# Application for granting new Exemption: Lead as an alloying element as a lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems

## 1. Name and address of applicant

COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Blvd A. Reyers 80
1020 Brussels
Contact: Mr. Riccardo Corridori
Tel: 027068966
corridori@cocir.org

## 2. Summary of the application

X-ray imaging and radiotherapy equipment has bearings and sliding surfaces of moving parts that are exposed to ionising radiation. Bearings and wear surfaces that are exposed to ionising radiation cannot use grease or oil lubricants as these substances will decompose and cannot easily or safely be replaced. The only dry lubricant material with a long life that does not decompose when exposed to ionising radiation has been found to be alloys that contain particles of lead.

## 3. Description of materials and equipment for which the exemption is required

Lead has been widely used for well over 100 years as a dry lubricant in various alloys, particularly as an alloying constituent of leaded bronzes. Alternative types of bearings have been developed in which greases and oils are used as lubricants but these substances degrade when exposed to ionising radiation. Most oils and greases are based on hydrocarbons, fluoro-organics and organo-silicones and are suitable for many types of electrical equipment but are not suitable for where they are exposed to ionising radiation. The only existing exemption that is applicable to lead as a lubricant is exemption 9b of Annex III. However, this is limited only to HVACR applications because oils and grease are not effective at low temperature and this exemption does not apply to medical devices.

All types of oil and grease degrade when exposed to ionising radiation such as X-rays and $\gamma$-radiation and so these are not suitable for bearings and wear surfaces of medical devices where there is exposure to ionising radiation. Examples of where lead is needed as a lubricant in medical device applications are as follows:

1. Bearings used for the doors of multisource radiosurgery equipment. The radiation source used in these products is the radioactive isotope cobalt 60 and the bearings are continuously irradiated. It is essential that the patient entry doors open and close easily to prevent radiation leakage. If an oil or grease lubricant were used, this would need to be regularly replaced as it would degrade due to radiation exposure from the cobalt-60 source. However, replacement of the oil or grease would be a very dangerous operation because of the continuous radiation exposure as the radiation is from a radio-isotope and so cannot be "turned off".

2. Lead is also used as a dry lubricant as an alloying addition to aluminium where 5% of lead is added to aluminium. This material is used for the bearings of linear sliders that are used for support systems that allow the patient or parts of the equipment to be moved smoothly to precise locations in angiography, radiotherapy and CT equipment. These bearings need to support very high loads but as they are exposed to ionising radiation, oil and grease lubricants will decompose and be unreliable. This would pose a risk to the patient if failure were to occur during an operation.

3. Some types of equipment such as is used for radiotherapy, use telescopic arrangements which requires accurate and precise movement to focus the radiation onto the correct location of the patient. Each part of the telescopic assembly has to use lead alloy bearings as these are exposed to ionising radiation that would degrade oils and greases. The image below shows an example of a lead alloy bearing.

