions detailed in the RoHS2 FAQ are always respected for radiopharmaceutical production installations:

If the installation exceeds the minimum requirements for one of the following criteria, it can be considered large-scale:

- *If heavy-duty cranes are needed for installation or de-installation, the installation can be considered large-scale.*

Heavy duty cranes are always used for the installation of Cyclotrons.

- *An installation that does not fit within a normal industrial environment, without the environment needing structural modification, can be considered large-scale. Examples for modifications are modified access areas, strengthened foundations etc.*

Cyclotrons always need to be installed in dedicated buildings with around 2 meters thick concrete radiation shielding. Self-shielded cyclotrons are so heavy that strengthened foundations are always necessary.

3.4. CONCLUSION

According to the elements explained above radiopharmaceutical production installations fit the exclusion provided by the RoHS Directive and are to be considered large scale fixed installations according to Article 3.(4) of the RoHS Directive. As such, they are explicitly excluded from the RoHS Directive scope according to Article 2, 4. (e).
This interpretation is confirmed by the RoHS2 FAQ interpretation

3.5. EQUIPMENT THAT ARE SPECIFICALLY DESIGNED TO BE PART OF A RADIOPHARMACEUTICAL PRODUCTION INSTALLATION

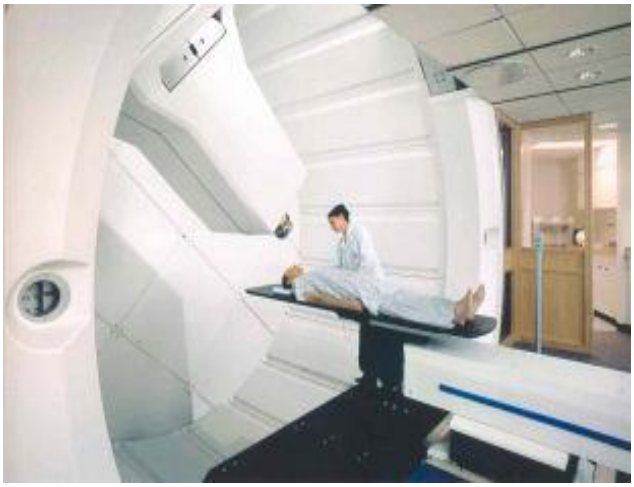
According to Article 2, 4. (c), equipment that are specifically designed to be part of a cyclotron system which could not fulfil their function if not installed in such system, are excluded as well from the scope of the RoHS Directive.

Article 2, 4. (c)

Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

4. PARTICLE THERAPY

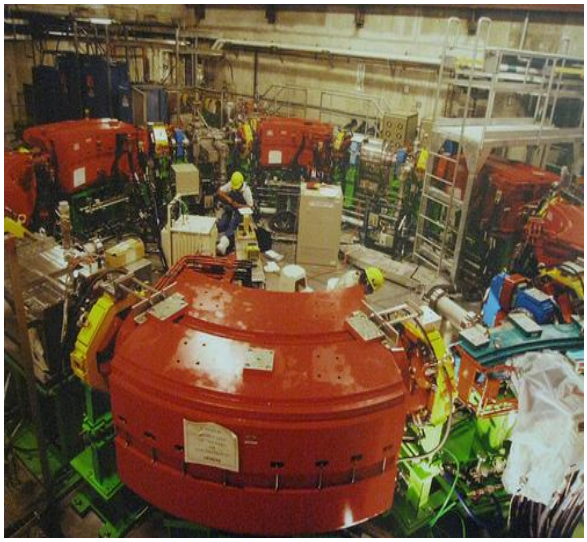
4.1. DESCRIPTION



Particle Therapy (PT) is a treatment which uses a beam of particles (protons or carbons) for radiation therapy, most often in the treatment of cancer. The main advantage of particle therapy is to better conform the dose distribution to a target volume when compared with other types of external beam radiotherapy. For carbon ion therapy the higher radiobiological effectiveness is another advantage for many tumours.
During treatment a beam of high energy particles is focused to cover a target volume. These charged particles damage the DNA of cells, ultimately causing their death or interfering with their ability to reproduce. Cancerous cells, because of their high rate of division and their reduced ability to repair damaged DNA, are particularly vulnerable to attack on their DNA.

Heavier particles have little lateral side scatter in the tissue; the beam does not broaden much, stays focused on the target shape and delivers only small doses to surrounding tissue.

Particles can be accelerated using a cyclotron or using a synchrotron.



Above, pictures of focalization magnets within beam lines.

4.2. INSTALLATIONS

The term Particle Therapy Installation or Center, as it can be seen on the picture below, indicates a complex installation of numerous apparatus, components and other devices located in a special construction to host them and to deliver the healthcare treatment to patients. It consists in fact of an entire building of considerable size, covering thousands of square meters of space. Core components are part of the stationary structure, which are connected by data cabling, power cabling and various supply lines. They are intended to be used permanently in the respective building. The weight of the whole installation may be several hundred tons. The expected lifecycle of the PT center may exceed 25 years. The machine is expected to last much longer as can be seen in the Lawrence Berkely Laboratories. The have a similar machine running since approx. 1935.

The building consists of several rooms, for examples:

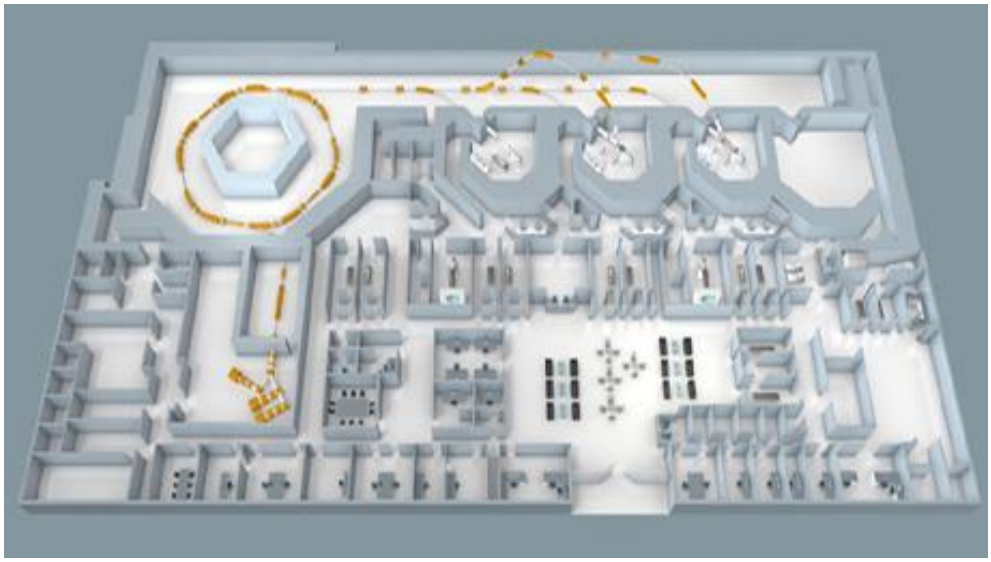
- 1 to 5 treatment rooms in which a patient can be treated (4 of these rooms are on the picture).
- The cyclotron or synchrotron is installed in a separate room.
- To transport the beam from the accelerator towards the different treatment rooms there is an area where the so-called “beam line” is installed.
- Each treatment room has a control room from where the doctor can control the room and the treatment for that room
- Different other rooms contain the power supplies, cooling equipment, etc.

Since the accelerator and beam line contain ionizing radiation, these rooms are shielded to protect the public, operators and the patient from radiation.

Worldwide only a limited number of PT sites currently exist, due to the high investments needed (exceeding easily 100 Mio Euro) and complex construction process and time. Particle therapy facilities are specialized structures specifically designed to fit the needs of the individual project. Installations are often used for both high-end radiotherapy treatment and research.

Listed below examples of equipment part of the particle therapy installation in the narrow sense, i.e., only the elements of the PT center that are part of the electrical installation with the purpose to generate a beam and apply such beam to patients for treatment purposes, consists of following:

- Ion sources
- Linear accelerators
- Synchrotron/cyclotron with
  - Dipole Magnets
  - Quadrupole Magnets
  - RF cavities
  - Beam extraction
  - High-energy beam transport (consisting of vacuum tubes and magnets)
- Multiple treatment rooms with
  - Beam outlet
  - Robotic patient positioning
  - Dose Monitoring system
  - Active beam scanning system
  - Imaging system
  - User interface
- Control rooms
- Integrated IT systems (therapy control / treatment planning systems)



Particle Therapy Centers are never exactly the same, as each customer has some specific requests and therefore the system is tailor-made.

4.3. LEGAL ANALYSIS

3.3.1 ROHS SCOPE

According to Art. 2, 1. RoHS Directive 2011/65/EU, it applies to electrical and electronic equipment ("EEE") falling under the categories set out in Annex I. Annex I comprises, amongst other equipment, category 8 (Medical Devices). Particle therapy installations are medical devices according to Directive 93/42/EEC.

4.3.2. LARGE SCALE FIXED INSTALLATION

Particle therapy does not fall into the RoHS scope as it has to be qualified as "large scale fixed installations".

The term large scale fixed installation is defined in the RoHS Directive Art. 3, (4) as follow:

"large scale fixed installation" means a large size combination of several types of apparatus and, where applicable, other devices, which are assembled, installed by professionals and intended to be used permanently in a pre-defined and dedicated location, and to be de-installed by professionals;

Particle therapy installations fit the definition criteria to be considered for large scale fixed installations:

a) To be a large size combination of several types of apparatus and other devices
b) To be assembled and installed by professionals
c) To be intended to be used permanently in a predefined and dedicated location
d) To be de-installed by professionals

With regards to a)
The PT installation consists of a number of apparatus, components and other devices. Generally such installations have the size of the treatment facility in which they are hosted and are composed by several types of different apparatus, such as: particle accelerator, beams extractors, gantry, collimators and filters, monitors and control instruments and sensors, control rooms, therapy rooms, etc.

Most components of the PT installation will be "finished appliances", because they deliver a function and have their own enclosure, specifically designed to be part of the installation. The weight of the whole electrical system is several hundred tons in a minimum configuration. For instance the cyclotron alone could weigh over 200 tons. Other extremely large and heavy parts are the beam line and the gantry. The gantry is the place where the beam is delivered to the patient at any desired angle. It contains the magnets to bend the ion beam, focus the beam but also scanning magnets and detectors to ensure that the beam is at the exact position needed for each unique treatment. All of this makes the gantries very heavy, between 150t and 670t depending on the size of the ions.

With regards to b) and d)
PT installation requires to be carefully installed, calibrated and tested by specifically trained professionals. The beam needs to be closely monitored and calibrated to ensure correct treatment. All the parts of the beam line are assembled with great caution and are tested extensively before use. Specific knowledge of particle therapy and its physics are needed for this installation. A safety policy also assures that all safety equipment is in place before the beam is started the first time.

As for the installations, the de-installation of such equipment could be performed only by specifically trained professionals. De-installers need to take into account the accumulated irradiation and thus specific safety policies need to be followed for the operations.

With regards to c)
The PT center is a complex and large installation, built into a large building, to which it is connected in multiple ways, e.g. via data cabling, power, cabling, water cooling installation and various supply lines. The configuration of each PT center is unique; the devices which make up the PT installation need to remain in place at their respective location in order to allow the PT center to function. All equipment of the several rooms are linked and a system test is performed for these complex systems.

With regards to RoHS II FAQs
At least, four of the conditions detailed in the RoHS II FAQs are always respected for PT centers:

If the installation exceeds the minimum requirements for one of the following criteria, it can be considered large-scale:

- *If, when installing or de-installing the installation, it is too large to be moved in an ISO 20 foot container because the total sum of its parts as transported is larger than 5,71m x 2,35m x 2,39m, then it can be considered large-scale.*

Cyclotron, treatment rooms, Gantry, beam line etc… will definitely never fit together in a ISO 20 foot container.

- *The maximum weight of many road trucks is 44 tonnes. Thus if, when installing or de-installing the installation, it is too heavy to be moved by a 44 tonne road truck, because the total sum of its parts as transported weighs more than the truck's load capacity, it can be considered large-scale.*

The truck load net capacity is close to 25 tons. This is the approximate weight of a small synchrocyclotron or a small gantry. For this reason, a complete PT center certainly doesn't fit in a 44 tonnes truck.

- *If heavy-duty cranes are needed for installation or de-installation, the installation can be considered large-scale.*

Heavy duty cranes are always used for the installation of Cyclotrons or Synchrocyclotrons. Furthermore other elements such as the gantry parts need also a heavy duty crane for the installation.

- *An installation that does not fit within a normal industrial environment, without the environment needing structural modification, can be considered large-scale. Examples for modifications are modified access areas, strengthened foundations etc.*

Cyclotrons and Synchrocyclotrons always need to be installed in dedicated buildings with around meters thick concrete radiation shielding. Self-shielded cyclotrons are so heavy that strengthened foundations are always necessary. Many other places such as the treatment rooms are also specifically designed, including for shielding purpose.

4.4. CONCLUSIONS

Particle therapy installations are large scale fixed installations according to Article 3. (4) of the RoHS Directive and are excluded from the scope according to Article 2, 4. (e).

