RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES:
INTERNATIONAL BASIC SAFETY STANDARDS

Introduction

1. In 1994, the 24th Pan American Sanitary Conference adopted resolution CSP24.R9 (1), in which it ratified the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (2). This resolution also urged the Member States to draw on the Standards to establish regulations and operational criteria, and asked the PAHO Director to continue to cooperate with the Member States in the development and implementation of national plans on radiation safety.

2. In 2005, a process to review these standards was undertaken by the intergovernmental organizations that sponsored them, taking into account the new scientific information produced since 1994 on the health effects of ionizing radiation, as well as experience acquired by the Member States in the application of the standards during that period. As a conclusion of this process, the need to revise and update the aforementioned standards was demonstrated in 2006.

3. The formal revision process began in 2007 and concluded in 2011. In 2006 and 2010, the Director of the Pan American Health Organization (PAHO) sent letters to the Member States to inform them about the process and tell them that, once the new standards were agreed upon, they would be submitted to the consideration of the PAHO Governing Bodies for their ratification.

Background

4. The first version of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources was published in 1962, and in
1967, 1982, and 1996 updates were published. Over the years, these standards have become the international reference on radiation safety and all Member States use them to establish their national regulations.

5. PAHO has actively participated in the review and revision process of the latest version of the standards, together with the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (NEA/OECD), the International Atomic Energy Agency (IAEA), the United Nations Food and Agriculture Organization (FAO), the International Labor Organization (ILO), the World Health Organization (WHO), the European Atomic Energy Community (EURATOM), and the United Nations Environment Program (UNEP), through a Joint Secretariat, known as Secretariat on the Revision of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources.

6. During this review and revision period, more than 60 meetings were held, among them the meetings of the Standards Secretariat, sessions and regional workshops organized by the interested agencies with a view to receiving observations from the Member States and from the groups of experts. Specific technical meetings were also convened for more complex or new matters.

7. The IAEA Board of Governors approved the new version of the standards in September 2011 and published the provisional version in Arabic, Chinese, Spanish, French, English, and Russian. This provisional version was sent to the governing bodies of each organization to proceed with the corresponding ratification processes. To date, these new standards have been formally ratified by the IAEA, FAO, UNEP, the NEA/OECD, and the ILO, as well as by WHO at the 131st Session of the Executive Board, held on 28-29 May 2012.

Situation Analysis

8. Radioactivity is a natural phenomenon and natural sources of radiation are characteristic of the environment. Radiation and radioactive materials can also be man-made and have applications in medicine, industry, agriculture and livestock, and research, as well as in nuclear power generation. Radiation risks to human health and to the environment from the use of radiation and radioactive materials should be evaluated and controlled through the application of adequate safety standards.

9. Since 1996, radiation applications, both in medicine and for other uses, have continued to increase considerably not only around the world but also in the Region of the Americas; similarly, the average dose of radiation that the population receives has increased. Medical exposure is particularly important since it is the leading cause of exposure to man-made radiation and it continues to show rising trends both with respect to doses per procedure and to the frequency of medical exposure throughout the world. In
some countries of the Region, such as the United States of America, for the first time in history, medical exposure has been higher than exposure to radiation from natural sources (5).

10. The Standards require countries to have a national regulatory infrastructure for radiation safety and protection. However, only 22 countries of the Region have regulatory authorities in this area and, in many cases where there do exist, they do not have sufficient technical capability nor resources to be able to adequately fulfill their functions. Where they exist, the regulatory authority is located in the ministry of health or in another governmental agency or may even be divided among several entities.

11. In addition to the regulatory weaknesses in Latin America and the Caribbean, the lack of adequately trained health workers, particularly medical physicists as required by the Standards, endangers patient safety, and even life. There continue to be a sizable number of overexposures in patients receiving radiation therapy, in both developed and developing countries. Some of these cases have led to health consequences, such as in the overexposure in Trinidad and Tobago confirmed by PAHO in 2010, and lives have even been lost, such as in the overexposures in Costa Rica and Panama, which is causing great concern among health authorities, regulatory bodies, the medical community, patients, the media, and the public.

