The cover photograph shows a source rack similar to the one in the industrial irradiation facility in San Salvador at which a serious radiological accident occurred in February 1989. The rack holds intensely radioactive cobalt-60 gamma source elements. Photograph by courtesy of Nordion International Inc., Kanata, Ontario, Canada.

THE RADIOLOGICAL ACCIDENT IN SAN SALVADOR

A REPORT PREPARED BY THE
INTERNATIONAL ATOMIC ENERGY AGENCY
IN CO-OPERATION WITH THE
PAN AMERICAN HEALTH ORGANIZATION OF THE
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FOREWORD

By the Director General

Technologies that make use of radiation continue to spread around the world: millions of people are employed in radiation related occupations and hundreds of millions of people benefit from these applications. The use of intense radiation sources for purposes such as the sterilization of medical products requires special care in the design and operation of equipment to prevent radiation injury to workers or to the public. Experience has shown that such technology is generally safely used, but controls have on occasion been circumvented and serious radiological accidents have ensued.

To the extent that reports on such accidents are incomplete or are unavailable to the scientific community, potentially valuable information is lost. Although the causes of accidents may be highly case specific, review of the circumstances in which they happen may yield generally applicable lessons that can be of help in preventing accidents in the future or in improving the response to those that do occur. Thus, the IAEA's review of the radiological accident in Goiânia, Brazil, in 1987, in which the misuse of an abandoned medical teletherapy source led to radiation injuries resulting in four deaths and to widespread contamination, has been found useful by the international radiation protection community in seeking to ensure the safety of major radiation sources.

The accident at an industrial irradiation facility in San Salvador was quite different from that in Goiânia, being limited to the external irradiation of workers. However, it did result in a fatality, as had similar accidents in Italy in 1975 and in Norway in 1982. There are more than 160 industrial irradiation facilities around the world that are as large as or larger than the one in San Salvador, and some of these are in countries that lack adequate infrastructures for radiation protection. An international review was undertaken to document the facts of the accident and to define generic lessons for the benefit of those having safety responsibilities for such facilities.

The report was prepared in co-operation with the Pan American Health Organization of the World Health Organization.

FIGURES

FIG. 13. Plan view of the positions in relation to the source rack of Workers A, B and C during the accident with dose rate contours in $Gy \cdot min^{-1}$. (Source: REAC/TS.)

FIG. 14. Dose rate contours for a standing figure: rates in $Gy \cdot min^{-1}$. (Source: REAC/TS.)

FIG. 15. Dose rate contours for a squatting figure: rates in $Gy \cdot min^{-1}$. (Source: REAC/TS.)

FIG. 16. Plan view of the positions in relation to the source rack of Workers A, B and C while attempting to free the source rack. (Source: REAC/TS.)

FIG. 17. Patients A, B and C: doses D incurred by different parts of the body. (Source: REAC/TS.)

FIG. 18. Patient A: corporal distribution of effects of exposure. (Source: REAC/TS.)

FIG. 19. Patient B: corporal distribution of effects of exposure. (Source: REAC/TS.)

FIG. 20. Patient C: corporal distribution of effects of exposure. (Source: REAC/TS.)

TABLES

TABLE I. Results of cytogenetic analyses made by the National Atomic Energy Commission of Argentina through the WHO Collaborating Centre on Radiation Emergencies: doses received by other workers on Day 6 in the second event.

TABLE II. Estimates of doses to the lower limbs and equivalent whole body doses made on Day 32 (Wednesday 8 March) by REAC/TS, Oak Ridge, USA, for Patients A, B and C.

TABLE III. Results of cytogenetic analyses made by the Angeles del Pedregal Hospital, Mexico City, and REAC/TS for Patients A, B and C.

TABLE IV. Cytogenetic dose estimates made by REAC/TS for Patients A, B and C.

TABLE V. Distribution of dicentrics in first division metaphases of lymphocyte cultures initiated on Day 35 (Saturday 11 March) for Patients A, B and C.

TABLE VI. Signs and symptoms for Patients A, B and C upon admission to the Angeles del Pedregal Hospital.

TABLE VII. Results of physical examinations for Patients A, B and C upon admission to the Angeles del Pedregal Hospital.

TABLE VIII. Vital haematological values for Patients A, B and C upon admission to the Angeles del Pedregal Hospital.

TABLE IX. Haematological recovery for Patients A, B and C.

