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IAEA RADIATION EVENTS DATABASE (RADEV)

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Abstract

Whilst the use of ionizing radiation continues to bring benefits to many people throughout the world there is increasing concern at the number of reported accidents involving radiation. Such accidents have had an impact on the lives of patients, workers and members of the public, the consequences of which have ranged from trivial health effects to fatalities. In order to reduce the number of accidents and to mitigate their consequences it is, therefore, necessary to raise awareness of the causes of accidents and to note the lessons that can be learned. The IAEA's database on unusual radiation events (RADEV) is intended to provide a world-wide focal point for such information.

1. Introduction

The use of radiation sources and radioactive material is well established throughout the world and brings substantial benefits to society when used in a safe and controlled manner. The IAEA, in addition to facilitating the transference of technology that utilizes the constructive properties of ionizing radiation, has a statutory function to establish international standards of safety and to provide for their application. The International Basic Safety Standards [1], which were jointly sponsored by FAO, IAEA, ILO, OECD/NEA, PAHO and WHO, establish requirements for protection against the risks associated with exposure to ionizing radiation and include a substantial appendix on Medical Exposure.

Even though many governments have adopted these international standards into their national arrangements, the large number of radiological accidents that have been reported worldwide implies that numerous radiation sources are not managed or regulated appropriately. Indeed, IAEA has, with the cooperation of Member States, already published a number of reports of accidents with significant consequences in order to provide feedback and identify lessons to be learned [2, 3].

Global awareness of the magnitude and seriousness of the problem was raised in September 1998 at the first international conference on the 'Safety of Radiation Sources and the Security of Radioactive Material' held in Dijon, France.

The conclusions of this conference were drawn to the attention of the IAEA Board of Governors at the General Conference. Subsequently, the IAEA Secretariat was requested to prepare and implement an *Action Plan* on the 'Safety of Radiation Sources and the Security of Radioactive Material'. The *Action Plan*, which was endorsed by the Board of Governors and the General Conference in 1999 covers the following seven areas: regulatory infrastructures; management of disused sources; categorization of sources; response to abnormal events; information exchange; education and training; and international undertakings. One of the actions under 'Information Exchange' is for the IAEA secretariat to fully develop and maintain an international database on unusual radiation events (RADEV) and to make it available to Member States.

2. BSS requirements for accidental Medical Exposures

As mentioned above, the BSS [1] includes requirements for Medical Exposures, amongst which are specific requirements relating to accidental medical exposures (as given below). RADEV has been designed to capture the details and lessons to be learned from such accidents.

The following is an extract from Appendix II (Medical Exposures) of the BSS:

II.29. Registrants and licensees shall promptly investigate any of the following incidents:

(a) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner or which may lead to undue acute secondary effects;
(b) any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and
(c) any equipment failure, accident error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended.

II.30. Registrants and licensees shall, with respect to any investigation required under para. II.29:

(a) calculate or estimate the doses received and their distribution within the patient;
(b) indicate the corrective measures required to prevent recurrence of such an incident;
(c) implement all the corrective measures that are under their own responsibility;
(d) submit to the Regulatory Authority, as soon as possible after the investigation or as otherwise specified by the Regulatory Authority, a written report which states the cause of the incident and includes the information specified in (a) to (c), as relevant, and any other information required by the Regulatory Authority; and
(e) inform the patient and his or her doctor about the incident.

3. Overall Objectives of RADEV

Capturing information about accidental medical exposures is only part of RADEV's remit. On a broader scale, RADEV includes many different types of events that have occurred outside the nuclear power programme. The overall objectives of RADEV are to:

(a) disseminate information on radiation events and feedback lessons that may help to prevent future accidents, or mitigate their consequences should they occur, and
(b) provide a tool to help Member States, the IAEA and other organizations to identify priorities in their radiation safety programme to facilitate the efficient allocation of resources.

In order to achieve these general objectives a centralized RADEV database is being established at IAEA's headquarters in Vienna to:

(a) provide a repository of information on accidents, near-misses and any other unusual events involving radiation sources not directly involved in the production of nuclear power or its fuel cycle;

(b) categorize events in a standardized manner to facilitate the search for events fitting particular profiles, the identification of causes and the lessons to be learned;
(c) provide a means to analyze trends in radiation events; and
(d) provide summary descriptions of events that can be used directly as training material.

RADEV is designed to capture lessons to be learned from radiation events and is not meant to be a real-time on-line database. A separate IAEA initiative is concerned with developing a 24-hour reporting system for missing and found orphan sources.

4. Events to be included

General Events

- events or potential events involving patients, workers or members of the public;
- events involving radiation sources which have been lost, found, stolen, or subject to unauthorized and inadvertent transfer/sale; and
- events that occurred during the transportation of sources that result or could have resulted in the loss or degradation of control of radiation sources.

Events Involving Patients

Many types of radiation events involving patients have been reported, including:

- Wrong patient exposed
- Wrong tissue exposed (correct patient)
- Wrong radio-pharmaceutical administered
- Wrong activity administered
- Wrong beam settings
- Delivered dose different from intended

The consequences of such events include: ineffective treatment, ineffective diagnosis, severe radiation burns, severe degradation in quality of life and, in some cases death directly attributable to high radiation exposure. Many of these events were caused by deficiencies in, or a lack of: design, testing and calibration of equipment; education, training and qualification of personnel; procedures; defense in depth; quality assurance. In some cases, events involving patients have also resulted in exposures of hospital workers, lost sources and exposures of members of the public.

5. Management and operation

The database has been designed to operate on a personal computer using Microsoft Access 97 or above. Copies of the RADEV software will be provided to selected organizations within Member States for their own use and users will be requested to provide data to IAEA on a regular basis. IAEA will be manage and operate the international RADEV database and will act as the central focal point for all users. IAEA will publish regular summary reports from RADEV and will provide electronic updates of the data to participating organizations. Confidentiality will be maintained by IAEA at all times and details such as names of individuals, hospitals and factories will not be divulged.

6. Implementation

The RADEV project is being implemented in 3 phases:

Phase 1: Establishment of the database. IAEA will collect currently available details of radiation accidents and test the software.

Phase 2 : Limited international trials. IAEA will provide a working version of RADEV to several international and national organizations (including professional organizations in the medical field) for testing and evaluation. Feedback from the trials will be reviewed by IAEA and any necessary changes made to the software.

Phase 3: Distribution of RADEV. IAEA will collect data from participating organizations, compile international statistics and produce summary reports. Electronic copies of the summary reports and the updated database will be available to participating organizations.

The current status at time of the Malaga Conference is that Phase 1 has been successfully completed and international trials are taking place.

References

[1] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR ORGANISATION, OECD NUCLEAR ENERGY AGENCY, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).

[2] INTERNATIONAL ATOMIC ENERGY AGENCY, Lessons Learned from Accidents in Radiotherapy, Safety Report No. 17, IAEA, Vienna (1998).

[3] INTERNATIONAL ATOMIC ENERGY AGENCY, Accidental Overexposure of Radiotherapy Patients in San José, Costa Rica, IAEA, Vienna (1998).