12. Constant technological advances in diagnostic imaging and radiation therapy will have an impact in the future on the population radiation dose throughout the world that is very difficult to predict. Although some developments have led to more sensitive and effective detection systems, the ease by which new technologies capture images could give rise to unnecessary radiation exposure in patients. Taking into account that in the Region there has been a rapid increase not only in the quantity of health centers and equipment, but also in their complexity, the deficit in the number of well-trained professionals has been exacerbated. In Latin America and the Caribbean, some 35 institutions provide training in medical physics, but 50% are concentrated in Argentina, Brazil, and Cuba (6).

13. Despite all the precautions that are adopted in the design and operation of nuclear or radiological facilities, the possibility exists for nuclear or radiological emergencies to occur because of decisions, intentional acts, or accidents. In some cases, these situations can give rise to exposure or to the release of radioactive material inside facilities and in public places, which could require emergency response measures to minimize the effect on the public health.

14. The Standards require that adequate preparations shall be established and maintained at local and national levels and, where agreed between States, at the international level to respond to nuclear or radiological emergencies. Effective medical response is also a necessary component in any radiological or nuclear emergency. In general, the medical response may represent a difficult challenge for the authorities due
to the complexity of the situation, often requiring specialized expertise, and special organizational arrangements and materials. For the response to be effective, adequate planning and preparedness are needed.

15. Every year, radiation and nuclear accidents and emergencies continue to occur in the Region, some with fatalities. The most recent radiation and nuclear accidents and emergencies reported in the Region occurred in Chile, Ecuador, El Salvador, the United States, Honduras, Peru, Trinidad and Tobago, and Venezuela. The affected countries sought support in countries with greater infrastructure in this area, such as Argentina, Brazil, or the United States, in addition to international support. Furthermore, the health sector’s response capacity, including medical response, is very weak in Latin America and the Caribbean, which often means that victims must receive care in specialized centers outside the Region.

16. Furthermore, the recent nuclear emergency in Japan has created great concern in governments, the media, and the public in the Region. There is a clear need to boost capacity building for response to radiation and nuclear emergencies by the countries of Latin America and the Caribbean, including linkage of international support, given the number of incidents and accidents that have occurred in recent years and the threat of malicious acts with radioactive substances as a way to injure people and property with the serious social and economic consequences that this would produce.

17. The Standards also establish basic requirements for the protection of workers from radiation hazards. Nevertheless, compliance with these requirements is still pending in most of the countries, in addition to the fact that there are large differences among them. Even though some countries (such as Brazil, Cuba, and Mexico) have advanced enormously concerning compliance with these requirements, many countries are far from doing so. One of the principal problems is the limited capacity that some countries have to provide personal dosimetry to all workers occupationally exposed to radiation (Bolivia, Chile, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Jamaica, Nicaragua, Panama, Paraguay, and Uruguay), while others do not have this service at the national level, such as in Honduras and in many other Caribbean countries, which either do not monitor the doses of workers, or else contract the service externally, usually in the United States.

18. Radioactive waste can be generated by a wide range of activities varying from activities in hospitals to nuclear power plants to mines and mineral processing facilities. Given the environmental impact and the risk that they represent to the public, radioactive waste needs appropriate management that includes its safe conditioning and storage. Few countries in the Region have an adequate radioactive waste policy and a centralized storage facility. Instead, this waste is frequently stored in the places where it was used, without appropriate conditioning or without a final decision being made, as happens in
19. The requirements established in the new standards are governed by the objectives, concepts, and principles of the Fundamental Safety Principles, and are based on the information obtained from the experience of the Member States in the application of the requirements of the previous safety Standards. Furthermore, they are based on broad research activities carried out by national and international scientific organizations concerning the health effects of radiation exposure and on measures and techniques for the safe design and use of radiation sources. They also take into account the conclusions of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the recommendations of the International Commission on Radiological Protection (ICRP). Because scientific considerations are only one part of the bases for adopting decisions with respect to protection and safety, the standards also used value judgments related to risk management that reflect international consensus.

