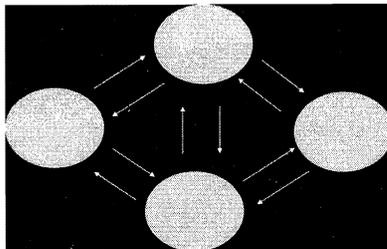


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DOCKETED
USNRC

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November 22, 2011 (9:45 am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Association of Device Distributors and Manufacturers (ADDM)
P.O. Box 91377 San Diego, CA 92169
www.addm.us

ABB Inc.

Advocates for Fair and Consistent Regulation

Baker Hughes, Inc. November 18, 2011

Berthold
Technologies USA
LLC
Secretary
US NRC
11555 Rockville Pike,
Rockville, MD 20852

Honeywell
International, Inc.

Industrial
Maintenance
Services, Inc. (IMS
Corp)

RE: Comments on proposed changes to agency's consumer products policy
statement
Docket ID NRC-2010-0292

Dear Secretary:

Industrial Nuclear
Company, Inc.

Enclosed is the draft policy statement with our comments.

IRSC, Inc.

We believe that this policy statement could benefit for the addition of definition of terms which are used throughout. We have proposed some definitions in this letter.

Metso Automation
USA, Inc.

QSA Global, Inc.

1. At the present time it appears unlikely that the total contribution to the exposure of the general public to radiation from the use of radioactivity in consumer products will exceed a fraction of limits recommended for exposure to radiation from all sources.

RMD, Inc.

Information as to total quantities of radioactive materials being used in such products and the number of items being distributed will be obtained through recordkeeping and reporting requirements applicable to the manufacture and distribution of such products. Periodically, the NRC staff conducts an overall reevaluation of this information to estimate the range of likely doses to the population. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of the combined exposure from multiple consumer products becoming a significant fraction of the permissible dose to the public, the Commission will, at that time, reconsider its policy on the use of radioactive materials in consumer products.

Source Production
and
Equipment
Company, Inc.

We agree and have no additional comment.

Rev.10112011

Template = SECY-067

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2. Approval of a proposed consumer product, and adding a new exemption from licensing provision to the regulations, depends upon both associated exposures of persons to radiation and the apparent usefulness of the product. In general, risks of exposure to radiation will be considered to be acceptable if it is shown that in handling, use, and disposal of the product, it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose limits in NRC regulations and as recommended by such groups as the ICRP, the National Council on Radiation Protection and Measurements, and the EPA, and that the probability of individual doses exceeding any of the specified limits is low and the probability of individual doses approaching a level that could cause immediate effects is negligible. Otherwise, a decision will be more difficult and will require a careful weighing of all factors, including benefits that will accrue or be denied to the public as a result of the Commission's action. Factors that may be pertinent are listed in paragraphs 9 and 10, below.

We believe there are generalities in this policy statement which need to be quantified. What value does “a small fraction, a few hundreds of individual dose ICRP recommendations ...” mean? We understand that the regulations are more detailed than policy statements, but one affects the other. There should be a specific statement on what the acceptable radiation dose is to a member of the public. We believe that the current dose limits to members of the public within NRC regulations for exempt products are reasonable and should remain in effect.

3. Products proposed for distribution will be useful to some degree. Normally, the Commission will not attempt an extensive evaluation of the degree of benefit or usefulness of a product to the public. However, in cases where tangible benefits to the public are questionable and approval of such a product may result in widespread use of radioactive material, such as in common household items, the degree of usefulness and benefit that accrues to the public may be a deciding factor. In particular, the Commission considers that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit.

Again, detailed information is required on how the NRC would deny applications based upon potential uses.

The NRC has stated in the past that frivolous uses of radioactive materials in consumer products not be considered, but the term frivolous is not defined in the policy statement. We believe that the terms ‘useful’ and ‘frivolous’ need to be defined. Frivolous use should be defined as using radioactive material in the form of adornments, such as jewelry or use in clothing, which do not serve a practical benefit or functional use. A useful product is one such as a gunsight which has as a direct benefit associated with it; illumination for the purpose of locating a target.

Define the term “adornment.” An adornment can be a product without a functional use, and is solely decorative, such as jewelry or clothing. Note that a radioluminescent watch under this definition, while jewelry, is not an adornment since it has a practical use, to tell time in the dark.

Define the term "toy." A toy would be a product directly marketed to children for play with no useful function. For example a gunsight sold as part of a paintball gun would not be considered a toy as it has a useful function, to aid shooting in low light conditions, but is marketed to adults as well as younger users.

4. Applications for approval of "off-the-shelf" items that are subject to mishandling, especially by children, will be approved only if they are found to combine an unusual degree of utility and safety.

Again we are aware that this is only a policy statement, but specifics are required. What are the guidelines for "an unusual degree of utility and safety?"

One basis the NRC has used in the past for the rejection of applications for exempt distribution of certain products containing radioactive materials is that "the end use of the product could not be easily foreseen." What the NRC means by this statement is that the possible misuses of the product can be foreseen. One example the NRC gives is the potential accidental radiation dose to adults and children by misuse or mishandling. The distributors of products in any industry should not be held liable for the intentional misuse of products. Products in any industry are subject to potential misuse, but they are not outright banned. For example, insect spray is harmful to adults or children due to the chemicals it contains, and there is no way to control the end use of the product (even less so than radioactive material in a reinforced glass tube encased in stainless steel). However there are instructions provided with the product describing the proper use and precautions which should be taken in its use.

