Questionnaire No. 5

"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"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed for the technical assistance in reviewing the requests for exemptions from the requirements of the RoHS Directive 2011/85/EU (RoHS II) by the European Commission. You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check.

As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online consultation on your request. Therefore we kindly ask you to reformulate your request taking the following points into consideration.

Questions

- Could you please disclose your assumptions which you took into account for quantifying the total amount of lead used in the EU used for dry bearings in medical devices?

1. Diagnostic radiology – data from one of seven manufacturers

    - 340 telescopes with 8 rolls sold per year; each roll contains 1 g lead:
    - 340* 8 *1g = 2720g (2.7kg) lead per year
    - Estimated total for 7 manufacturers = 7 x 2.7 = 18.9 kg.

2. Data from second manufacturer who supply radiotherapy equipment; 80 units per year with 0.1kg lead in each so total 8kg/year

3. Third manufacturer uses bearings that contain 1 gram of lead and sell 35 machines per year in the EU containing this bearing so a total of 35 grams per year

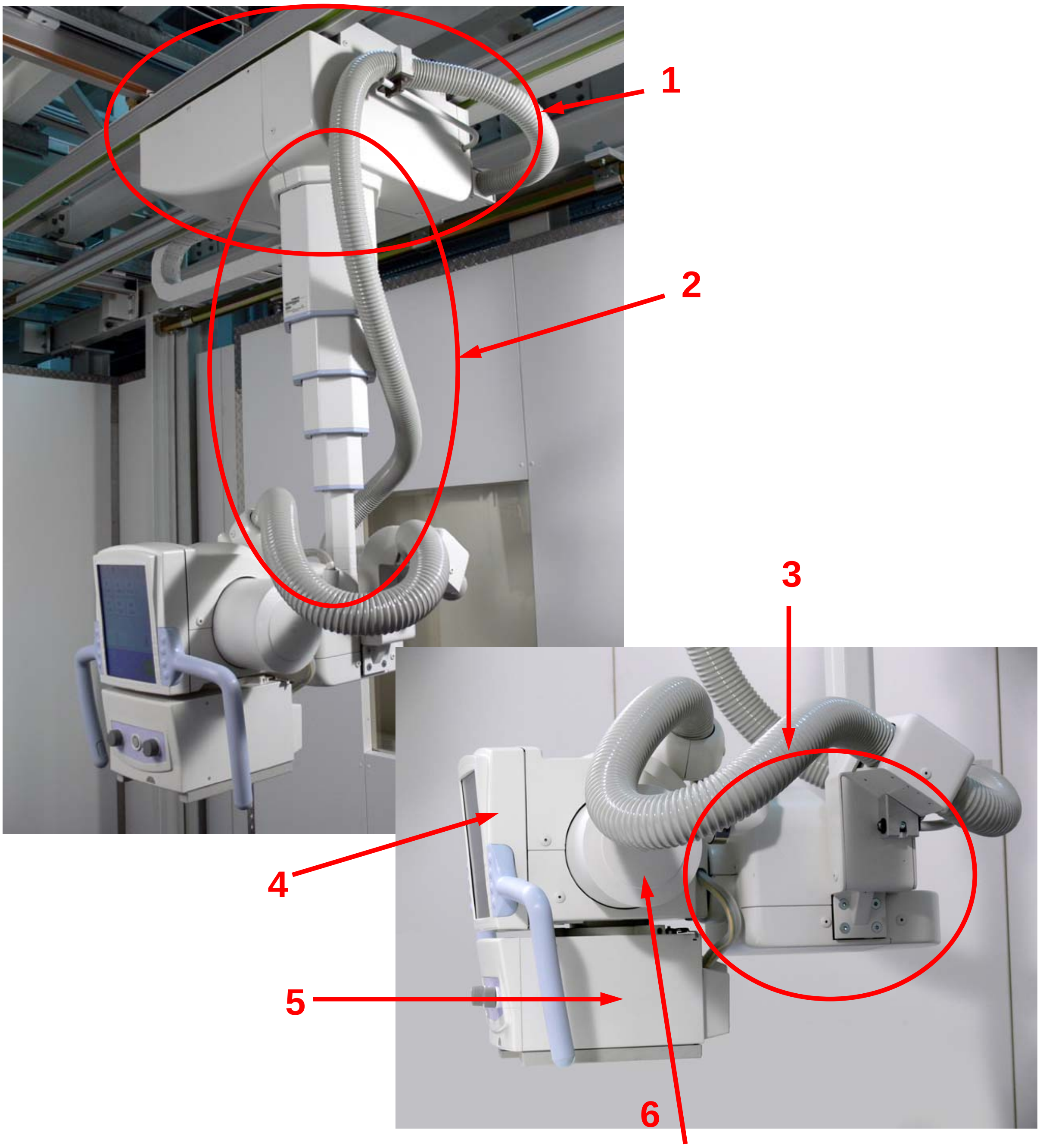
This totals ~30 kg per year but may omit some niche applications so we estimated a maximum quantity of ~50kg per year.

1. Could you please compare this amount to the quantity of lead which is used to the lead containing sections for radiation shielding?

Radiotherapy example: Approximately 1 tonne of lead is used as radiation shielding in radiotherapy linear accelerators. One manufacturer has estimated that there are 1000 radiotherapy machines in use in the EU so 1000 tonnes of lead.