CONTENTS

1. INTRODUCTION

On 5 February 1989, a radiological accident occurred at an industrial irradiation facility near San Salvador, the capital of the Republic of El Salvador (see Fig. 1). Prepackaged medical products are sterilized at the facility by irradiation by means of an intensely radioactive cobalt-60 source in a movable source rack. The accident happened when this source rack became stuck in the irradiation position. The operator bypassed the irradiator's already degraded safety systems and entered the radiation room with two other workers to free the source rack manually.

The three workers were exposed to high radiation doses and developed the acute radiation syndrome. Their initial hospital treatment in San Salvador and subsequent more specialized treatment in Mexico City were effective in countering the acute effects. However, the legs and feet of two of the three men were so seriously injured that amputation was required. The worker who had been most exposed died six and a half months after the accident, his death being attributed to residual lung damage due to irradiation, exacerbated by injury sustained during treatment.

The report details the events leading up to the accident, the circumstances of the accident itself and the response to it. From the facts established, lessons are derived for operators and suppliers of irradiators, national authorities, medical staff and international organizations. Detailed information on dosimetric and medical aspects of the accident for the specialist reader is presented in the appendices and annexes.

2. THE BACKGROUND IN EL SALVADOR

El Salvador has been in a state of civil war since 1979. The national economy has been disrupted by armed attacks on transport links, military targets and economic targets such as factories and installations of the electricity generation and distribution system. The danger of being identified as an economic target has led to a tendency in managers of enterprises to divulge information relating to the security of commercial operations (including safety aspects) on a 'need to know' basis only, particularly for technical installations such as the irradiation facility at which the accident occurred. The commercial and economic isolation of the country because of the civil war was a factor in the accident.

The Ministry of Labour and Social Security in El Salvador is responsible for the administration of matters under the Labour Code. The Labour Code covers the responsibilities of managements and of workers in respect of hygiene and safety

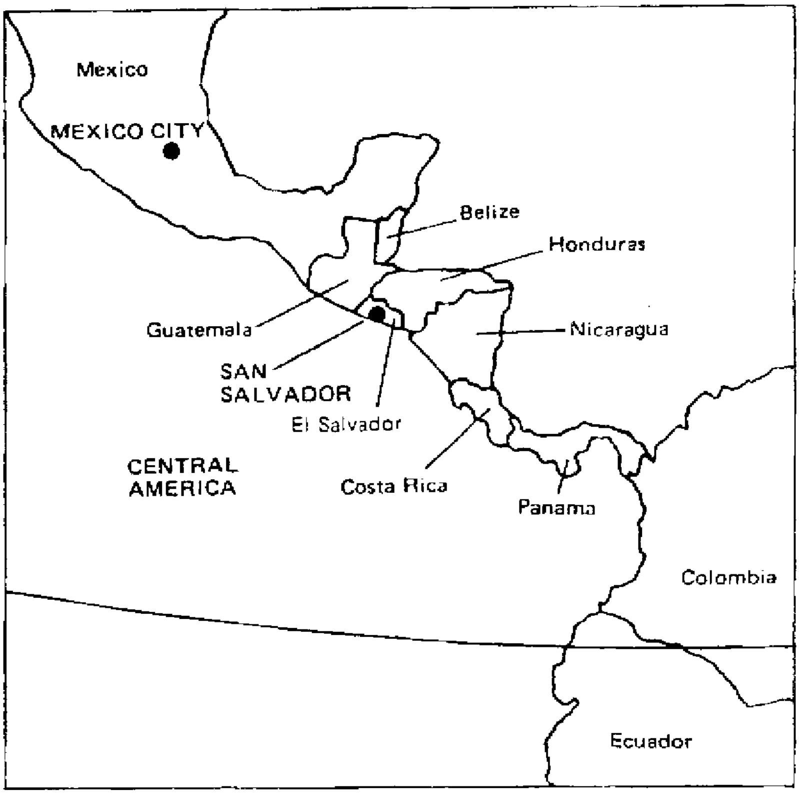

FIG. 1. Central America, showing the locations of San Salvador and Mexico City.

measures in the workplace. However, neither the Code nor any of the sets of regulations derived from it makes any provisions for the use of ionizing radiations. Within the Ministry, under the General Directorate for Social Security, there is a Department of Occupational Hygiene and Safety; however, this Department has no expertise in radiological protection.

The Institute of Social Security (ISSS) of El Salvador is an autonomous institution affiliated to the Ministry of Labour and Social Security. One of its main functions is to collect social security payments from employers and employees, and from the proceeds to make social security provisions and to provide health care. In respect of health care, the ISSS runs its own hospitals. After the accident the three injured workers were treated at the Primero de Mayo Hospital of the ISSS in San Salvador. This has both an emergency department and radiotherapy facilities. The ISSS Department for Occupational Hazard Prevention is located on the same premises.