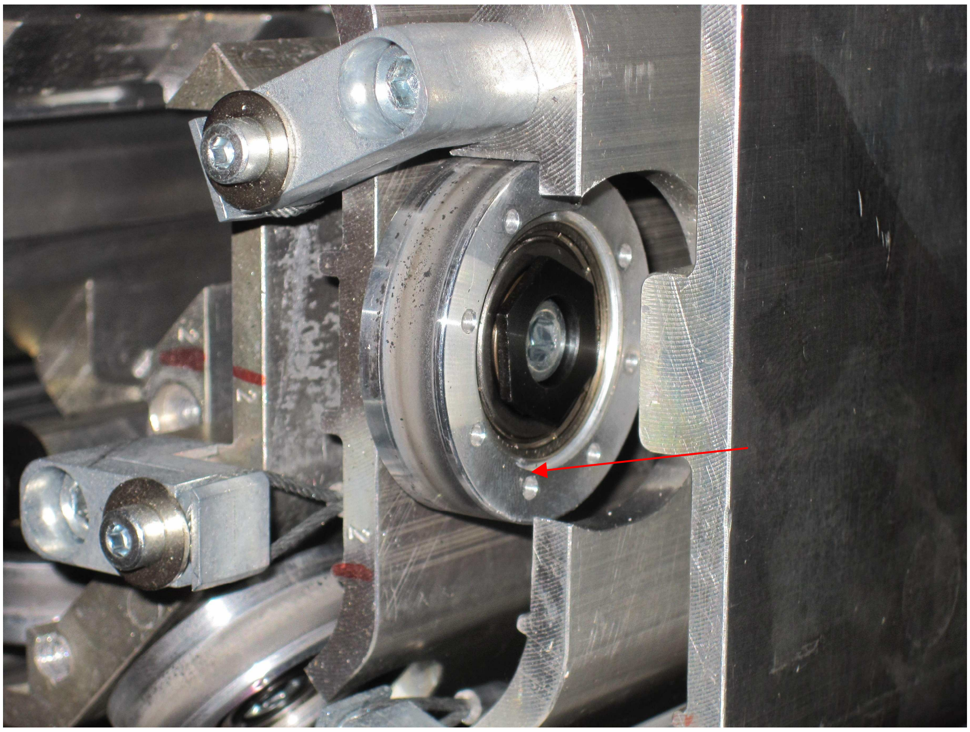

**Figure 1.** Lead bearing used in environment exposed to ionising radiation

Aluminium containing up to 5% lead and leaded bronzes some of which contain over 10% lead are used as types of grease-free bearing materials. Lead dissolves in molten copper but is insoluble in solid copper alloys and so forms an irregular dispersion within the copper alloy matrix when the melt freezes. Lead also does not dissolve in aluminium and so forms a dispersion of small lead particles. Lead metal in these alloys is present always at the bearing surface as fresh particles are continuously exposed as the bronze or aluminium alloy wears. The coefficient of friction of leaded bronze against steel with no grease lubricant is typically ~0.1 or a little higher after some wear has occurred. Steel on steel has a coefficient of friction of 1.0.

Lead addition to alloys is used by the medical industry as a dry lubricant at locations exposed to ionising radiation where oils and greases would decompose and become ineffective. Ionising radiation causes all organic (carbon based) materials including oils, grease and fluoropolymers such as PTFE to decompose and these materials would have to be regularly replaced if they were used. Lead is used to provide a low friction bearing surface that is not affected by ionising radiation so that no maintenance is required and no significant deterioration in performance occurs. Lead-based bearings are often used with some grease added because lead alone is not always adequate as the sole lubricant but the combination of lead with some grease, even after this has partially degraded, is suitable without maintenance over very long periods so that use of the medical equipment is not interrupted.

Bearing surfaces have to have certain characteristics to perform consistently and reliably. Apart from having a low coefficient of friction, they must have all of the following properties[1]:

- Low rate of wear
- Adsorb and discard small particles such as dirt and abraded particles - leaded bronzes are able to do this[2]
- Adapt to surface roughness - lead smears over rough surfaces
- High compressive strength – metals such as bronzes and aluminium do not easily distort under load
- Corrosion resistance – this is important as oxides and corrosion products will have poor lubrication properties
- Low shear strength (at bearing surface interface). Lead has low shear strength and so fills irregularities between surfaces.
- Structural uniformity – this is achieved with alloys but not as thin coatings, as lubrication is lost when the coating wears off.

## 4. Justification for exemption – Article 5 criteria

This exemption is required because there are no alternative materials or designs that that have been found to perform the same function as lead – based bearing materials.

Currently, lead is the only known material that is suitable over long periods of use as a dry lubricant where exposure to ionising radiation occurs. To provide long term lubrication, the material must have the following properties:

- Should be a relatively soft material but not deform significantly under load
- Does not cold weld unlike gold and indium
- Must not degrade and loose lubricant properties
- Must not become radioactive when exposed to ionising radiation
- Must be able to wear over time with no change in performance. Thin coatings are unsuitable as they will rub off and need to be replaced

In addition to the list above, bearings inside vacuum (X-ray tubes) must not emit volatile gases although lead bearings in x-ray tubes are already covered by exemption 2 of Annex IV of the RoHS recast directive.

[1] http://www.copper.org/applications/industrial/bronze_bearing.html
[2] http://www.magnoliabronze.com/hilead.htm

Lead is the only known material that meets all of these requirements as well as those listed in section 2 above. Lead is used as an alloying constituent such as 5% lead in aluminium or as lead bronzes typically having 5 – 20% lead. Lead does not dissolve in aluminium (or in solid copper) and so is present in these alloys as a dispersion of small particles that act as a dry lubricant. As the surface wears, more lead particles are exposed so that the lubricant properties remain. No other material meets all of the above essential requirements. There are no alternative designs possible as it is necessary to have radiation resistant surfaces that rub against each other with low friction force and only dry bearings achieve this.

## 5. Analysis of possible alternatives

Potential alternative materials that are not affected by ionising radiation include:

| Material | Properties |
|---|---|
| Gold | Pure gold is too soft so that it completely rubs away from the bearing surface. Where thicker layers of gold are used, this could cold weld so that surfaces would seize. |
| Silver | Tendency to cold weld and so would seize and is much harder than lead. |
| Tin | Pure tin is harder than lead and has a higher shear strength so is a poor lubricant. Reacts with copper to form hard crystalline particles (see below). |
| Alloys based on indium | Too soft and will cold weld to almost any surface (even glass) |
| Copper | Ductile copper is a poor lubricant and becomes harder due to "cold working" so is not suitable. |
| PTFE and other fluorinated polymers | Degrades when exposed to ionising radiation |
| Molybdenum disulphide, graphite and hexagonal boron nitride | Excellent lubricant properties due to their layered structure but they are mainly used only as a dispersion in an organic support such as a heavy grease which would be degraded by the ionising |