4.5. EQUIPMENT THAT ARE SPECIFICALLY DESIGNED TO BE PART OF A PARTICLE THERAPY INSTALLATION

According to Article 2, 4. (c), all the equipment that are specifically designed to be part of a Particle Therapy Installations and that could not fulfil their function if not installed in such installations, are excluded as well from the scope of the RoHS Directive.

Article 2, 4. (c)
Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

5. RADIATION THERAPY INSTALLATION (LINEAR ELECTRON ACCELERATOR)

5.1. DESCRIPTION

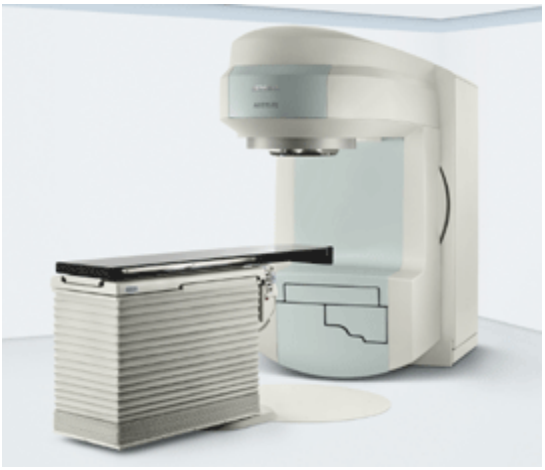
Radiation therapy uses high-energy radiation to shrink tumours and kill cancer cells. X-rays, gamma rays, and charged particles are types of radiation used for cancer treatment. A linear accelerator (LINAC) is the device most commonly used for external beam radiation treatments for patients with cancer. The linear accelerator is used to treat all parts/organs of the body. It delivers high-energy x-rays to the region of the patient's tumour. These x-ray treatments can be designed in such a way that they destroy the cancer cells while sparing the surrounding normal tissue.

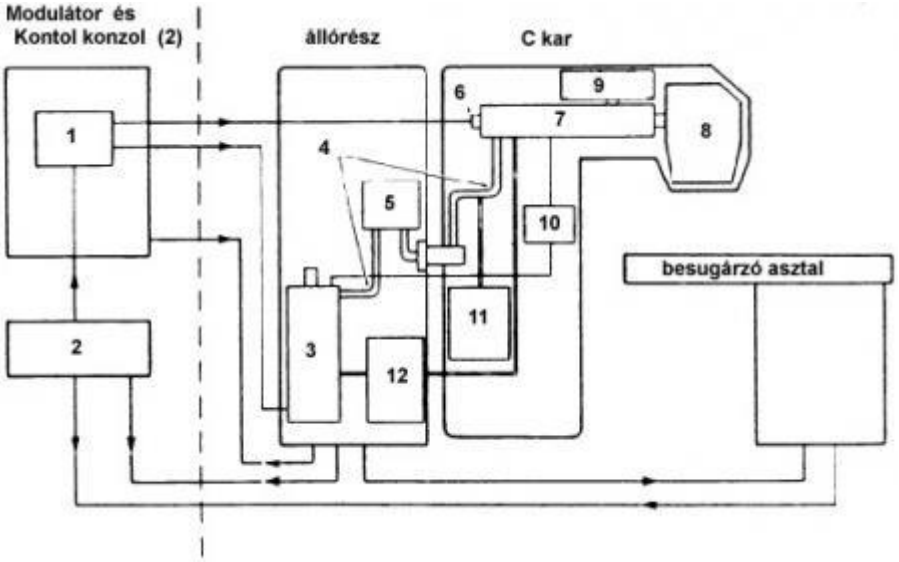
The radiation used for cancer treatment may come from a machine outside the body, or it may come from radioactive material placed in the body near tumor cells or injected into the bloodstream. A patient may receive radiation therapy before, during, or after surgery, depending on the type of cancer being treated. Some patients receive radiation therapy alone, and some receive radiation therapy in combination with chemotherapy.

Major components of a Radiation Therapy Installation are:

1) Stationary structure
2) Gantry
3) Gun (to produce the electrons to be accelerated in the waveguide)
4) Magnetron or Klystron based RF (= Radio Frequency) power source (to produce the radio frequency energy)
5) RF circuit (to send radio frequency energy from the RF power source to the accelerating waveguide)
6) Accelerating waveguide (to accelerate the electrons)
7) Bending magnet envelope (to filter and redirect the electrons)
8) Collimator (to render the beam usable for treatments)
9) Dosimetry System (to measure the dose being delivered, compare it with the planning Dose and turning off the beam when the actual dose reaches the planned dose)
10) Imaging System (to visualize tumors and critical structures)

The figure here below shows the main unit of a linear accelerator which is just the front end of the whole installation delivering the radiation to the patient.