There is no regulatory control of nor any appropriate infrastructure for radiological protection in El Salvador. The country's only resources in this field are two persons in the Department of Nuclear Medicine of the Rosales Hospital, run by the

Ministry of Health. This 'team', which has no permanent staff and receives no funding, presently consists of a professor of physics at a local university who works unpaid at the Rosales Hospital and a non-technical member of the hospital staff who assists him. Donated equipment is used to provide a personnel monitoring service. However, it may take a long time to effect the repair or replacement of an item of equipment, and this monitoring service is intermittent.

In 1986 the IAEA funded the visit of an expert to El Salvador to help in the drafting of proposals for the regulatory control of sources of ionizing radiations. Owing to the civil war, the proposals were not given a high priority in the regulatory programme. Nevertheless, some enabling provisions were included in Decree 955 of 1988, Articles 191 and 192 of which gave the Ministry of Health the responsibility for controlling the use of radiation sources and the authority to promulgate regulations. At the time of the accident no regulations existed, but new proposals were being drafted.

3. THE IRRADIATION FACILITY

Note: *Observations on factors contributory to the accident are presented in italic script.*

3.1. HISTORY OF THE IRRADIATION FACILITY AND DESCRIPTION OF THE MODEL JS6300 GAMMA STERILIZER

The accident occurred at an industrial irradiation facility near San Salvador, El Salvador, that was built in 1974 and commissioned in 1975. The facility has a Model JS6300 Gamma Sterilizer designed, manufactured and installed by Atomic Energy of Canada Limited, which now trades as Nordion International Inc., hereinafter referred to as 'the supplier'. In irradiators of this design, the product packages to be sterilized are loaded into large product boxes and moved by pneumatic cylinders (pistons) around a centrally located, vertical rectangular source rack. The source rack contains cobalt-60 gamma source elements in the form of rods contained in 'source pencils'. The source is shielded when not in use by lowering it into a pool of water, making it a Category IV irradiator under the international classification[1].

[1] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety Aspects of Gamma and Electron Irradiation Facilities, IAEA, Vienna (in preparation).

The Model JS6300 was designed for relatively small product throughputs, having a maximum source capacity of 9.25 to 18.5 PBq (250 to 500 kCi) using cobalt-60. However, the initial loading of the irradiator was only 4.0 PBq (108 kCi). The source was never replenished, and by the time of the accident its radioactivity had decayed to approximately 0.66 PBq (18 kCi).

The irradiation facility is owned by a company that manufactures intravenous solutions and blood dispersion sets. The sets are sterilized by irradiation or with autoclaves. At the time of commissioning of the facility in 1975 the company was owned by a Mexican–Salvadorian–Costa Rican consortium. Later that year it was sold to a consortium in the United States of America. It returned to Salvadorian ownership in December 1987.

During the facility's building and commissioning stages, the supplier trained three operators in operational and radiological protection aspects. However, these three trained operators left the company after it changed ownership in 1975. From this time onwards any training of operators was informal and oral only.

In 1975 an incident occurred in which the product boxes obstructed the movement of the source rack. The rack was deformed, allowing the pencils to fall out. However, the installed safety systems and the operators' training were sufficient to prevent any occupational exposure. The supplier was informed and sent staff to the plant to effect repairs.

The civil war in El Salvador has exacerbated the economic problems of the country, engendering a 'make do and mend' attitude at the plant, as elsewhere. One result of this was that the company did not seek to replenish the source material within the normal time period. Eventually, in 1981, the owner of the plant negotiated with the supplier for the replenishment of the source. A representative of the supplier travelled to San Salvador, only to turn back at the airport in consequence of the escalating civil war. In 1982 and 1984, the owner of the plant again communicated with the supplier about replenishing the source. However, because of the security situation, the supplier did not send a representative to El Salvador. The owner of the plant had kept up telephone contact with the supplier over the fourteen years since 1975. However, the facility had not had the benefit of the radiological safety audits that normally accompany any replenishment of the source by the supplier.