CT system example: One CT system contains at least 16 kg lead used for radiation shielding and as counterweight. Thousands of such systems are sold in the EU per year. In addition, thousands of conventional x-ray-systems are sold in the EU. These also contain lead for shielding.

2. Could you provide a typical layout design for radiotherapy equipment including the load values for patient support sliders? Are there design options available to reduce the load values, thus allowing the use of graphite bearings?



This refers to the design shown in the above image.

Key to above and quantities of lead used:

Description lead used in X-ray diagnostic device:

- 1 telescopic trolley
- 2 telescopic tube set (43kg, 18kg act proportionately with the bearings)
- 3 arm (32kg)
- 4 Operation (7kg)
- 5 collimator (19kg)
- 6 X-ray emitters (27kg)

The lead-bearing rollers are installed in the telescope tube set. This telescope is attached to the top carrier. The telescopic tube set must have a draw length of 1800mm be able to cover the necessary medical applications. At the turn of the telescope tube set components arm, deep cover, radiator and the front panel are connected. These components have a mass of up to 103kg. The different distances of the centres of mass of these components to the central axis of the telescope tube set results in a torque of up to 760Nm on the telescopic tube set. This means a stress of up to 2500N per roll. These enormous demands on the telescope tube set and the wheels must be considered in the design for a lifetime of 10 years. Weaker bearing materials would be unsuitable and greases and oils cannot be used because they may drip onto patients as well be affected by stray radiation. Similarly, the vibration behaviour of the telescope tube set is not to be underestimated. Tests have shown that with a material combination of steel-steel bearing, the structure reverberates much longer than the material combination of aluminium-aluminium. This in turn affects the efficiency of the device. Comparative testing of materials and many years of continuous testing have shown that only the aluminium-lead alloy was a suitable material for this application giving the longest lifetime and best precision and reliability.

The demands of the imaging device are also increasing so that the performance must become more powerful. This has implications on the weights of the components, which become even heavier. With new designs it is difficult to find a compromise design that is not heavier to maintain the life of the bearings. Thus, a reduction of the weights on the telescope tube set by the constant advancement in medical technology is not possible at present.

Each axis of the X-ray machines has a drive motor and the lightest weight models have been selected. Increasing weight of the assembly retards the acceleration of this heavy mass and has a disproportionate effect on the size of these drives.

3. Could you please evidence the time span of 5 years which is assumed to be needed for the long term reliability testing of lead-free bearings?

The tube set with its wheels is a very complex assembly. It is very important that wear behaviour is thoroughly understood because the wear behaviour has a large influence on the handling and the accuracy of the system. Several intense endurance tests are necessary to study wear behaviour of materials and designs. First, there may be many different materials to be tested. Also, the crowning (e.g. shape), the basic hardness, any wear coatings and the surface roughness all have a significant impact on the behaviour of the material.

The following tests must be carried out for this:

- Test with static load (2500N)
- Roller test for continuous operation on a special test (this must cover each roller moving a distance equivalent to about 320km with a 2500N load). This test alone requires a period of approximately 8 months
- Duration of test tube set in rollers (testing as a complete assembly). One material can be tested at a time for wear behavior to determine the long term behaviour. These tests must also be equivalent to movement over a distance of about 320 km. These tests are required for each material, each taking a period of approximately four months.

Experience has shown that one series of tests is usually not sufficient, but several repeat tests are needed. Thus, a period of 5 years is needed for detailed testing.

Another issue is that medical equipment manufacturers do not normally have expertise in tribology and so would need to obtain specialist assistance for wear testing and probably also radiation testing if this is affected. Evaluation of alternative materials which are exposed to more intense radiation but with lower wear forces can typically take 6 months to 1 year to complete. Linear Accelerator manufacturers have historically found that accelerated life testing of the MLC head (one part of the accelerator) has taken 1 Year when any design change has been made.

4. When did you start with efforts to redesign of bearings in radiotherapy equipment and radiosurgery equipment and for patient and equipment support systems?

Each manufacturer is at a different stage of R&D and faces different problems to solve due to differing design requirements

In the past, alternative materials were considered but at that time no suitable alternatives could be identified. A few COCIR members have not carried out research recently because they could not identify suitable alternatives to test but most had started work by 2010 and some in 2011. The recent availability of new types of graphite based bearing will enable research into the possibility of this material being carried out by all COCIR members who use lead bearings and so this will be added to the materials to be tested.

One manufacturer discovered in October 2011 that the wheels on their tube set contain lead and so began research for an alternative material. As this is a very complex and complicated issue, as described above and in the dossier, this research has is including internships and post graduate research for students.

Lead containing bearing material is used for supporting and guiding sliding tungsten leaves (used as radiation shielding) which are high precision devices produced to tolerances of ±10µm and are manufactured by EDM wire erosion. (tungsten leaves are separated by thin lead sheet which acts as a dry lubricant). Alternative materials must be capable of being manufactured using this process and would need to have sufficient lubricity and durability. Graphite is a friable material and it is not likely to be possible to achieve this precision or maintain these dimensions for the life of the equipment but further research and development will be needed to evaluate this material as stated in section 4.