To: All Members of RASSC

REGULATORY CONTROL OF CONSUMER PRODUCTS –
IS THERE A NEED FOR GUIDANCE?

In the revised Basic Safety Standards¹, a consumer product is defined as “a device or manufactured item into which radionuclides have deliberately been incorporated or produced by activation, or which generates ionizing radiation, and which can be sold or made available to members of the public without special surveillance or regulatory control after sale”. Thus, consideration by the regulatory body involves two issues: firstly, is the addition of radioactivity to the product justified and, if it is deemed to be justified, can the item be exempted from regulatory control and therefore be made freely available to the public.

Both the Basic Safety Standards (1996 version) and the revised Basic Safety Standards define the generic criteria for exemption from regulatory control, namely that

(a) Radiation risks arising from the practice or a source within a practice are sufficiently low as not to warrant regulatory control, with no appreciable likelihood of situations that could lead to a failure to meet the general criterion for exemption; or

(b) Regulatory control of the practice or the source would yield no net benefit, in that no reasonable control measures would achieve a worthwhile return in terms of reduction of individual doses or of health risks.

The criteria for exemption can be considered to be met if, on the basis of a safety assessment, the annual effective dose expected to be incurred by any member of the public from the practice or source is of the order of 10 µSv or less in a year. The revised Basic Safety Standards also provides derived values of total activity and activity concentration for a large number of radionuclides which, if not exceeded, should ensure that the 10 µSv criterion is met, therefore providing for automatic exemption from regulatory control. If these derived values are exceeded, it does not mean that exemption is not possible but rather that a safety assessment is required to support a regulatory decision.

¹ A slightly different definition of consumer products is used in the 1996 BSS. The criteria for exemption from regulatory control are the same in the 1996 BSS and the revised BSS.
Regulatory control of consumer products is already addressed in part in a number of different safety standards, of which the following are the most important:

1. The Basic safety Standards (1996 version) and the revised Basic Safety Standards, which specify requirements to be met by the government, by the regulatory body and by suppliers of consumer products;
2. The transportation requirements of TS-R-1;
3. The draft Safety Guide “Justification of Practices” (DS401) which provides specific examples of the application of the principle of justification to consumer products;
4. The Safety Guide “Application of the Concepts of Exclusion, Exemption and Clearance” (RS-G-1.7), which provides generic guidance on exemption of radioactive substances from regulatory control; and
5. The Safety Guide Regulatory Control of Radiation Sources (GS-G-1.5) which has a short chapter dealing with the regulatory control of consumer products.

Previously, the Nuclear Energy Agency (NEA) has published a number of documents dealing with the regulatory control of consumer products. The NEA report on ionization chamber smoke detectors became the definitive document in allowing their sale to the public even though the individual activity of americium-241 in each smoke detector exceeded the exemption limit in place at the time. In 2007 the European Commission (EC) published a report on consumer product availability in the European Union, including a summary of the regulatory approaches adopted in Member States. In addition, the Radiation Protection Unit has recently completed an initial review of the neutron irradiation of gemstones (a practice carried out in a number of IAEA Member States) and identified a number of issues related to both justification and regulatory control.

The IAEA has had some preliminary discussions with both the NEA and the EC about the development of a safety standard that deals with all aspects of the life-cycle of consumer products. Currently, different aspects are covered in different existing and planned safety standards but there is no one document that deals with all of the associated issues for all such products. It should be noted that many of these consumer products are currently marketed worldwide and it is important to improve harmonization in the approaches to justification, regulatory control and exemption which may otherwise inhibit global trade.
This issue has been highlighted by the Radiation Safety Standards Committee (RASSC) in its 2008-2010 Three Year Report as one that merits attention in the future. As a first step towards agreeing the best way to proceed, a topical session on consumer products will be included in the next meeting of RASSC in June 2011. A number of presentations will be made and, following discussion, the advice of RASSC will be sought on the importance of this issue, what priority should be given to it within the Secretariat and what specific actions should be taken. The recommendations from RASSC will also be discussed with WASSC in the joint session.

28th April 2011.

Tony Colgan
RASSC Scientific Secretary