A console computer controls the various features of the linear accelerator, e.g. positioning, dosimetry, beam, interlocks. The console computer and the other control elements must be able to withstand significant amounts of high energy photons, neutrons and unwanted perturbation ("noise"), which are generated by the high voltage components in the modulator, the production of radio frequency and the presence of strong electro-magnetic fields.

Various devices measure and process relevant data, e.g. from the ionization chambers (dose, dose rate, dose pulse delivered to the patient etc.) and the dosimetry channels/boards.

The installation consists of a number of further elements, most of which are specifically designed for the specific solution, while others are "off-the-shelf" or slightly modified standard devices, such as computer monitors, computer mice, computer keyboards for healthcare devices, Uninterrupted Power Supply systems, computer routers, power conditioners, "chillers", power supplies, emergency power, radiation warning light and safety door interlock switches.

5.2. LEGAL ANALYSIS

4.2.1 ROHS SCOPE

According to Art. 2, 1. of RoHS Directive 2011/65/EU, it applies to electrical and electronic equipment ("EEE") falling under the categories set out in Annex I. Annex I comprises, amongst other equipment category 8 (Medical Devices).

The Radiation Therapy Installation falls under the MDD (Directive 93/42/EEC), thus qualifies as a medical device.

4.2.2. LARGE SCALE FIXED INSTALLATIONS

A Radiation Therapy Installation does not fall into the RoHS scope as it has to be qualified as a "large scale fixed installation".

The term large scale fixed installation is defined in Art. 3, (4) as follows:
"large scale fixed installation" means a large size combination of several types of apparatus and, where applicable, other devices, which are assembled, installed by professionals and intended to be used permanently in a pre-defined and dedicated location, and to be de-installed by professionals;

A Radiation Therapy Installation fits the definition criteria:

a) To be a large size combination of several types of apparatus and, where applicable, other devices.
b) To be assembled and installed by professionals.
c) To be intended to be used permanently in a predefined and dedicated location.
d) To be de-installed by professionals.

As Radiation Therapy Installations are:

- assembled, installed and intended to be de-installed by professionals,
- a combination of several types of apparatus and other devices,
- intended to be used permanently in a pre-defined and dedicated location
- of "large size".

With regards to b), c) and d)
A Radiation Therapy Installation is assembled, installed and will have to be de-installed by professionals.

The Radiation Therapy Installation solution is intended to be used permanently in a pre defined and dedicated location. The system is typically installed in a dedicated room in a "bunker floor". Its base frame is poured in concrete in a defined pit. The installation is very heavy; the accelerator alone weighs around 8 tons. Gantry and stationary structure are made of heavy steel. The hand control arm is fixed to the ceiling with an overhead suspension mounting plate. The installation is connected to a separated cooling water installation. In order to install and operate the system, various components and systems must be installed, e.g. air conditioning, cooling water system, concrete foundation, radiation shielding, control systems, e.g. for magnetic fields, power conditioner, radiation warning light, emergency power and safety door interlock switches, patient video observation system, control console cabinet.

While, in principle, it is possible to re-locate the core components of the linear accelerator and to install such components at a different place, this would imply a complete de-installation and disassembly of the system. Radiation therapy installations are designed to be permanent.

5.3. CONCLUSION

Accordingly, Radiation Therapy Installations are “large scale fixed installation” in the meaning of Art. 3 (d) of RoHS Directive.

5.4. EQUIPMENT THAT ARE SPECIFICALLY DESIGNED TO BE PART OF A RADIATION THERAPY INSTALLATION

According to Article 2, 4. (c), equipment that are specifically designed to be part of a Radiation Therapy Installation which could not fulfill their function if not installed in such system, are excluded as well from the scope of the RoHS Directive.

Article 2, 4. (c)
Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

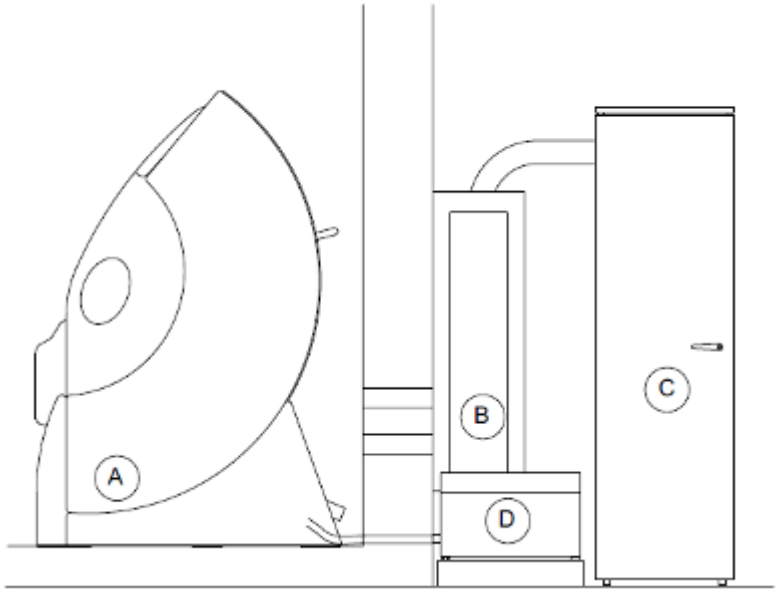
6. MAGNETOENCEPHALOGRAPHY

6.1. DESCRIPTION

Magnetoencephalography (MEG) is a medical diagnostic instrument that detects minute magnetic fields elicited by the brain. The information is used in, for example, epilepsy diagnostics and pre-surgical mapping of functional brain areas. To operate, the detectors in the MEG systems have to be kept at a cryogenic temperature of 4 K (–269 °C) using liquid helium.
Magnetoencephalography (MEG) uses an array of SQUID detectors to detect extremely small electrical signals from within the brain. This information is used to generate 3D maps of the brain by detecting and mapping minute brain signals. These signals are extremely small (of the order of tens of femtoteslas – 1/1,000,000,000th the strength of earth's magnetic field) and the main global manufacturer's MEG, for example has 306 special superconducting quantum interference devices (SQUIDs) used as detectors. The detection of such small signals is only possible in the absence of external electromagnetic noise and this noise can only be eliminated by cooling the detector to cryogenic temperature of 4 K (-269 °C) using liquid helium.

The core of an MEG system, the probe unit with a patient bed or a patient chair inside of a magnetically shielded room.

MEGs are installed in specific heavy shielded rooms (magnetically shielded room, MSR, weighing up to 10 tons) against electromagnetic interferences. MEG installations are composed of different rooms which have to satisfy very strict requirements to eliminate electromagnetic noise. Electromagnetic site survey is an indispensable part of the site planning to find a suitable location. A remote location in a dedicated building or wing is sometimes necessary, and even in existing buildings modifications are necessary to adjust for the magnetically shielded room and equipment. Each installation is tailor-made and unique given the site-specific environmental and construction restrictions and specific customer requests regarding the content of the MEG system. The installation of a MEG system including site modifications could take up to 8 months; with new buildings built for purpose it could be even longer. Actual shielded room installation, MEG system installation and system start up takes about two months.

