TRANSSC 23
24-25 October 2011
Item 5.2

DS458: Radiation Safety and Regulatory Control of Consumer Products

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Consumer Product: 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.*

- manufactured items (goods)
- items generating radiation (cathode ray tubes)
- activated products (gemstones)
Issues (1)

- Manufacture is a planned exposure situation
  Regulatory body has to make a decision

- Only justified practices can be authorized (GSR-part 3(BSS) and DS401)
  Role and procedures of regulatory body – not a moral guardian

- Control after sale to the public is not realistic
  Items must comply with the exemption criteria

- Individual doses are expected to be small

- International harmonization is desirable
  Items are sold worldwide, including over the Internet
Correct application of the principle of exemption

The general criteria for exemption are 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 radiation risks criterion is considered to be met if, in all reasonably foreseeable circumstances, the individual dose is of the order of 10 µSv per year or less – based on a safety assessment.

Activity concentrations have been developed for individual radionuclides for exemption without further consideration.

Exemption is also possible based on physical and chemical form, dose rate, type approval etc.
Basic Criteria

• the radiation risks are sufficiently low so as not to warrant regulatory control
• regulation would provide no net benefit

dose criteria

activity concentration or total activity

REGULATE BECAUSE YOU NEED TO, NOT BECAUSE YOU CAN
Ambitions of the Safety Guide

What do we want to achieve?

• Explain the role of the regulatory body

• Clarify understanding and application of the exemption criteria

• Address transport and storage of large numbers of items (safety assessment)

• Assist regulatory bodies with application of graded approach (better use of resources)

• Improve international harmonization
1. INTRODUCTION
- Background
- Objective
- Scope
- Structure

2. FRAMEWORK FOR RADIATION PROTECTION OF THE PUBLIC
- Radiation protection principles
- Responsibilities – Government, Regulatory Bodies, Suppliers, Providers and Distributors
- Notification, authorization and reporting
- Exposure situations
- Public exposure
- Dose constraints
- Regulatory aspects
- Graded approach
- General radiation protection requirements
- Administrative requirements
3. EXPOSURE OF THE PUBLIC DUE TO CONSUMER PRODUCTS
- Application of Radiation Protection Principles
- Justification of consumer product use
- Authorization process: responsibilities of regulatory body
- Authorization process: responsibilities of supplier
- Authorization process: responsibilities of designers and manufacturers
- Optimisation of protection and safety
- Generic criteria for exemption
- Exemption values

4. SAFETY ASSESSMENT
- General – exposure pathways
- Public exposure scenarios
- Transportation and storage scenarios
- Accident and misuse scenarios
- Management of waste, including recycling, storage and disposal scenarios
5. INTERNATIONAL TRADE HARMONIZATION
   • General
   • Harmonization of international trade of consumer products

6. SAFETY OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE MATERIAL ADDED FOR FUNCTIONAL REASONS
   • Ionisation chamber smoke detectors (ICSD)
   • Items luminised with radioluminous paint (e.g. timepieces and compasses)
   • Items incorporating gaseous tritium light sources (GTLS) (e.g. timepieces, compasses, fishing floats, torches, telephone dials and keyrings)
   • Electronic devices (e.g. lamp starters, valves, surge voltage protectors, discharge and metal vapour lamps)
   • Others (if any)

7. SAFETY OF CONSUMER PRODUCTS CONTAINING ADDED RADIOACTIVE MATERIAL WITH PARTICULAR PHYSICAL AND CHEMICAL PROPERTIES
   • Items containing thorium (e.g. gas mantles and camera lenses and ophthalmic lenses)
   • Items incorporating uranium (e.g. tiles and tableware)
   • Others (if any)
8. SAFETY OF CONSUMER PRODUCTS CONTAINING GENERATORS OF IONIZING RADIATION
   • Radiation generators and electronic tubes (e.g. cathode ray tubes)
   • Negative ion electron tubes
   • Others (if any)

9. SAFETY OF CONSUMER PRODUCTS CONTAINING RADIATION INDUCED RADIONUCLIDES
   • Irradiated gemstones
   • Others (if any)

REFERENCES

ANNEXES

DEFINITIONS (if necessary)
## Timetable

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<th>STEP</th>
<th>Description</th>
<th>Timeline</th>
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<td>1</td>
<td>Preparing a DPP</td>
<td>DONE</td>
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<td>2</td>
<td>Approval of DPP by the Coordination Committee</td>
<td>Aug 2011</td>
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<td>3</td>
<td>Approval of DPP by the Safety Standards Committees</td>
<td>Oct-Dec 2011</td>
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<td>4</td>
<td>Approval of DPP by the CSS</td>
<td>Mar 2012</td>
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<td>5</td>
<td>Preparing the draft</td>
<td>2012</td>
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<td>6</td>
<td>Approval of draft by the Coordination Committee</td>
<td>Mar 2013</td>
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<td>7</td>
<td>Approval by the Safety Standards Committees for submission to Member States</td>
<td>Jun 2013</td>
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<td>8</td>
<td>Soliciting comments by Member States</td>
<td>Sep 2013</td>
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<td>9</td>
<td>Addressing comments by Member States</td>
<td>Early 2014</td>
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<td>10</td>
<td>Approval of the revised draft by the Coordination Committee</td>
<td>Mar 2014</td>
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<td>11</td>
<td>Approval by the Safety Standards Committees for submission to the CSS</td>
<td>Jun 2014</td>
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<td>12</td>
<td>Endorsement by the CSS</td>
<td>Oct 2014</td>
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<tr>
<td>13</td>
<td>Establishment by the Publications Committee and/or Board of Governors (for SF and SR only))</td>
<td>Oct 2014</td>
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<tr>
<td>14</td>
<td>Target publication date</td>
<td>2015</td>
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• TECDOC: Exemption from regulatory control of goods containing small amounts of radioactive material

• Technical input from NEA and EC

• Consultants’ meetings: 2012 and 2013

• Technical meeting: 2012 (?)
Potential joint sponsors

- **NEA** previously published standards for consumer products and recently established a WG in response to requests from its Member States.

- **EC** has published extensive reports that identify many anomalies and lack of a harmonized approach.

- **ISO** has the expertise in standards for type approval.

- **IAEA** is the organization to develop standards that can be applied globally.
# Comments Received

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<th>Clarification/Editorial</th>
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<th>Rejected</th>
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<td>6</td>
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<td><strong>Germany</strong></td>
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<td><strong>United States</strong></td>
<td>16</td>
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**Argentina:** 7 clarification/editorial (7) - 6 accepted; 1 rejected

**Germany:** 20 clarification/editorial (16) - 15 accepted; 1 rejected

essential (4) - 3 accepted; 1 rejected

**United States:** 16 clarification/editorial (14) - 12 accepted; 2 rejected

essential (2) - all accepted
Comments rejected

Expand scope to include existing exposure situations from past practices such as lightning conductors incorporating radioactive sources

**Reason for rejection:** quantity of radioactive material and associated doses to the public would not normally allow lightning conductors to be classed as “consumer products”
Next Steps

TRANSSC:

- Comment on scope and content of document
- Approve DPP

RASSC/WASSC

- Comment on scope and content of document
- Consider input from TRANSSC
- Make final decision
Thank you for your attention!

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