Please be aware that these decisions have the ability to disrupt commerce in the US and it is imperative that there be a technical basis for the rejection of any products for commercial distribution.

5. The Commission has approved certain long-standing uses of source material, many of which antedate the atomic energy program. These include:

(a) Use of uranium to color glass for certain decorative purposes;
and

(b) Thorium in various alloys and products (e.g., gas mantles, optical lenses, tungsten wire in such things as electric lamps and vacuum tubes) to impart desirable physical properties.

No comment.

6. The Commission also approved the use of tritium as a substitute luminous material for the long-standing use of radium for this purpose on watch and clock dials and hands.

As you are aware, the NRC policy on consumer products was issued in 1965 as is outdated. It does not take into consideration changes in radiation dose calculations revised in various reiterations of the ICRP since the time of issuance. It also does not take into consideration the advances in technology in the manufacturing of products containing radioactive sources. It is our understanding that in 1965 there were still some radioluminescent products being

manufactured with radionuclides with high very radiotoxicity levels such radium and to a lesser extent, strontium. Modern illumination products use tritium, which has a much lower radiotoxicity and dose potential. Additionally in 1965 products such as watches were painted with radioactive material, whereas today they use Gaseous Tritium Light Sources (GTLS), which have less dose potential.

7. The Commission has approved additional uses of byproduct and source material in consumer products. These include the following:

- (a) Tritium and other radionuclides in electron tubes;*
- (b) Americium-241 in smoke detectors; and*
- (c) Thorium and uranium in piezoelectric ceramic, which is used in many electronic products and other consumer products.*

Note that there is a long history of use of these products with low dose potential to users.

8. In approving uses of byproduct, source, or special nuclear material in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In some cases, other limitations, such as quality control and testing, considered important to health and safety are also specified. In the case of class exemptions, specific safety criteria are included in the regulations, which require the applicant to evaluate many pathways of exposure of the public.

The NRC has had a comprehensive and successful system in place for many years evaluating the safety of devices in broad context of use besides the radionuclide and activity in the product. The review process also includes how the source is secured in the device, the end use of the product, prototype testing and potential doses to users under normal and accident conditions.

We do not favor the use of the term “health and safety” and suggest it should be replaced with “radiation doses to users”.

9. In evaluating proposals for the use of radioactive materials in consumer products the principal considerations are:

- (a) The potential external and internal exposure of individuals in the population to radiation from the handling, use and disposal of individual products;*
- (b) The potential total cumulative radiation dose to individuals in the population who may be exposed to radiation from a number of products;*
- (c) The long-term potential external and internal exposure of the general population from the uncontrolled disposal and dispersal into the environment of radioactive materials from products authorized by the Commission; and*
- (d) The benefit that will accrue to or be denied the public because of the utility of the product by approval or disapproval of a specific*

product

What method is used to determine the type and number of products under 9(b)? How are the number and type of products a person is exposed to controlled? Is this possibly misinterpreted to be “from a number of pathways” available from the product?

What is the criteria used to evaluate public benefit under 9(d)?

10. The general criteria for approval of individual products are set forth in paragraph 2, above. Detailed evaluation of potential exposures would take into consideration the following factors, together with other considerations, which may appear pertinent in the particular case:

- (a) The external radiation levels from the product.*
- (b) The proximity of the product to human tissue during use.*
- (c) The area of tissue exposed. A dose to the skin of the whole body would be considered more significant than a similar dose to a small portion of the skin of the body.*
- (d) Potential of the radionuclides to cause exposures from intakes. Materials that result in lower cumulative exposures when taken into the body would be considered more favorably than materials that result in higher exposures from intakes.*
- (e) The quantity of radioactive material per individual product. The smaller the quantity the more favorably would the product be considered.*
- (f) Form of material. Materials with a low solubility in body fluids and the environment will be considered more favorably than those with a high solubility.*
- (g) Containment of the material. Products which contain the material under very severe environmental conditions will be considered more favorably than those that will not contain the material under such conditions.*
- (h) Degree of access to product during normal handling and use. Products which are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.*

What criteria is used to determine if children can access a product? An example would be “can they use their hands or teeth to remove the source”, which would be more accessible or “would they require a tool or object to inflict blunt force?”, which would be less accessible.

Recent efforts to restrict certain general license devices by radionuclide and activity were voted down by the Commission. There was no radiation safety basis for these proposed regulations. We hope there will continue to be the same flexibility for certain products which have established activity limits in the regulations and NUREGS, for which the NRC has allowed greater activity limits than those listed if the product proved to meet all the radiation dose requirements.

If you have any questions please call me at 781.767.2176 or email me at schapel@irsc-inc.com.

Sincerely,

Sean C. Chapel

Sean C. Chapel,
President, ADDM

President, IRSC, Inc.

Rulemaking Comments

From: Sean C. Chapel [schapel@irsc-inc.com]
Sent: Sunday, November 20, 2011 7:47 PM
To: Rulemaking Comments
Subject: Comments on Consumer Products Statement
Attachments: ADDM COmments on Consumer Product Policy Statement11182011Final.pdf

Hello,

Please accept the attached comments from the ADDM on the revised NRC Consumer Products Statement.

If you have any questions please let me know.

Thanks

Sean

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