20. The new standards are intended above all to be used by governments and regulatory bodies. The requirements stipulated in them can also be applied by health authorities, professional organizations, and service providers, as well as technical support organizations or providers of radiation sources.

21. The new standards establish requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources. They apply to three categories of exposure—occupational exposure, public exposure, and medical exposure—and for all exposure situations, whether planned, existing, or emergency.

22. Requirements for the protection of people are established without distinction of sex or race. Nevertheless, specific requirements are identified and established for special risk groups, such as the risk to the embryo or fetus due to exposure of a pregnant woman; the risk of health effects for a breast-fed infant due to ingestion of radioactive substances; radiation exposure of children and pediatric patients; or occupational exposure of apprentices or students aged 16 to 18 years. Furthermore, it is established that notification of the employer by a female worker if she suspects that she is pregnant or if she is breast-feeding shall not be considered a reason to exclude a female worker from work.

23. The new standards have been developed to identify environmental protection as an issue that should be evaluated, while providing for certain flexibility to include the results of environmental assessments that are proportional to the radiological risks in decision-making processes. They also include criteria for protection against exposure to radon, which are based on the latest studies by WHO and on the recommendations of the ICRP. Concerning transportation of radioactive materials, they establish adapting to the provisions of the Regulations for the Safe Transport of Radioactive Material of the
IAEA \( (12) \) and all relevant international conventions. With regard to nuclear or radiological emergencies, they stipulate that the government should establish and maintain, in the territories of the State and within its jurisdiction, a disaster management system to respond for the purpose of protecting human life and health and the environment \( (13) \). Workers’ health surveillance programs will be based on the technical and ethical guidelines for occupational health established by the ILO \( (14) \). Medical exposure of volunteers within the framework of a biomedical research program should be in keeping with the provisions of the Declaration of Helsinki \( (15) \) and take into account the guidelines published by the Council for International Organizations of Medical Sciences (CIOMS) \( (16) \), together with the recommendations of the ICRP in this regard \( (17) \). The radionuclide content of foods subject to international trade that could contain radioactive substances as a result of a nuclear or radiological emergency should be governed by the guidelines published by the Joint FAO/WHO Codex Alimentarius Commission \( (18) \). To establish acceptable levels of radionuclides in drinking water, the values published by WHO should be considered \( (19) \). With regard to medical exposure, quality assurance programs must be established taking into account the principles established by WHO, PAHO, and the competent professional bodies.

**Action by the Pan American Sanitary Conference**

24. The Conference is invited to review the information provided in this document and consider adopting the proposed resolution in Annex A.

**References**


http://www.icrp.org/publication.asp?id=ICRP_Publication_103


http://www-pub.iaea.org/books/iaeabooks/6477/Preparedness-and-Response-for-a-Nuclear-or-Radiological-Emergency-Safety-Requirements


15. World Medical Association. 18th World Medical Assembly, Helsinki; 1974; as amended by the 59th World Medical Assembly; Seoul (Korea); 2008.


Annexes
PROPOSED RESOLUTION

RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES:
INTERNATIONAL BASIC SAFETY STANDARDS

THE 28th PAN AMERICAN SANITARY CONFERENCE,

Having reviewed the document *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards* (Document CSP28/17, Rev. 1);

Mindful of the significant increase in the use of ionizing radiation in the areas of medicine, industry, agriculture and livestock, and research in the Region, and of the possible harmful effects to human health and to the environment;

Recognizing the international harmonization initiatives with regard to radiation safety undertaken by various intergovernmental organizations such as the European Atomic Energy Community, the United Nations Food and Agriculture Organization (FAO), the International Atomic Energy Agency (IAEA), the International Labor Organization (ILO), the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (NEA/OECD), the World Health Organization (WHO), the United Nations Environment Program (UNEP), and the Pan American Health Organization (PAHO), which, through a Joint Secretariat and in consultation with the Member States and with relevant scientific and professional organizations, revised the previous International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources of 1996, in light of, among other aspects, the recommendations developed in 2007 by the International Commission on Radiological Protection (ICRP) and the conclusions of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR),
RESOLVES:

1. To endorse the new standards for *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*,
   
2. To urge Member States to rely on the orientation that these standards give when they establish or update national rules or regulations and operating criteria in the area of radiation safety.
   
3. To request the Director, in accordance with the availability of resources in the Organization, to continue to cooperate with the Member States in the development, adoption, and implementation of national radiation safety plans in accordance with the aforementioned international basic standards.
Report on the Financial and Administrative Implications for the Secretariat of the Proposed Resolution

1. **Agenda item:** 4.12, Rev. 1: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

2. **Linkage to Program and Budget 2012-2013:**

   **Area of work:** Health Systems Based on Primary Health Care

   (a) **Strategic Objective of work:**

   - **SO1:** with regard to application of the International Health Regulations.
   - **SO5:** with regard to radionuclear emergencies.
   - **SO8:** with regard to protection of the environment from radioactive contaminants and of the occupational health of workers exposed to radiation.
   - **SO12:** with regard to access to safe and high quality diagnostic imaging and radiation therapy services.

   (b) **Expected result:**

   Improve the safe use of ionizing radiation and protect patients, workers, the general public, and environment from health hazards. Include or update national regulations on aspects of radiation safety applicable to all uses and situations and strengthen (and create where they do not exist) regulatory authorities consonant with each country’s risks.

3. **Financial implications:**

   The strategy has financial implications for the Organization.

   (a) **Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US$ 10,000, including staff and activities):**

   Many of the activities will be carried out in collaboration with the IAEA. Nevertheless, for support for countries that are not IAEA members, and to strengthen health sector regulatory authorities, PAHO support is necessary. Approximately $100,000 per biennium would be desirable.

   (b) **Estimated cost for the biennium 2012-2013 (estimated to the nearest US$ 10,000, including staff and activities):**

   $50,000
(c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities?

$10,000

4. Administrative implications

(a) Indicate the levels of the Organization at which the work will be undertaken:

At the regional and country level.

(b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

Additional support is currently being provided by Ileana Fleitas, medical physicist and expert in radiation protection, located in the Cuba office. We currently cover her subsidy with extra-budgetary funds, but its continuity would need to be guaranteed for coming bienniums.

(c) Time frames (indicate broad time frames for the implementation and evaluation):

Improvement of radiation safety is a continuous process that ranges from the establishment or strengthening of regulatory infrastructures (legal framework and regulatory authorities) to improvement of the procedures in practice. As a consequence, this includes several bienniums.
### ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. **Agenda item**: 4.12, Rev. 1: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

2. **Responsible unit**: Health Systems Based on Primary Health Care / Drugs and Health Technologies Project

3. **Preparing officer**: Dr. Pablo Jiménez

4. **List of collaborating centers and national institutions linked to this Agenda item:**
   - Ministries of health of each country and territory in the Region.
   - National regulatory authorities.
   - National and subregional disaster prevention and relief organizations of each country and territory.
   - Several collaborating centers and NGOs for the promotion of the safe use of radiation in medicine, and for response to radionuclear emergencies.
   - International Atomic Energy Agency.

5. **Link between Agenda item and Health Agenda for the Americas 2008-2017:**
   This subject is related to all the values of the Health Agenda for the Americas, but principally to reducing inequities and strengthening Pan American solidarity.
   
   This agenda item also contributes in:
   
   (a) Strengthening the national health authority.
   
   (b) Increasing access to quality health services.
   
   (c) Strengthening health security.
6. **Link between Agenda item and Strategic Plan 2008-2012:**

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<thead>
<tr>
<th>Strategic Objective</th>
<th>Description</th>
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<td><strong>1:</strong></td>
<td>with regard to application of the International Health Regulations.</td>
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<td><strong>5:</strong></td>
<td>with regard to radionuclear emergencies.</td>
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<tr>
<td><strong>8:</strong></td>
<td>with regard to protection of the environment from radioactive contaminants and of the occupational health of workers exposed to radiation.</td>
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<tr>
<td><strong>12:</strong></td>
<td>with regard to access to safe and high quality diagnostic imaging and radiation therapy services.</td>
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7. **Best practices in this area and examples from countries within the Region of the Americas:**

**Quality and safety of diagnostic imaging and radiation therapy services**

The quality of a radiology service carries great weight because of the importance of obtaining accurate diagnoses or efficient therapies, which in many cases, determines the cure or survival of a patient. Undoubtedly, quality control programs also improve the quality of radiological images and reduce the dose of radiation that patients and health workers receive.

Recent research by PAHO demonstrates that a great deal still remains to be done in this sphere. A study conducted in several countries in PAHO sentinel hospitals for bacterial pneumonia surveillance found that the quality of thoracic exploration in children under 5 is poor. None of the participating hospitals had a quality assurance program and there were large differences in the radiation doses the children received and in the quality of the images in the different centers.

Furthermore, the existence of minimally trained health workers endangers the safety and even the life of patients. There is also a deficit of skilled personnel, particularly medical physicists. Taking into account that in the Region there has been a rapid increase not only in the quantity of health centers and equipment, but also in their complexity, the deficit in the number of well-trained professionals has been exacerbated. In Latin America and the Caribbean, some 35 institutions provide training in medical physics, but 50% are concentrated in Argentina, Brazil, and Cuba. There continue to be a sizable number of overexposures in patients receiving radiation therapy, in both industrialized and developing countries. Some of these cases have led to health consequences, such as in the overexposure in Trinidad and Tobago confirmed by PAHO in 2010, and lives have even been lost, such as in the overexposures in Costa Rica and Panama, which is causing great concern among health authorities, regulatory bodies, the medical community, patients, the media, and the public.

Constant technological advances in diagnostic imaging and radiation therapy will have an impact in the future on the population radiation dose throughout the world that is very difficult to predict. Although some developments have led to more sensitive and effective detection systems, the ease by which new technologies capture images could give rise to
unnecessary radiation exposure in patients.

Evaluation of the levels of radiation doses from medical exposure is particularly important since it is the leading cause of exposure to man-made radiation and it continues to show rising trends both with respect to doses per procedure and to the frequency of medical exposure throughout the world. In some countries of the Region, such as the United States of America, for the first time in history, medical exposure has been higher than exposure to radiation from natural sources.

**Regulatory infrastructure**

The advantages and hazards of radiation use, in medical, industrial, or research applications, are well known. Ionizing radiation can produce acute effects (e.g., burns) and long-term effects (e.g., cancer and hereditary diseases), which are also known as non-stochastic (deterministic) and stochastic effects. The high potential risk to health involved in its use makes it necessary to adopt special radiation protection measures for patients, workers, the public, and the environment.

The harmonization of international standards and guidelines not only makes it possible to use resources effectively and prevents duplication of effort, but also creates synergies and maximizes the impact of standards developed separately by the different organizations.

One of the fundamental requirements of the International Standards is the establishment of a national regulatory infrastructure for radiation safety and protection. However, only 22 countries of the Region have regulatory authorities in this area and, in many cases where they do exist, they do not have sufficient technical capability or resources to be able to adequately fulfill their functions. Where they exist, the regulatory authority is located in the ministry of health or in another governmental agency or may even be divided between the two.

**Occupational exposure**

Ionizing radiation exposure occurs in many occupations. Artificial sources of radiation are commonly used in the manufacturing industry, defense, academic and research institutions, and in the nuclear energy industry. They are also widely used by physicians for the diagnosis and treatment of many diseases.

