Comments of the International Atomic Energy Agency on the
draft revised International Health Regulations of the World Health Organization

Following are the International Atomic Energy Agency’s (the “IAEA”) comments on the draft revised International Health Regulations (the “IHR” (Document A/IHR/IGWG/3)) of the World Health Organization (the “WHO”). The IAEA has now been given an opportunity to provide comments on the working paper containing an initial proposed revision of the International Health Regulations, as sent to all Member States and other bodies involved, in January 2004 (Document IGWG/IHR/Working paper/12.2003).

The IAEA provides the following comments, which are both general and also specific to the draft revised IHR. Additionally, the following comments also include suggested issues requiring clarification. The IAEA may provide further comments later, and the IAEA would like to be invited to comment on later drafts of the IHR.

A. GENERAL COMMENTS

At the outset it is recalled, that the IAEA is specifically authorized under the terms of its Statute to inter alia, “establish… standards of safety for…protection of health and minimization of danger to life and property…and to provide for their application”. In addition, a number of international norms, including standards, codes, guides and conventions have been developed under the auspices of the IAEA, to regulate the peaceful and safe use of nuclear energy.

It should be noted, that many of these safety standards concerning radiation protection and emergency preparedness and response, are co-sponsored by the WHO. These safety standards include:

- International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (1996), which are jointly sponsored by the Food and Agriculture Organization (FAO), IAEA, International Labour Organisation (ILO), Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (NEA/OECD), Pan American Health Organization (PAHO), and WHO, and have been adopted inter alia by the WHO on 27 January 1995 when it was noted by the WHO Executive Board at its 95th Session and endorsed by the XXIV Pan-American Sanitary Conference on 28 September 1994 following a recommendation from the 113th meeting of the PAHO Executive Committee.;

- “GS-R-2”: Preparedness and Response for a Nuclear or Radiological Emergency (2002) (co-sponsored by WHO), which is jointly sponsored by FAO, IAEA, ILO, NEA/OECD, PAHO, OCHA and WHO. The safety standard establishes requirements for emergency preparedness and response for a nuclear or radiological emergency in any State. Its adoption is intended to minimize the consequences for people, property, and the environment of any nuclear or radiological emergency;


In general, the most important comment of the IAEA concerns the broadened scope of application of the draft revised IHR, to cover “radio-nuclear” sources, which is a significant departure from the current IHR. In particular, the IAEA’s comment is primarily to ensure that the competence and
respective role of the IAEA is maintained and that there is consistency between the draft revised IHR and the relevant international instruments adopted under IAEA auspices.

Scope

The International Health Regulations currently in force, is limited to three “notifiable diseases”: cholera, plague and yellow fever. The scope of the draft revised IHR covers diseases “that presents a risk of significant harm to humans caused by biological, chemical or radio-nuclear sources” (Article 1, Definitions).

The IAEA clearly acknowledges the importance of international response to any public health emergency, including emergencies associated with “radionuclear sources”. In this context, the IAEA notes the recognition within the draft revised IHR of the competence and respective role of the IAEA. For example, reference is made to Article 12 (Cooperation of WHO with international organizations and bodies), which requires WHO to coordinate its activities with, inter alia, the IAEA, in particular, when the notification or verification of, or response to, an event falls within the IAEA’s competence. In this context, it should also be noted that the IAEA is the main co-ordinating body for implementation of the "Joint Radiation Emergency Management Plan of the International Organizations" ((the J-Plan) of which WHO is a participant), the purpose of which is to describe the inter-agency framework for preparedness for and response to an actual, potential or perceived nuclear or radiological emergency. In addition, paragraph 4.80 and 5.11 of IAEA Safety Standard GS-R-2, concerning, respectively, national arrangements to treat exposed or contaminated people and co-ordination of emergency response between international organisations, are also of relevance.

Additionally the IAEA notes, that Article 15 (Criteria for recommendations) provides that the WHO Director General is required to consider “relevant international standards and instruments...." In this context, reference is made to the safety standards of the IAEA and also the relevant international instruments established under the IAEA’s auspices. In particular, the IAEA refers to the four IAEA conventions identified in the document concerning the draft revised IHR and its relations with other international instruments (Document A/IHR/IGWG/INF.DOC./1), as areas of possible overlap: the Convention on Early Notification of a Nuclear Accident (the “Early Notification Convention”), the Convention on Early Notification of a Nuclear Accident and the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (the “Assistance Convention”); the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management; and the Convention on Nuclear Safety (see Annex 1 for a brief description of these conventions).

Of special note, is the Early Notification Convention and the Assistance Convention (both of which WHO is a party to), while each only provide general frameworks, both are in fact the key elements of the international legal framework for international co-operation, co-ordination, exchange of information and the prompt provision of assistance in the event of a nuclear or radiological emergency, with the aim of minimizing the consequences to protect life, property and the environment.

In this regard and concerning the interpretation of the draft revised IHR, the IAEA refers to Article 58, paragraph 1 (Relationship with other international agreements) of the draft revised IHR which provides criteria that seek to reduce the possibility of “conflicts” with other international instruments, such as those mentioned above. The IAEA notes in this context, that it is proposed that the draft revised IHR and other relevant international agreements (such as those mentioned above) should be interpreted so as to be “mutually supportive” and that the provisions of the draft revised IHR shall not affect the rights and obligations of any State Party deriving from other international agreements, provided they are compatible with the “purpose” of the draft revised IHR. Notwithstanding the above, the IAEA, at the outset, considers it fundamental that there is consistency between the relevant international instruments adopted under IAEA auspices and the draft revised IHR.
B. SPECIFIC COMMENTS

PART I - DEFINITIONS, PURPOSE AND RESPONSIBLE AUTHORITIES

Article 1 Definitions
Contamination: the definition should be consistent with the safety standards of the IAEA.

Disease: the definition is unclear at present and seems to suggest that the definition includes as an illness, exposure to “radionuclear” sources? In the context of international instruments adopted under IAEA auspices, there is no understanding of such exposure as being a disease or illness. This matter should be clarified.

Radionuclear: we understand that the term “radionuclear” is used in a highly specialized sense in nuclear medicine (ie. tests in nuclear medicine in which radiopharmaceuticals are used). Consequently, it should be determined what “radionuclear” sources means (ie. radioactive sources and/or nuclear material). In any event, the definition should be revised and be consistent with criteria specified in the safety standards of the IAEA.

Article 3 Responsible authorities

Article 3.3: the IAEA notes, that this Article attempts, inter alia, to clarify the functions of the National IHR Focal Points and their relationship with WHO IHR Contact Points. However, the IAEA is concerned to ensure that, where there is a public health emergency concerning “radionuclear sources”, there is co-ordination and clear lines of responsibility and authority between the National IHR Focal Points (as provided in the draft revised IHR) and the competent authorities (and points of contact) responsible for emergency response for nuclear or radiological emergencies (see Article 7, the Early Notification Convention. In addition, IAEA Safety Standard GS-R-2, paragraphs 4.29, 4.30 and 4.31 are also of relevance. Additionally and in this context, with regard to the provision and receipt of communications/information, it is important that the concerned parties are aware of the content to be provided and also the organisation to which it should be sent.

Article 5 Notification

Article 5: attention should also be paid to IAEA Safety Standard GS-R-2, paragraph 4.15 concerning the notification of a “transnational emergency”.

PART II - INFORMATION AND RESPONSE

Article 9 Provision of information by WHO

Article 9.3: add “and relevant international organizations” after “States Parties”. The IAEA considers that relevant international organizations should also receive the information. Attention should also be paid to IAEA Safety Standard GS-R-2, paragraph 4.84 concerning the provision of information to the public.

Article 10 Determination of a public health emergency of international concern
Article 10: In the context of the definition of a “public health emergency of international concern”, attention should be paid to the IAEA Safety Standard GS-R-2 and the definition of “transnational emergency” (page 61).

Article 10.5(a): add “and relevant international organizations” after “States Parties”. The IAEA considers that relevant international organizations should also receive the information.

Article 11 Response

Article 11.2: we note, that the WHO may, at the request of a State Party, mobilize international teams of experts for on-site assistance, in response to public health threats and other events. However in this context, we are of the view that not only is there a need to ensure co-operation and co-ordination with the IAEA, as stated in Article 12, clause 1 but additionally the relevant instruments (eg. the Assistance Convention) and existing arrangements (eg. the J-Plan) concerning emergency assistance and response for nuclear or radiological emergencies, need to be strictly followed.

PART III - RECOMMENDATIONS

Article 15 Criteria for recommendations

Article 15: with respect to (the issue, modification or termination of) temporary recommendations, the consideration by the WHO Director General, of subparagraphs (d) and (e) “may be subject to the limitations imposed by the urgent circumstances”. It is not clear to the IAEA what this will mean in practice, particularly where the public health emergency of international concern, involves “radionuclear” sources. In particular, as has already been mentioned above, there are a number of relevant international standards and instruments adopted under IAEA auspices, which deal with “urgent circumstances” with the aim of minimizing the consequences to protect life, property and the environment.

Article 15(d): to add “and by the International Atomic Energy Agency” after “Commission”.

PART IV - POINTS OF ENTRY

Article 20 Competent authorities

Article 20: the term contamination is used in this article. The definition of contamination resulting from radionuclides should take into account the definition of contamination in the IAEA safety standards including the radiological criteria for radionuclides in commodities (see GOV/2004/54-GC(48)/8, see also the specific values of activity concentration for radionuclides that may be used for bulk amounts of material, and guidance on their application (the BSS, RS-G-1.7: “Application of the Concepts of Exclusion, Exemption and Clearance”)), the WHO drinking water guidelines and the levels for food published by the Codex Alimentarius Commission.
PART V PUBLIC HEALTH MEASURES

Chapter II Special provisions for conveyances and conveyance operators

Article 22 Conveyance operators
Article 22.1(a): add “or other international organizations” after WHO.
Article 24.1(b): add “or other international organizations” after WHO.

PART VIII - GENERAL PROVISIONS

Article 45 Information sharing during a suspected intentional release

Article 45: concerning the “intentional release of a biological, chemical or radionuclear agent”, the IAEA understands that a “malicious” act or activity means a wrongful act or activity intentionally done or engaged in without legal justification or excuse (e.g. smuggling) or an act or activity intended to cause death or physical injury to any person, material damage to any person (e.g. theft) or damage to property or to the environment. In light of the above, an intentional release, as provided in the draft revised IHR infringes upon planned and controlled releases, as a legitimate practice, within authorized limits, of liquid or gaseous radioactive materials that originate from regulated nuclear activities (eg. see Article 2(c) Joint Convention).

With regard to the “intentional” (malicious) acts and the provision of information concerning such acts to an international organization and/or other State Parties, it should be noted that this matter is being addressed in the context of proposed amendments to the Convention on the Physical Protection of Nuclear Material, adopted under the auspices of the IAEA, on 26 October 1979. In particular, to cover co-operation (including the exchange of information) in the case of a credible threat of sabotage of nuclear material or nuclear facilities used for peaceful purposes, or in case of sabotage thereof. It should be noted, that there should be consistency with whatever terms are to be applied and those contained in Annex 2 of the draft revised IHR.

Article 45: add “and other international organizations” after WHO.

PART IX THE IHR ADVISORY PANEL, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

Chapter I The IHR Advisory Panel

Article 47 Composition
Article 47.1: add “and other international organizations” after “State Parties”.

Chapter II - The Emergency Committee

Article 49 Procedure
Article 49.7: add “and other international organizations” after “State Parties”.


ANNEX 1

A. Core capacity requirements for surveillance and response

Subparagraph 3(e) (At the national level): add “or competent authorities” after “government ministries”, and add “radiation protection, emergency response” after “customs”.

ANNEX 2

A. Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern

Annex 2, 4th last line of page 43: see comments above regarding Article 45
With regard to draft revised IHR, the following international instruments adopted under IAEA auspices are of relevance:

**A. INSTRUMENTS ON NOTIFICATION AND ASSISTANCE IN CASE OF A NUCLEAR ACCIDENT OR RADIOLOGICAL EMERGENCY**

In 1986, in the aftermath of the Chernobyl accident, two multilateral treaties in this field were negotiated under the IAEA auspices, namely, the Convention on Early Notification of a Nuclear Accident and Convention on Assistance in the Case of Nuclear Accident and Radiological Emergency.

**Convention on Early Notification of a Nuclear Accident**

The Early Notification Convention prescribes procedures for immediate reporting and prompt provision of supporting information in the event of a nuclear accident with actual or potential international transboundary effects. The Convention applies to all uncontrolled releases of radioactive materials from any facility or activity under the jurisdiction or control of a State Party (the accident State Party), which have resulted or may result in international transboundary effects that could be of radiological safety significance to another State.

In the event of an accident covered by the Convention, the State in which it has occurred is required to: immediately notify, directly or through the IAEA, other States which may be physically affected, and the IAEA, of the nature of the accident, the time of its occurrence and, where appropriate, the exact location; and promptly to provide them, through the same notification procedure, with additional information, as is available, relevant to minimizing radiological consequences in the affected States.

The IAEA is responsible for immediate onward transmission of the received notification of any nuclear accident to all affected States and to relevant international organizations. It is also required to provide promptly, upon request, any State Party, Member State of the IAEA or relevant international organization, with additional information provided by the accident State Party. A State Party without nuclear activities but bordering on a State having an active nuclear programme may receive assistance from the Agency in the context the Convention's objectives.

Since a nuclear accident may result in transboundary release requiring protective actions in countries situated far away from the place of the accident, by adhering to the Early Notification Convention a State will benefit from the prompt provision of information regarding any accident at an early stage, a prerequisite for timely and effective implementation of urgent protective measures in order to avoid or minimize detrimental effects to the population.

**Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency**

The Assistance Convention created an international framework for the prompt and coordinated provision of assistance in case of a nuclear or radiological emergency. States Parties cooperate among themselves, and with the IAEA, to facilitate prompt assistance to minimize consequences of a nuclear accident or radiological emergency and to protect life, property and the environment from the effects of radioactive releases. The Assistance Convention applies irrespective of whether a
nuclear accident or radiological emergency originated within the State Party requesting assistance, under its jurisdiction or control or elsewhere.

A State Party may request assistance from any other State Party, either directly or through the IAEA; assistance may also be requested from the Agency, as well as from other international organizations. In order to facilitate the provision of such assistance, States Parties are required, within the limits of their capabilities, to notify the Agency of experts, equipment and materials which could be made available for the provision of assistance, and the terms under which they could be provided. The Agency circulates to States Parties and Member States regular updates of such information.

Participation in the Assistance Convention offers rapid access to international assistance in the form of technical expertise, equipment, monitoring and medical treatment as well as assistance in preparing emergency plans, training, development of procedures and standards to deal with nuclear accidents and radiological emergencies.

B. CONVENTIONS RELATING TO NUCLEAR SAFETY

Convention on Nuclear Safety

Under the Convention on Nuclear Safety, each Contracting Party undertakes to establish and maintain a legislative and regulatory framework with respect to the safe management and operation of land-based civil nuclear power plants, and to implement a number of measures based on general internationally accepted safety considerations regarding - for example - the availability of financial and human resources, the assessment and verification of safety, quality assurance, and emergency preparedness. The Convention also addresses technical aspects of the safety of such nuclear installations, including siting, design and construction, as well as operation. The Convention provides for the convening of peer review meetings at which Contracting Parties report on how they implement each of the obligations under the Convention.


The Joint Convention is the first legal instrument to address directly, on a global scale, the issue of safety in connection with spent nuclear fuel and radioactive wastes, specifically those resulting from civilian nuclear reactors and other civilian applications. The Convention may also apply to spent fuel and radioactive waste from military or defense programmes if and when such materials are transferred permanently to and managed within exclusively civilian programmes, or when they are declared by the Contracting Party as spent fuel or radioactive waste for purposes of the Joint Convention. The Joint Convention applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear facilities. The Convention also contains requirements with respect to the transboundary movement of spent fuel and radioactive waste and the safe management of disused sealed sources. The Convention also provides that a Contracting Party shall in the framework of its national law take the appropriate steps to ensure that the possession remanufacturing or disposal disused sources takes place in a safe manner. Furthermore that a Contracting Party shall allow for re-entry into its territory of disused sealed sources if in the framework of its national law it has accepted that they be returned to a manufacturer qualified to receive and possess the disused sealed sources. As in the Convention on Nuclear Safety, the Joint Convention provides for peer review, i.e. the convening of meetings at which Contracting Parties report on how they implement each of the obligations under the Convention.
The importance of the CPPNM, which entered into force in 1987, resides in its being the only international legally binding undertaking in the area of physical protection of nuclear material aimed at averting potential dangers of the unlawful taking and use of nuclear material. It entered into force in 1987.

The scope of the Convention is twofold. The Convention applies mainly to nuclear material used for peaceful purposes while in international nuclear transport, with some additional provisions related to nuclear material in domestic use, storage and transport.

The CPPNM obliges Contracting Parties to ensure protection at the levels specified in the Convention of nuclear material used for peaceful purposes on their territories, ships or aircraft during international nuclear transport. The Contracting Parties commit themselves not to undertake, or authorize the undertaking of, such international nuclear transport unless assurances are provided that nuclear material will be protected at the required levels. Contracting Parties must also apply the agreed levels of protection to nuclear material which, during transit from one part of its territory to another, will pass through international waters or airspace. The Convention also establishes measures related to the prevention, detection and punishment of offences relating to nuclear material.

Possible amendments to the CPPNM reflect an extension of its scope to cover: the physical protection of nuclear material used for peaceful purposes, in domestic use, storage and transport and the protection of nuclear material and nuclear facilities used for peaceful purposes against sabotage; the importance of national responsibility for the establishment, implementation and maintenance of a physical protection regime; the Physical Protection Objectives and Fundamental Principles; the basis for cooperation in the case of a credible threat of sabotage of nuclear material and nuclear facilities or in the case of sabotage thereof; and new offences relating to sabotage, nuclear smuggling, and offences that are contributing to, and organizing or directing, the commission of an offence.