| | |
|---|---|
| | radiation. Thin coatings can be applied to metal parts by other techniques such as chemical vapour deposition or by spray coatings in volatile solvents but these will wear off and then have to be regularly replaced.<br>Pure graphite is physically weak compared to aluminium or copper alloys and would not have sufficient strength for these applications |
| Metal / graphite composites | Several manufacturers supply graphite / metal bearings such as "Graphalloy"[3]. These have fairly low coefficient of friction (0.1 – 0.2) and are used as dry bearings in circumstances where oil and grease cannot be used such as at high and low temperatures. They are not used where oil or grease can be used because they have inferior performance. They are made by infiltrating molten metal into porous graphite and so their physical strength is far less than alloy bearings with lead additions. |

Bearing surfaces with a requirement for a long unattended life must be relatively hard so that they wear slowly. Copper and aluminium are sufficiently hard but have high coefficients of friction whereas lead and tin are soft and so have lower coefficients of friction but cannot be used alone when there is a large load because they would wear too quickly and need to be replaced. Hard metals with dispersions of soft metals such as lead in leaded bronze and aluminium – lead alloy are ideal. An important property of leaded bronze and aluminium containing lead is its low coefficient of friction. Published values vary depending on the test method used and the following are typical values:

| Metal | Coefficient of friction (static) |
|---|---|
| Copper / lead alloy on steel | 0.22 |
| Copper on copper | ~ 1.0 – 1.6 |
| Aluminium on aluminium | ~1.0 – 2.0 |
| Tin on cast iron | 0.32 |
| Gold on gold | 2.8 |

Published coefficient of friction data shows that copper-lead alloys (i.e. a leaded bronze) have lower coefficient of friction than all other metals for which data is available.

**Copper alloys containing tin** without lead are "bronze". Lead-free bronze does not have the excellent lubrication properties of leaded-bronze (copper + tin +

[3] http://www.graphalloy.com/html/where_to_use.html

lead) because tin is soluble in copper and chemically reacts to produce intermetallic CuSn compounds that are in the form of irregular hard particles that have no lubrication properties. No free tin will be present in copper-tin alloys.

**Some coatings such as molybdenum sulphide and boron nitride** have low values of friction coefficient but the thin coatings will all wear off and have to be frequently replaced causing the equipment to be unavailable for periods of time. For equipment that contains radio-isotope sources, this poses a serious safety risk to workers.

**Graphite bearings** filled with metal are physically stronger than pure graphite but are much weaker than copper or aluminium alloys with lead. For example:

- Tensile strength of Graphalloy with copper 38 MPa
- Yield strength of leaded bronze ~6% lead 120 MPa

This is a significant limitation for medical applications where high strength is required such as for patient support sliders. It is also a limitation for patient entry door bearings because the doors are very heavy because they need to have thick sections of lead radiation shielding.
Another type of graphite based bearing has graphite embedded into higher strength alloys[4]. The lubricant is pure graphite in the form of discs that are supported by bronze or steel. This design is however unsuitable for door bearings and the type of bearing shown in figure 1.

**Silver and gold** - RoHS recast exemption 2 in Annex IV is for "lead in bearings of X-ray tubes". The anodes inside the tubes rotate to prevent overheating and as the tube has to maintain a vacuum, organic materials such as greases and oils cannot be used as these will emit gases which will contaminate the anode and prevent x-ray emission. Inside x-ray tubes, silver and gold bearings have been evaluated but were found to have poor wear resistance, and they are noisy as a result (this is not acceptable during surgery) and small silver or gold particles are produced. X-ray tube life would be shortened by using these metals as bearings.

## 6. Life cycle assessment

There are no practical alternatives to lead for this application:

- Oil and grease lubricants degrade and will need to be regularly replaced
- Thin bearing material coatings will wear away and have to be regularly replaced.

The life cycle implications of the main potential options are:

### 6.1. Materials production phase:

[4] http://www.lubroglide.com/Products/OilLess/OilLess.htm

**Lead** is mined in large quantities as a primary metal with about 8 million tonnes per year being produced. Consumption world-wide is increasing despite the RoHS restrictions due to its main uses for batteries and buildings. Extraction and refining of lead from its ores is well controlled in most countries so that lead pollution does not occur. Sulphur dioxide that is produced as a by-product is used to make sulphuric acid.