With the exception of mining, the average doses of the majority of occupational exposures from artificial sources, including the nuclear industry, are below 2 mSv per year. Doses in the medical professions—medical, dental, and veterinary—are usually low. Eighty percent of radiology technicians who work in computerized tomography (CT) and conventional radiography do not have measurable doses. However, some image-guided procedures in radiology require the worker to be very close to the patient, which increases the risk of substantial exposure. Physicians involved in interventionist radiology are the occupational group most exposed in diagnostic radiology. The annual effective dose that workers receive in a positron emission tomography (PET) service is 8 mSv.

Within this group, occupational exposure in technical personnel is 2 to 4 greater than exposure of the physicians in these services.

The Standards establish basic requirements for the protection of workers from radiation
hazards. Nevertheless, compliance with these requirements is still pending in most of the countries, with large differences among them. Even though some countries (such as Brazil, Cuba, and Mexico) have advanced enormously concerning compliance with these requirements, many countries are far from doing so. One of the principal problems is the limited capacity that some countries have to provide personal dosimetry to all workers occupationally exposed to radiation (Bolivia, Chile, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Jamaica, Nicaragua, Panama, Paraguay, and Uruguay), while others do not have this service at the national level, such as in Honduras and in many other Caribbean countries, which either do not monitor the doses of workers, or else contract the service externally, usually in the United States.

**Radioactive waste**

Radioactive waste can be generated by a wide range of activities varying from activities in hospitals to nuclear power plants to mines and mineral processing facilities. Given the environmental impact and the risk that they represent to the public, radioactive waste needs appropriate management that includes its safe conditioning and storage.

Lack of management of disused radioactive sources appears to be common in the countries of Latin America and the Caribbean. Few countries in the Region have an adequate radioactive waste policy and a centralized storage facility. Instead, this waste is frequently stored in the places where it was used, without appropriate conditioning or without a final decision being made, as happens in Bolivia, Colombia, Costa Rica, Ecuador, El Salvador, Haiti, Honduras, Jamaica, Nicaragua, Panama, or Paraguay.

**Radiological and nuclear emergencies**

Despite all the precautions that are adopted in the design and operation of nuclear or radiological facilities, the possibility exists for nuclear or radiological emergencies to occur because of decisions, intentional acts, or accidents. In some cases, these situations can give rise to exposure or to the release of radioactive material inside facilities and in public places, which could require emergency response measures to minimize the effect on the public health.

Adequate preparations shall be provided for and maintained at local and national levels and, where agreed between States, at the international level to respond to nuclear or radiological emergencies.

Effective medical response is also a necessary component in any radiological or nuclear emergency. In general, the medical response may represent a difficult challenge for the authorities due to the complexity of the situation, often requiring specialized expertise, and special organizational arrangements and materials. To be effective, adequate planning and preparedness are needed.

Radiation or nuclear accidents and emergencies continue occurring every year in the Region. Several of these radiation or nuclear accidents, some of them with fatalities, have been publicized. The most recent radiation or nuclear accidents and emergencies reported in the Region have been in Venezuela, Trinidad and Tobago, Ecuador, Chile, Peru, Honduras, El Salvador, and the United States. Furthermore, the recent nuclear emergency in Japan has created great concern in governments, the media, and the public in the Region.
There is a clear need to boost capacity building for response to radiation and nuclear emergencies by the countries of Latin America and the Caribbean, including linkage of international support, given the number of incidents and accidents that have occurred in recent years and the threat of malicious acts with radioactive substances as a way to injure people and property with the serious social and economic consequences that this would produce. The Region has faced various accidents in recent years, in which the affected countries sought support in countries with greater infrastructure in this area, such as Argentina and Brazil, in addition to international support. Furthermore, the health sector’s response capacity, including medical response, is very weak in Latin America and the Caribbean, which often means that victims must receive care in specialized centers outside the Region.

8. **Financial implications of this Agenda item:**

Many of the activities will be carried out in collaboration with the IAEA. Nevertheless, for support for countries that are not IAEA members, and to strengthen health sector regulatory authorities, PAHO support is necessary. Approximately $100,000 per biennium would be desirable. In particular, $50,000 for the rest of the 2012-2013 biennium.