Test and Measurement Coalition

RoHS Scope Review of Category 9 Products

Lead Shielding Dossier

1. Use of lead shielding for radiation protection

1.1. General

Lead is widely used in test and measurement instruments that are used in the presence of ionizing radiation (primarily x-rays and gamma rays) and in instruments that detect and measure ionizing radiation. In these instruments, lead is used to:

- Shield sensitive electronic components from the damaging effects of radiation.
- Shield radiation detectors from background radiation
- Collimate or limit a detector's field of view to prevent radiation from entering the detector from unwanted sources.
- Adjust a radiation detector's energy response by attenuating lower energy photons while allowing transmission of higher energy photons.
- Shield the user from radiation produced by the test and measurement equipment

1.2. Technical Characteristics

Lead is often used because of its excellent attenuation properties and its relatively low material cost and low processing (molding, machining, etc.) costs. In many applications, lead attenuates x-rays more efficiently than any other material commercially available. How well a shield absorbs radiation is a function of the material it is made of, its thickness and the type and energy of the radiation it is exposed to. Generally, as the energy of the radiation increases, the thickness of the shielding must increase or a material with a higher attenuation coefficient must be used. Standards indicating minimum thickness of lead include NCRP Report 102, Appendix B, IEC 60601-1-3, Clause 29.207 and Radiological Health Handbook, Section III

1.3. Trends

There are no current trends within the test and measurement industry to replace lead shielding of x-ray radiation with alternative materials.

2. Substitution of Lead

2.1. Substitutes for Lead

Tungsten is a common alternative to lead. It has slightly lower attenuation properties, is significantly more expensive than lead, and is costlier to process than lead (it is very hard and difficult to machine). Tungsten loaded polymers are available, but have lower attenuation properties than solid tungsten since they are a mixture of tungsten powder and polymer. These polymers can be injection molded, but the tungsten loading causes significant wear on tooling, reducing its useful life by half.

Steel may be used instead of lead, but its lower attenuation properties are a drawback, as more material is needed to make up for the reduced attenuation. At x-ray energies below 75 kVp, 3mm of steel is needed to provide the same attenuation as 0.5mm of lead. (The Swedish Radiation Protection Institute's Regulations on Radiation Shielding of X-ray Installations for Veterinary Diagnostics)

Concrete offers less attenuation than tungsten or steel, but offers low cost when space is available. At x-ray energies of 100 kVp, approximately 80mm of concrete is needed to provide the same attenuation as 1mm of lead. (Radiological Health Handbook, revised edition January 1970)

Materials with greater attenuation properties exist but many are radioactive and are not suitable for use in shielding.

2.2. Selection and Testing of Substitutes

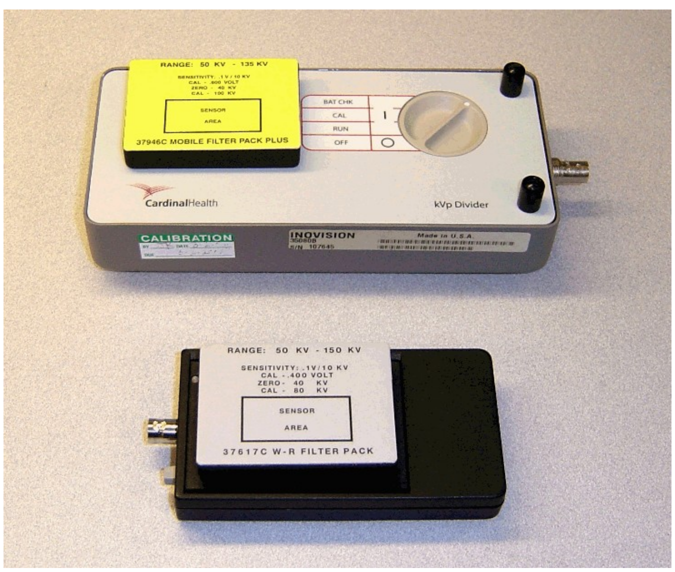
2.2.1. When lead is used to provide shielding, alternative materials must be identified and shields or collimators redesigned to make them larger (due to reduced attenuation) and tested. The redesigned shielding may cause other related components to be redesigned and tested. In some cases, the complete system may need to be redesigned to accommodate the needs of the new shielding material. In any case, radiation testing to ensure that the shielding remains effective must be performed. Additional testing may also be required to ensure that the substitute shielding meets the product's qualification requirements.

2.2.2. Selection of alternate materials to replace lead foils used to adjust a radiation detector's energy response involves identification and selection of viable alternates and rigorous radiation testing to ensure that the detector meets its specified energy response.

2.2.3. Where a test and measurement instrument relies on the attenuation properties of lead and/or other materials as a basic operating principle, the attenuation/transmission properties of lead and/or the combined effect of all filter materials must be taken into account. The process of finding viable alternatives to lead filters requires a great deal of research, modeling and radiation testing.

2.3. Impact of Substitution

2.3.1. Many of the test and measurement instruments that are used to measure ionizing radiation rely on the attenuation properties of lead and other materials as a basic operating principle. For example, non-invasive kVp meters or voltage dividers, such as the Fluke Biomedical Model 35080B and 35080M rely on the attenuation properties of lead and other materials for their basic operation (Ref. U.S. Patents 4,843,619 & 4,916,727). These products are used in hospitals and imaging centers to perform quality assurance measurements on x-ray machines. The process of finding alternatives to lead filters in this case is much more difficult because the instrument's response is not based on the attenuation/transmission properties of only lead but on the combined effect of all of its filter materials. As a result, not only the lead filter material would change, all of the other filters would need to change too because of the interaction of the attenuation/transmission properties of the substitute materials with the other filter materials. An average redesign cost of €300K-500K per product is expected.