**Silver and gold** are widely distributed but both occur at low concentrations in a variety of ores. Silver is often recovered as a by-product from mining other metals including gold, lead and zinc. Extraction of silver and gold ores involves mining very large quantities of rock which has a very high energy consumption and generates very large amounts of waste (especially gold mining). Refining is usually carried out using highly toxic cyanides and accidents have occurred which have caused very serious damage to the environment. Mining, extraction and refining of gold consumes far more energy than lead as shown by published figures:

- Gold 143,000 MJ/tonne[5]
- Lead 168 MJ/tonne[6]

Lead refining in the EU is well controlled due to strict legislation so that harmful effects are rare. Cyanide used for gold extraction and refining is very toxic and has caused several serious accidents in the EU[7].

### 6.2. Use phase

Silver and gold bearings would be much more noisy and will have give shorter lifetimes than lead due to excessive wear and so that equipment needs to be repaired or replaced more frequently and this creates waste. Thin coatings of molybdenum sulphide, etc, will wear off and have to be frequently replaced.
Shorter lifetimes and more frequent repairs create waste and additional emissions from vehicle transportation of engineers who repair and maintain the equipment.

### 6.3. End of life

Medical equipment is usually recycled at end of life and the metals recovered for reuse. Modern safe recycling processes recover most of the metals discussed here with very high yields and with no risk to workers, local populations or the environment. Where unsafe recycling processes are used in developing countries, there is a risk to local people who recycling of any metals due to the hazardous chemicals used for the processes used although there is an added risk if the metals are toxic. At end of life, silver and gold are recovered due to their high value but in countries where unsafe recycling is carried out, environmental and

[5] From http://www.eoearth.org/article/Gold_mining_and_sustainability:_A_critical_reflection
[6] Calculated from data in http://www.epa.gov/dfe/pubs/solder/lca/lfs-lca-final.pdf
[7] For example http://archive.rec.org/REC/Publications/CyanideSpill/ENGCyanide.pdf

health damage due to the use of cyanide and other chemicals can pose a significant risk.

## 7. Other information

The total quantity of lead used in the EU for use as dry bearings in medical devices is 20kg per year.

## 8. Re-use and recycling of materials from waste EEE

When medical equipment reaches end of life it is recycled because it has a significant value from its metals content. Dry bearings without oils or grease are easier and safer to recycle than waste containing oil-based lubricants. Equipment consisting of mostly metals is usually recycled by dismantling, shredding and then thermal processes to melt and refine. Alloys are commonly refined using pre-planned schedules to utilise the various types of scrap metal available to produce a range of standard alloys. In this way, it is often not necessary to remove unwanted constituents and alloys are synthesised by adding selected types of scrap to the melt to obtain the required alloys which are cast and then reused with very high yields.

The implications of recycling processes for bearings having oil-based lubricants and with dry-lubricants would be:

**Bearings with oils or grease** – Oils and grease lubricants create hygiene problems when melting scrap metals as they decompose to emit a wide variety of substances as vapours some of which are toxic and carcinogenic. These substances can include polycyclic aromatic hydrocarbons (PAH) and halogenated materials which can also generate chloro- and bromo-dioxins and furans. These substances must be collected and safely destroyed by the various processes that are used in modern metals refineries but unsafe emissions may occur in developing countries where simpler processes, such as burning on open fires, are used.

**Dry oil-free bearings** – the advantage of dry bearings is that no emissions of toxic organic substances can occur. There is a small risk of lead emissions if the melt temperature is high and gases are blown through the melt but usually, lead in the melt oxidises at the surface to form a "dross" that is removed for further treatment and recovery for re-use. Lead metal and other constituents can be recovered from dross using modern lead refining processes so that no lead waste is generated.

## 9. Proposed plan to develop substitutes and timetable

For high strength bearings suitable for use in ionising radiation, only metallic alloys have been found to be suitable. As described here, no alternatives to lead have been found during research by manufacturers. The only potential alternative to lead as a dry lubricant may be graphite loaded alloys but these have not yet been evaluated by medical equipment manufacturers. Research to assess this potential substitute will require the following:

| **Design and construction of bearings for each application** | **1 year (to 2013)** |
|---|---|
| Evaluation of graphite bearing performance using accelerated testing | 1 year (to 2014) |
| If these test results are satisfactory, then re-design medical devices that utilise leaded bearings | At least 2 years to complete (to 2016) |
| Long term reliability testing of medical equipment constructed with lead-free bearings to simulate 25 year lifetimes | Complete for all types of equipment after 5 years (to 2021) |
| If long term trials are satisfactory, clinical trials would follow to obtain data for Medical Device Directive approval | Further 1 year (to 2022) |
| Time required for obtaining medical device directive approval | 1 year (to 2023) |

If graphite is found to be unreliable, then no other substitutes are currently available for evaluation. Manufacturers would however search for alternative designs and materials but cannot predict when this will be successful

## 10. Proposed wording for exemption

**Lead as an alloying element for use as a dry lubricant for bearings and wear surfaces in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems**