Studies carried out under ‘Practical Arrangements’

between Argentina (ARN) and the IAEA (NSRW)

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The ‘Practical Arrangements’ between Argentina (ARN) and the IAEA (NSRW)

- The ‘Practical Arrangements’ set forth a framework for non-exclusive cooperation between Argentina (Nuclear Regulatory Authority, ARN) and the IAEA (NSRW) in the area of radiation safety and monitoring.

- The ‘Practical Arrangements’ identify activities in which cooperation between Argentina (ARN) and the IAEA (NSRW) may be pursued subject to their respective mandates, governing regulations, rules, policies and procedures.
Primary activities identified under the ‘Practical Arrangements’

- ‘Development of regulatory guidance on radiological protection in radiotherapy, addressing in particular the potential increase in the risk of second cancers’.

- ‘Development of a harmonized approach for managing radionuclide activity concentrations in food, drinking water and non-food commodities.’
Achievements
Two outputs

1. Considerations on potential regulatory actions for radiation protection in radiotherapy:
   Monitoring unwanted radiation exposure.

2. Regulatory control of radioactivity in products generally available for public consumption and use.
1. Considerations on potential regulatory actions for radiation protection in radiotherapy: Monitoring unwanted radiation exposure in radiotherapy
Monitoring unwanted radiation exposure in radiotherapy – key concepts

- Unwanted (adventitious) radiation exposure in radiotherapy, **URER**.

- Prospective increase of primary malignancies attributable to radiotherapy, **PIPMAR** (ex- ‘second primary cancers’).
Panorama
Up to 25% of people develops cancer.
In countries with reasonable medical services, around 50% of cancer sufferers will receive radiotherapy and incur URERs.
A growing fraction of cancer patients undergoing radiotherapy will be cured.

This comprehend a large cohort of people who were exposed to URERs, which might be subject to PIPMARs.

Should a regulator ignore this panorama?
Our view is that regulators should confront this situation!

- Thus, the ultimate aim of our work is to suggest exploring the possibility of potential regulatory requirements for monitoring and recording URERs.

- Additional aims are to facilitate understanding and potential quantification of PIPMARs, and facilitating the implementation of radiation protection principles (justification and optimization).

- Finally, a long term aspiration is to improve the currently available information on the potential size of PIPMARs in order, *inter alia*, to facilitate the developing of preventive health policies.
It should be underlined, however, that the considerations and suggestions from our work should not be construed as recommending any public health action in relation to PIPMAR!

(This does not mean that the conclusions of our work would be inconsequential to potential public health actions!)
For instance, under the principle of “people-centred health services”, the potential benefits and harms of monitoring and registering URERs could be discussed with people cured by radiotherapy, however asymptomatic these people might be. With the support of well-designed educational materials this might help to optimize informed decision-making consistent with individual values, preferences and context.
Content of our work

- A comprehensive review of the *basic concepts*.
- A general *discussion* on the relevant issues.
- An exploration of the *techniques available for estimating URERs*, including proxies of established quantities and estimates based on modelling assessments, physical measurements and biological dosimetry.
- A review of the relevant *regulatory policies*.
- Suggestions and proposals
Basic Conclusions

1. Regulators with competence in the radiation protection of patients should investigate further the issue of PIPMARs.
2. In order to be able to control properly generic justifications of specific radiotherapy procedures, regulators should benefit from a wide knowledge of URERs.
Basic Conclusions

3. Systematic monitoring and registering of URERs should be a tool for controlling the optimization of protection in justified radiotherapy procedures.
Main Conclusion

For the purpose of controlling properly radiation protection of patients undergoing radiotherapy, it is highly convenient that:

1. URERs be monitored and registered and, therefore,
2. Regulatory actions be explored for requiring monitoring and registering of URERs.
It is consequently suggested that the IAEA in consultation with regulatory authorities of its Member States explore the possibility to establish international guidance for assisting national authorities in establishing requirements for monitoring and recording URERs.
The document

“Considerations on potential regulatory actions for radiation protection in radiotherapy: Monitoring unwanted radiation exposure in radiotherapy”

is available for downloading from

2. Regulatory control of radioactivity in products generally available for public consumption and use
Antecedents

- After the Chernobyl experience, the General Conference of the IAEA passed a resolution asking for a solution to this issue\(^1\).
- However, while progress has been made towards an international consensus on appropriate standards, the issue still need to be addressed.

Aim

Responding to the growing concerns raised on this issue and as a result of the Argentina (ARN) /IAEA (NSRW)’s Practical Arrangements, a discussion document is being prepared on:

‘Regulatory control of radioactivity in products generally available for public consumption and use’
Meaning

**Consumer products** are those products generally available for public consumption and use, comprehending any merchandise, including food, drinking water, non-edible products and in general any good or item (individual article or unit), readily available to members of the public for consumption or use.
Main issue

What concentrations of radionuclides in consumer products are considered ‘acceptable’ and therefore should be free of any regulation?
Associated questions

Whether to differentiate between:

- naturally-occurring and artificial radionuclides;
- products to which radionuclides are artificially added and those that are present naturally;
- products that are considered edible and those which are not; and,
- products that are consumed (e.g., eat, drink or ingest) and items that are used (e.g., take, hold, deploy).
Another challenging question

Should consumer products incorporating radionuclides from diverse initial situations be controlled differently?

- Radionuclides could reach consumer products from:
  - an extant presence in the environment,
  - an authorized discharge from a regulated activity,
  - a non-anticipated accidental situation
Content of our work

- **Assessment of the current situation:**
  - Terminology
  - Relevant components of the RP system
  - Traditional approaches (Codex, WHO, IAEA)
  - Scope of regulatory control:
    - exclusion and exemption (ICRP 104)
Content of our work

- Views from States’ relevant authorities
- Problems with current approaches.
- Recommendations for a harmonized system that:
  - be easier to implement, but
  - still ensures a high level of radiation safety
In this report, the Commission recommends approaches to national authorities for their definition of the scope of radiological protection control measures through regulations, by using its principles of justification and optimisation.
ICRP 104

- The report provides advice for deciding the radiation exposure situations that should be covered by the relevant regulations because their regulatory control can be justified, and, conversely, those that may be considered for exclusion from the regulations because their regulatory control is deemed to be unamenable and unjustified.
ICRP 104

- The report also provides advice on the situations resulting from regulated circumstances but which may be considered by regulators for exemption from complying with specific requirements because the application of these requirements is unwarranted and exemption is the optimum option.
Potential recommendations

- Redefine and use the term *consumer product*.

- Avoid the term *contamination*.

- For practical and epistemic reasons, question the use of dosimetric quantities for controlling the presence of radioactivity in consumer products.
Potential recommendations

- The presence of radionuclides in consumer products should be regulated, regardless of their origin.
- The amount of natural radionuclides present in widely and unrestrictedly available consumer products could serve as an indicator of acceptable levels of radioactivity of any origin.
Potential recommendations

- Due to the ubiquity and usual general global distribution of consumer products, national frameworks should be coherent and consistent with consensual international guidance established by governing bodies of relevant international intergovernmental organizations.
Potential recommendations

- The separation of consumer products between those that are edible and those that are not is not universal because the definition of edibility involves cultural attitudes. Thus,
  - the control criteria of consumer products should in principle be independent of their edibility, but however,
  - since consumer products generally recognized as edible may present a special sensibility for people; in such cases, an ad hoc approach dealing separately with edible and non-edible consumer products could be considered.
Potential recommendations

- Criteria for controlling consumer products that introduce differences among gender or age are difficult to implement in practice.

- However, because women and children are generally more sensitive to radiation, those levels that are considered safe for women and children should be used as the main criteria, which should be established based on consideration of a notional ‘person’ representative of those at higher risk.
In sum....
National systems for controlling consumer products could be framed on the following criteria:

- Legislators should establish the type of radioactivity in consumer products to be within the legal regulatory system of control, and what should be outside it and therefore excluded them from the law and its derived regulations defining regulatory control, because such control is unamenable; and,

- For not excluded situations, regulators should establish the radioactivity levels under which consumer products could be exempted from some or all regulatory control requirements, because regulatory control actions are unwarranted.
The suggestions provided for controlling radioactivity in consumer products are intended to establish the generic framework for defining the scope of regulatory control of consumer products, with flexibility being given to national authorities to manage specific situations.
It is expected that our suggestions will be an important step forward in clarifying a number of issues related to the control of radioactivity in consumer products. Until now, these issues have not been properly resolved and have been the subject of differing interpretations and confusion.
The document

“Regulatory control of radioactivity in products generally available for public consumption and use”

will be available in January 2019.

An interim draft summary is available in

Argentina (ARN) formal proposal following the studies carried out under the ‘Practical Arrangements’
Argentina formally request that:

DPP be developed for establishing guidance for:

- Monitoring and recording unwanted (adventitious) radiation exposure in radiotherapy.
- Regulatory control of radioactivity in products generally available for public consumption and use.
Thank you!

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