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

Background

1. The purpose of this document is to inform the Governing Bodies of the Pan American Health Organization (PAHO) regarding the progress made in the implementation of the standards set forth in Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, approved by the 28th Pan American Sanitary Conference of PAHO in 2012 *(1)*.

2. Radioactivity is a natural phenomenon, and natural sources of ionizing radiation are present in the environment.[1] However, radiation and radioactive materials can also be artificial, with applications in medicine, industry, agriculture, livestock, and research, as well as in nuclear power generation. In any case, ionizing radiation is not without risks to human health and the environment.[2]

3. The first version of the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) was published by the International Atomic Energy Agency (IAEA) in 1962, and subsequently updated in 1967, 1982, and 1996.

4. The latest version of the BSS was co-sponsored and endorsed by the governing bodies of eight intergovernmental organizations: the European Commission, the Food and Agriculture Organization of the United Nations, the IAEA, the International Labor Organization (ILO), the Nuclear Energy Agency of the Organization for Economic Cooperation and Development, PAHO, the United Nations Environment Program, and the World Health Organization (WHO). The final version was first published in English by

[1] In this document, the word radiation always refers to ionizing radiation even where this is not explicitly stated.

[2] Radiological hazards have two types of effects: *a)* deterministic (where exposure of human tissues or organs to ionizing radiation can cause cell death on a scale large enough to affect the function of the exposed tissue or organ, and even lead to death, and which are only clinically observed in a person if the radiation dose exceeds a certain threshold); and *b)* stochastic (where exposure to radiation can also cause non-lethal transformation of cells, which continue to maintain their ability to divide and, after a period of latency, produce cancer in the exposed person [somatic cells], or produce hereditary effects [germline cells]).

the IAEA in 2014 and subsequently in the other five official languages of the United Nations *(2)*. In the case of PAHO, the 28th Pan American Sanitary Conference had endorsed the interim edition of the BSS in September 2012, through Resolution CSP28.R15 *(3)*.

5. Subsequently, in 2017, through Resolution CSP29.R2, the 29th Pan American Sanitary Conference adopted the Sustainable Health Agenda for the Americas 2018–2030: A Call to Action for Health and Wellbeing in the Region *(4)*, whose target 5.5 refers to the need to apply the requirements of the International Basic Safety Standards in diagnostic and therapeutic services that use health technologies involving ionizing radiation. More recently, in 2019, the 57th Directing Council, through Resolution CD57.R2, adopted the Strategic Plan of the Pan American Health Organization 2020–2025) *(5)*, in which indicator 8.d refers to the number of countries and territories that have regulations and oversight that ensure access to quality and safe radiological services by implementing BSS requirements.

Analysis of Progress Achieved

International Cooperation

6. In Resolution CSP28.R15, PAHO is requested to continue to cooperate with Member States in the development, adoption, and implementation of national radiation safety plans in accordance with the BSS. This affects activities related to the protection of patients, workers, the public, and the environment from radiation in various scenarios in which radiation exposure may occur, whether in planned situations (e.g., medical and industrial uses of radiation sources), naturally existing situations (e.g., radon exposure in homes), or emergency situations (e.g., radiological or nuclear accidents).

7. In 2013, the Interagency Committee on Radiation Safety (IACRS) established a working group made up of IACRS member organizations, including PAHO, to promote the systematic and consistent implementation of the BSS in all Member States. In addition, as a member of IACRS, PAHO has continued to collaborate and develop specific technical documents on complex aspects of the BSS that require further clarification or international consensus, such as new dose limits for the lens of the eye, the use of detection devices at airports, radon monitoring, human imaging for non-medical purposes, radioactivity in food, drinking water and commodities, and operational magnitudes for exposure to external radiation, among others.[3]

8. In addition, PAHO and the IAEA formally signed practical agreements on topics of common interest in 2012, and later in 2017 *(6)*. The most relevant areas of this joint cooperation are those related to radiation safety regulations; quality assurance in radiotherapy, radiology, and nuclear medicine; medical physics; radiological and nuclear emergencies; combatting cancer; noncommunicable diseases; nutrition; environmental health; training of health personnel; and knowledge and information management in the field of health. During this period, in order to support implementation of the BSS and provide assistance in relation to the needs raised by Member States, joint cooperation

[3] The technical documents are available for consultation on the IACRS website: http://www.iacrs-rp.org.

between PAHO and the IAEA has included the development of guides and technical documents, assistance in training and coaching (including jointly organized events), and participation in joint expert missions.

9. The most relevant international events organized or sponsored by PAHO on the subject of dissemination, application, and implementation of the BSS have been the regional BSS workshops held in Costa Rica and Jamaica (2012), Uruguay (2013), Chile (2015), Antigua and Barbuda (2017), and Argentina (2019); the international conferences on radiation protection in medicine held in Germany (2012), Spain (2016), Peru (2017), and Austria (2017 and 2020); and the global radiation and nuclear safety congresses held in the United Kingdom (2012), South Africa (2016), and South Korea (2021), as well as the regional congresses held in Brazil (2013), Argentina (2015), Cuba (2018), and Chile (2022).

10. The BSS state the steps that must be taken to maintain an adequate level of radiation safety, but not how to implement them. Accordingly, during this period several safety guides and technical documents have been published to provide further guidance to Member States on how to implement the requirements, including: *a)* Establishment of Guidance Levels in General Radiography and Mammography (IAEA, the Regional Cooperation Agreement for the Promotion of Nuclear Science and Technology in Latin America and the Caribbean (known by its Spanish acronym, ARCAL) and PAHO) *(7)*; *b)* the National Program for Radiological Protection in Medical Exposures (IAEA, Ibero-American Forum on Radiological and Nuclear Regulatory Agencies, and PAHO) *(8)*; *c)* Radiation Protection and Safety in Medical Uses of Ionizing Radiation (IAEA, ILO, WHO, and PAHO) *(9)*; *d)* Quality Control Protocols for Radiodiagnosis in Latin America and the Caribbean (IAEA and PAHO) *(10)*; and *e)* Mammography Services Quality Assurance: Baseline Standards for Latin America and the Caribbean (PAHO) *(11)*.

11. It is also important to mention the development of the ARCAL Regional Strategic Profile 2022–2029, which establishes a strategic cooperation framework for the countries of Latin America and the Caribbean based on descriptive analyses of the most pressing problems and needs in the field of radiation protection and safety *(12)*.

Update on trends and uses of radiation in medicine

12. Health technologies and diagnostic and therapeutic procedures using ionizing radiation have evolved rapidly, with huge benefits for public health. Thanks to these technological innovations, multiple diseases can now be diagnosed at an earlier stage and more accurately, and it is easier to treat and cure them. In the Region of the Americas, diagnostic imaging, interventional radiology, nuclear medicine, and radiotherapy services have increased in all countries in both number and technological complexity in response to major public health challenges involving both communicable diseases (including COVID-19) and the increase in chronic noncommunicable diseases. This increase is

expected to continue in the near future as a result of progress in countries' implementation of the Strategy for Universal Access to Health and Universal Health Coverage, adopted by the PAHO Directing Council in 2014 *(13)*.

13. Globally, of all the different ways the population is exposed to artificial radiation, medical applications are the most common, according to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) *(14)*. It is estimated that about 4.2 billion radiological examinations, 6.2 million cycles of radiotherapy treatments, and 1.4 million radionuclide treatments are performed annually. Computerized tomography makes the largest contribution (about 62%) to the collective effective dose, followed by interventional radiology (8%), and diagnostic nuclear medicine (about 7%).

14. However, the distribution of radiological procedures for diagnosis and treatment remains highly uneven both globally and regionally, and remains highly concentrated in high- and upper-middle-income countries. About 70% of all radiological medical examinations are performed in these countries. This disparity is even more noticeable in nuclear medicine, as high- and upper-middle-income countries account for more than 90% of procedures. Access to radiotherapy procedures is similarly concentrated, with around 95% of all treatments in high- and upper-middle-income countries.

National regulatory infrastructures

15. The BSS require each country to have a regulatory body. This is defined as an "authority or a system of authorities designated by the government of a State as having legal authority for conducting the regulatory process, including issuing authorizations, and thereby regulating the nuclear, radiation, radioactive waste and transport safety" *(2)*.

16. The risk posed by ionizing radiation is highly variable and widespread. For example, medical uses include low-risk procedures such as dental exposures and specialized bone densitometry studies, as well as high-risk procedures such as radiotherapy treatments in which the doses administered could be lethal, and image-guided interventional procedures in which radiation can cause injuries. As a result, the government and the regulatory body should take a graded approach when determining and implementing the regulatory requirements set out in the BSS.

17. In most countries of the world and in the Region of the Americas, national legislation empowers more than one body to regulate radiation protection and safety. In 10 countries of the Region, the competencies of each regulatory body are defined according to the origin of the radiation; X-rays for medical use are distinguished from radiation of nuclear origin. In 12 other countries, a single regulatory body responsible for all exposure categories and situations is located either outside the health sector (eight countries) or within ministries of health (four countries). In two countries, several government agencies are competent to regulate protection against ionizing radiation under federal, provincial, and state jurisdictions *(15, 16)*.

18. There are also countries where there is no clearly defined regulatory body, as is the case in most Caribbean Community countries, which only recently became IAEA Member States. Ministries of health, advised by PAHO, have often acted as de facto regulatory body when it has been necessary to authorize complex medical facilities or solve issues related to radiation safety and protection. Fortunately, the recent incorporation of these countries as IAEA Member States has made it possible to develop and implement technical cooperation programs to establish regulatory infrastructures and to train personnel in this area.

19. A regulatory body should have effective independence so that its regulatory activities and enforcement actions are not subject to pressure or conflicts of interest that could undermine safety. Nevertheless, health authorities always have authority regarding the quality and safety of health care, authorization of health centers and services, and protection of public health in general. In addition, some BSS requirements are exclusive to health authorities. Therefore, regardless of a regulatory body's location or the scope of its authority, for a regulatory exercise to be efficient, activities must always be conducted in close cooperation with the health authorities.

Lessons Learned

20. The demand for diagnostic imaging, interventional radiology, nuclear medicine, and radiation therapy services has increased worldwide and in the Region due to several factors, such as the emergence of new clinical applications, a growing and aging population, changes in lifestyle, and an increase in the number of health care programs and reforms. In this context, the BSS is the international reference for radiation safety requirements, with important implications for policy development and decision-making. The current version of the BSS *(2)*, sponsored and endorsed by eight intergovernmental organizations, has contributed to greater coherence between the various safety and security arrangements in different countries.

21. The work of the IACRS is essential to promote systematic and coherent implementation of the BSS in all Member States, and to reach international consensus on more complex aspects of the BSS. The technical cooperation activities organized jointly by the different IACRS member organizations, and in particular those organized jointly in the Region of the Americas by the IAEA and PAHO, as well as the activities focused on national coordination among the different government agencies, have been very well received by the national counterparts that participated in them.

22. Appropriate national regulatory infrastructures are the first requirement to reduce the likelihood of radiological or nuclear accidents and, in case of occurrence, to mitigate their impact. Safety regulation is a national responsibility, but the risks associated with radiation can extend beyond national borders; international cooperation helps to promote and enhance safety worldwide through shared experiences and greater capacity to control hazards, prevent accidents, respond to emergencies, and mitigate harmful consequences.

Action Needed to Improve the Situation

23. While most Member States have used the BSS when establishing or updating national rules or regulations, and have employed operational criteria in the field of radiation safety, it will take time for them to make the necessary changes to existing national radiation protection systems in order to fully comply with BSS requirements. Necessary actions for improvement include:

a) Coordination between regulatory bodies and health authorities should be encouraged, in particular for the authorization of health services that use ionizing radiation.

b) National regulatory infrastructures should be established where none exist; and where they do exist, they should progressively adapt to a scenario in which health technologies are using ionizing radiation in increasingly numerous and complex ways, in order to guarantee an adequate level of safety for patients, health workers, the public, and the environment.

c) Member States should continue to update their national regulations in accordance with the BSS and international guidelines. These regulatory frameworks must be dynamic and adaptable to the emergence and incorporation of new health technologies.

d) Training plans for both users and staff of regulatory bodies should be reviewed and updated.

e) The participation of professional societies and other appropriate stakeholders in regulatory processes should be encouraged.

Action by the Executive Committee

24. The Executive Committee is invited to take note of this report and provide any comments it deems pertinent.

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