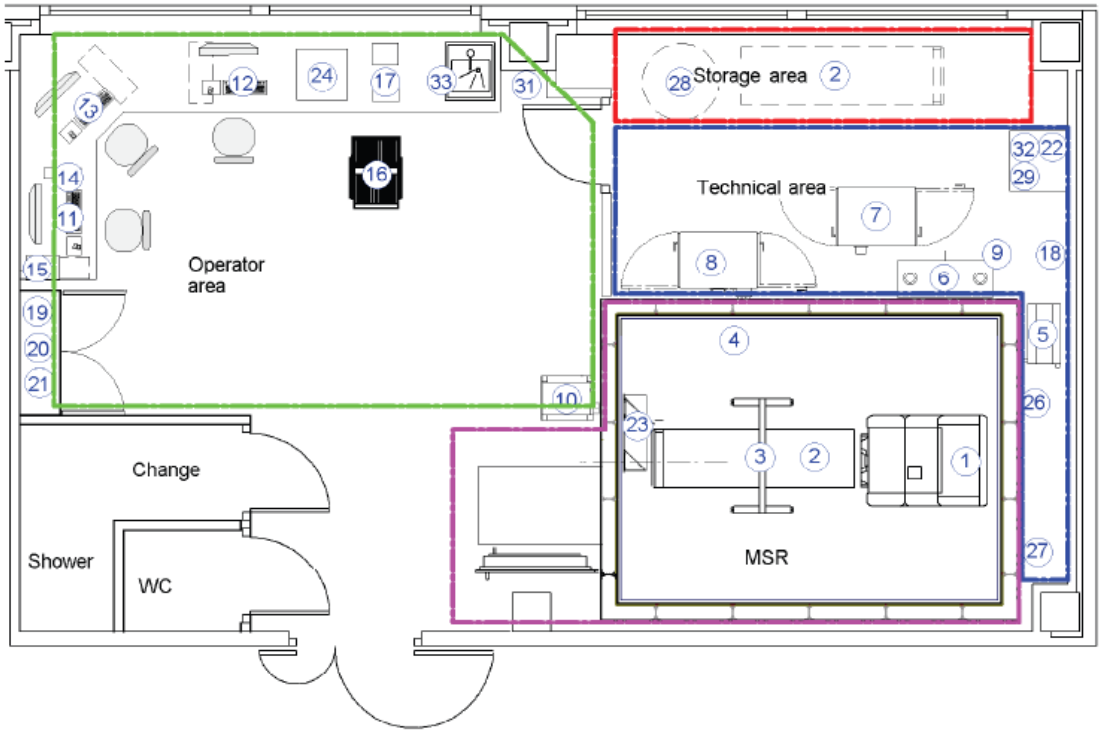


The electronics modules are the Filter cabinet (B), the Electronics cabinet (C) and the Lifting unit (D). They are located and operated in the technical area of the MEG laboratory.

A complete MEG installation comprises several sub-systems:

- Probe unit with superconducting sensors and front-end electronics. A MEG probe unit also houses an integrated EEG (electroencephalography) and bio potential signal amplifier
- Patient support (chair, bed)
- Electromagnetic interference filtering unit
- Main electronics unit
- Lifting unit (external, cannot be located inside the MSR because of magnetic noise) to move the unit between different measurement positions
- Data acquisition computer
- Data analysis computers (separate from data acquisition, analysis performed off-line)
- Three-dimensional digitizer to align the MEG with anatomic and functional data from other imaging modalities such as MRI, CT, SPECT
- Patient surveillance such as intercom and closed-circuit television, built specifically for MEG to avoid electromagnetic interference
- Liquid and gaseous helium handling. MEG may optionally be integrated with helium gas recycling and re-liquification subsystems
- Isolated and un-interrupted mains power supply
- Patient stimulation equipment (audio-visual, somatosensory)
- Interference suppression (active external magnetic field compensation)
- IT networking and peripherals, including data storage
- Shielded room lights, ventilation, optional alarms (e.g. air oxygen content)
- Other optional and additional equipment requested by customer, e.g. stimulators, monitoring equipment etc.

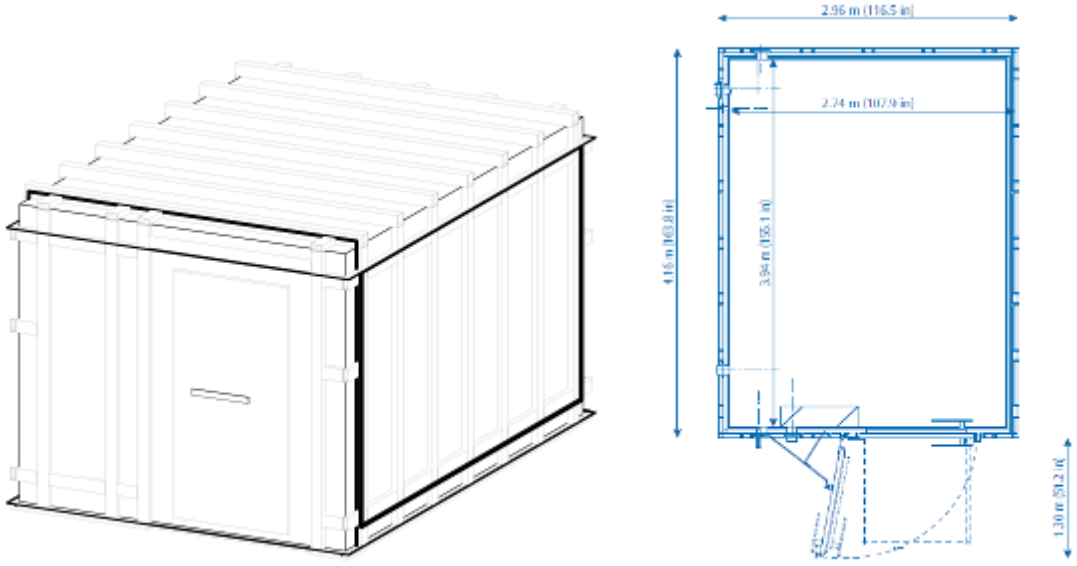
EXAMPLE OF A MEG INSTALLATION



MSR = Magnetically shielded room
1. Probe unit
2. Patient bed or chair
Probe unit in two positions
3. Back projection screen
4. CCTV camera
5. Lifting motor
6. Filter cabinet
7. Electronics cabinet
8. Stimulus cabinet
9. Main grounding point
of the Filter cabinet
10. Video projector
11. Data acquisition workstation (DACQ)
12. Data analysis workstation (DANA)
13. Stimulus control PC
14. Intercom terminal to MSR
15. CCTV monitor to MSR
16. 3D-digitization chair
17. 3D-digitizer
18. Helium safety exhaust duct
19. Isolation transformers
20. UPS for DACQ workstation
21. UPS for Electronics cabinet
22. MEG subnetwork switch
23. Periscope
24. Printer
25. Data storage server
26. MSR air in port
27. MSR air out port
28. Movable, non-magnetic, liquid He transfer dewar
29. IT cross-connection cabinet for MEG subnet
30. Air compressor for MSR door
31. Oxygen level monitoring device
32. EAS electronics
33. Water supply

A view from operator's area. The open door metal-framed door is the entrance to the magnetically shielded room.

MEG Shielding Against Interferences



A magnetically shielded room.

Since the magnetoencephalographic signals are very weak, several methods to shield MEG system against external interference are necessary. As discussed above, selection of a proper location where interference is minimized is the first step. Secondly, the MEG sensor must always be placed in a magnetically shielded room which is made of shells comprising high-permeability metal alloy sandwiched with a high-conductivity metal. Depending on the disturbances on the site, 1, 2, or 3 concentric shielding shells are used, resulting in a construction with a mass from 5 tons to

well excess of 10 tons. A typical inside dimension of the room is 3 by 4 square meters. Third, active compensation realized with an external magnetic field detector, and electronics control unit and compensation coils around the room may be used. Fourth, spatial filtering tuned to nearby magnetic sources due to brain instead of the distant noise sources can be used, realized both in hardware and software means.

6.2. LEGAL ANALYSIS

7.1.1. ROHS SCOPE

According to Art. 2, 1. of RoHS Directive 2011/65/EU, it applies to electrical and electronic equipment ("EEE") falling under the categories set out in Annex I. Annex I comprises, amongst other equipment category 8 (Medical Devices).

The MEG Installation falls under the MDD (Directive 93/42/EEC), thus qualifies as a medical device.

6.3. MEG INSTALLATION AS LARGE SCALE FIXED INSTALLATIONS

A MEG Installation does not fall into the RoHS scope as it has to be qualified as a "large scale fixed installation".

The term large scale fixed installation is defined in Art. 3, (4) as follows:
"large scale fixed installation" means a large size combination of several types of apparatus and, where applicable, other devices, which are assembled, installed by professionals and intended to be used permanently in a pre-defined and dedicated location, and to be de-installed by professionals;

A MEG Installation fits the definition criteria:

a) To be a large size combination of several types of apparatus and, where applicable, other devices.
b) To be assembled and installed by professionals.
c) To be intended to be used permanently in a predefined and dedicated location.
d) To be de-installed by professionals.

With regards to b), c) and d)
A MEG Installation is assembled, installed and will have to be de-installed by professionals. The installation takes up to several months.

The MEG Installation solution is intended to be used permanently in a pre-defined and dedicated location carefully selected, planned and built for the purpose. The system is typically installed in a dedicated room specifically designed and shielded, while all the other components of the installation are located in separated labs and rooms.
While, in principle, it is possible to re-locate the core components of the MEG installation and to install such components at a different place, this would imply a complete de-installation and disassembly of the system and complete planning, building and installation process that is equivalent to that of an entirely new site. MEG installations are designed to be permanent.

6.4. CONCLUSION

Accordingly, MEG Installations are "large scale fixed installation" in the meaning of Art. 3 (d) of RoHS Directive.

6.5. EQUIPMENT THAT ARE SPECIFICALLY DESIGNED TO BE PART OF A MEG INSTALLATION

According to Article 2, 4. (c), equipment that are specifically designed to be part of a MEG Installation which could not fulfil their function if not installed in such system, are excluded as well

from the scope of the RoHS Directive.

Article 2, 4. (c)
Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

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