Fluke Biomedical Non-Invasive kVp Dividers

2.3.2. Lead foils are also used to adjust a radiation detector's energy response when used in radiation survey meters (below) and other applications. Alternative materials must be identified and rigorously tested to ensure that the detector meets its specified energy response in order to provide an accurate measure of the radiation detected. These instruments are used in medical, nuclear power, and homeland security applications. To assess of the safety of the radiation environment lead foil is commonly wrapped around Geiger-Mueller detectors to provide energy compensation by flattening the detector's energy response. The alternative material cost in this case may not be significant, but an average redesign cost of €100K-200K per product is expected.

Victoreen® Advanced Survey Meter

2.3.3. Where lead shields or collimators are used, alternative materials must be identified and shields or collimators redesigned to make them larger (due to reduced attenuation) and to support the manufacturing methods suitable for the new material. The increase in size may cause other related components to be redesigned. For example, the Fluke Biomedical Model 35080M, Non-Invasive Voltage Divider, employs two lead shields to both shield its detectors from stray radiation and to collimate its field of view to only the x-rays passing through a set of filters (attenuators). Replacing the existing lead shields with tungsten shields adds approximately €800 to the cost of the unit; a 75% cost increase. This cost increase can be expected for all non-invasive kVp meters in the market place today. An average redesign cost of €100K-200K per product is expected.

2.3.4. In large systems, such as x-ray testers used in manufacturing test of assembled printed circuit boards (below), where lead may be replaced with concrete, €200K is the estimated additional cost of hardware for development (concrete is a new material in electronics). An additional cost of €400K is also needed to develop robotic arm placement of boards under test. For a design based on concrete shielding the operator can no longer stretch over 10-20 meters of concrete to place the PCB under test in the centre test area. Certification costs of €200K are expected because special safety interlocks and test rules the apply to equipment emitting radiation. A total redesign cost of €800K per system is expected. Transportation costs, both from contract manufacturer of pre-shaped concrete blocks (the lead shielding of the model shown comprise 52 separate lead block sub-assemblies) to the producer of the x-ray test systems and from the producer to customer would increase. The cost of WEEE processing due to increased weight of concrete compared to lead would also increase. WEEE costs typically range from €45-80 /kg of product. X-ray testers are used in manufacturing test of assembled printed circuit boards, and are the only way of detecting internal voids, marginal joints or insufficient solder in solder joins. Due to the need for stability of product for clear x-ray pictures and the shielding itself, the products are heavy with up to 1 ton of lead shielding.

Agilent Medalist 5DX X-Ray Tester

2.3.5. Where test and measurement instruments that measure ionizing radiation are installed in monitoring and control or safety related applications, such as nuclear power plants, qualification of new products is required. For example, the radiation monitors (below) in nuclear power facilities provide assurance that radiation levels do not exceed maximum permissible levels as set forth in the United States Nuclear Regulatory Commission (USNRC) radiation protection standards. Products of this class are typically qualified to seismic, corrosive atmosphere, EMI/RFI, and radiation tolerance standards. An average redesign and qualification cost of €300K-500K per product is expected.

Victoreen® Off-Line Gaseous Effluent Monitor and Wide Range Ion Chamber Area Monitor

3. Requests/recommendations

3.1. Exemptions

An exemption is needed for lead shielding for radiation protection in test and measurement equipment. The applications include:

- Shielding electronic components from the damaging effects of radiation.
- Shielding, collimation, and energy compensation for radiation detectors.
- Shielding for users of test and measurement equipment that produces ionizing radiation

Tungsten and steel substitutes are available for some shielding applications of lead, however standards for thickness of material have to be developed covering the energy levels of radiation used in test and measurement. Concrete is technically feasible and widely accepted with appropriate thickness requirements in standards. However the impacts of using concrete are: increased weight and volume of products impacting energy required for transportation, and safety of handling during manufacture, transport and installation.

We note that lead is exempt in RoHS in CRTs where the lead in glass provides protection to users from low levels of x-ray radiation energy in the CRT tube. We believe this precedent for lead shielding must be taken into consideration. Furthermore, as the majority of our applications involve much higher energy levels the radiation laws for high energy X-ray equipment regarding safety of installation and use must be considered by the Commission. To this end the Commission must establish agreement with local competent authorities in each member state regarding use of lead substitutes for high energy X-ray equipment – standards for thickness of material and impacts on local radiation safety laws and user licensing have to be considered before industry can truly assess impacts of a viable substitute for lead in radiation shielding for protection.

In summary we are requesting one additional exemption for lead shielding radiation applications in test and measurement equipment.

3.2. Phase-in period

If the exemption is not granted we estimate a transition phase-in period of ten years from the entry into force of the revised RoHS Directive would be required to re-design products currently using lead shielding for radiation protection. Phase-in can only start following prior amendments to standards and regulations outside RoHS that currently apply to high energy X-ray equipment. In our opinion substituting lead with concrete as not viable for safety and environmental reasons outlined above.