The key factors from the description here and in Section 2 are that over the fourteen year period from 1975:

(a) *there was no regulatory control of radiological protection matters nor any readily available expertise in El Salvador;*

(b) *operators trained by the supplier of the irradiator had left at an early stage and subsequent training was only oral and informal;*

(c) *there was no direct access other than by telephone to the supplier and the supplier's radiological expertise.*

One result of these shortcomings was a serious loss of understanding over the years of the functions of the installed safety systems and of what was important for radiological safety. The remainder of this section describes the facility and its operation at the time of commissioning and at the time of the accident. For clarity, the changes are shown in italic type. To supplement the description in the text of the design and layout of the facility, three detailed drawings have been included at the end of the report. (Figs 2–4: *see inside back cover.*)

3.2. THE RADIOACTIVE SOURCE

Radioactive cobalt-60 metal is the radiation source in the JS6300 Gamma Sterilizer. The cobalt-60 source elements are contained in doubly encapsulated stainless steel source pencils approximately 45 cm long, with solid stainless steel end caps approximately 1 cm in diameter (see Fig. 5). Each source pencil is identified by a

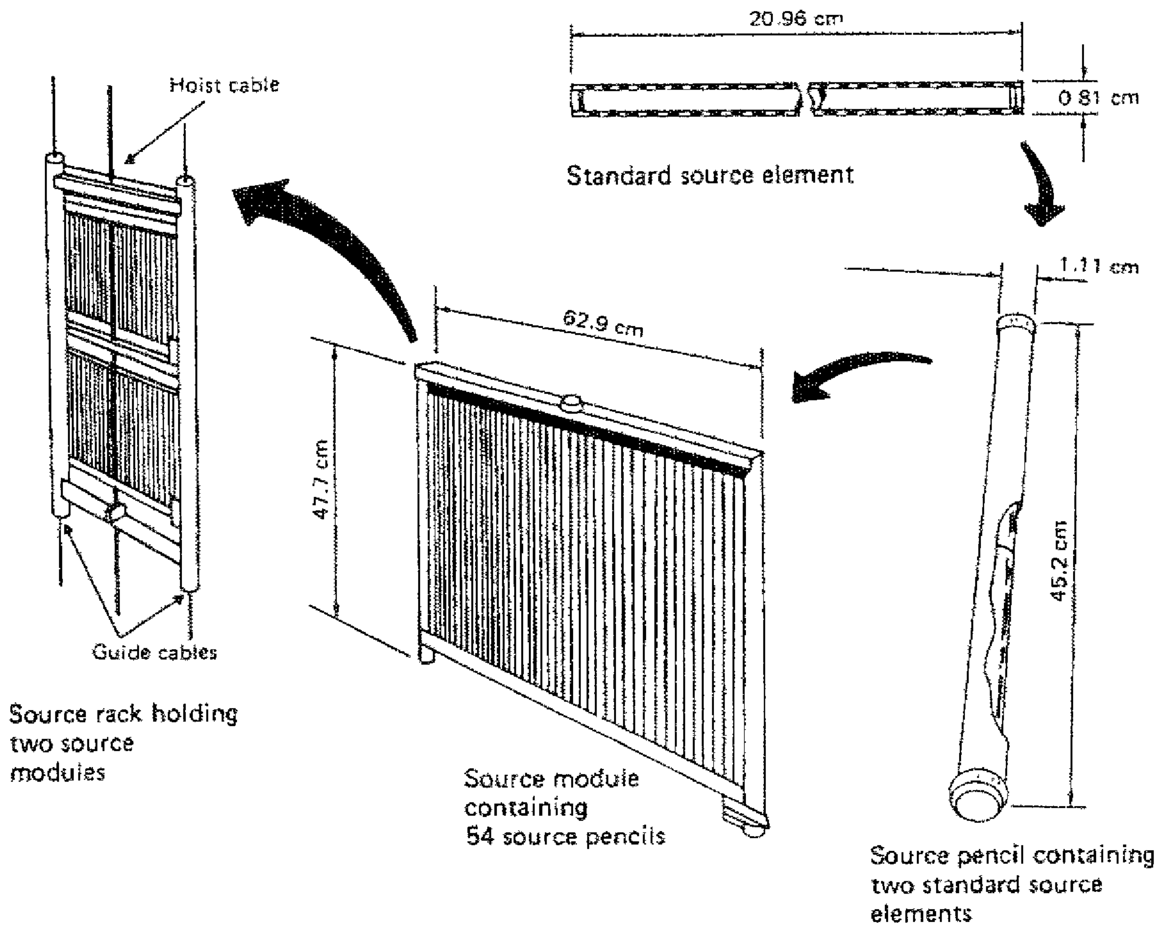

FIG. 5. The source rack with two source modules, each containing up to 54 source pencils with two standard source elements in each pencil. (By courtesy of Nordion International Inc.)

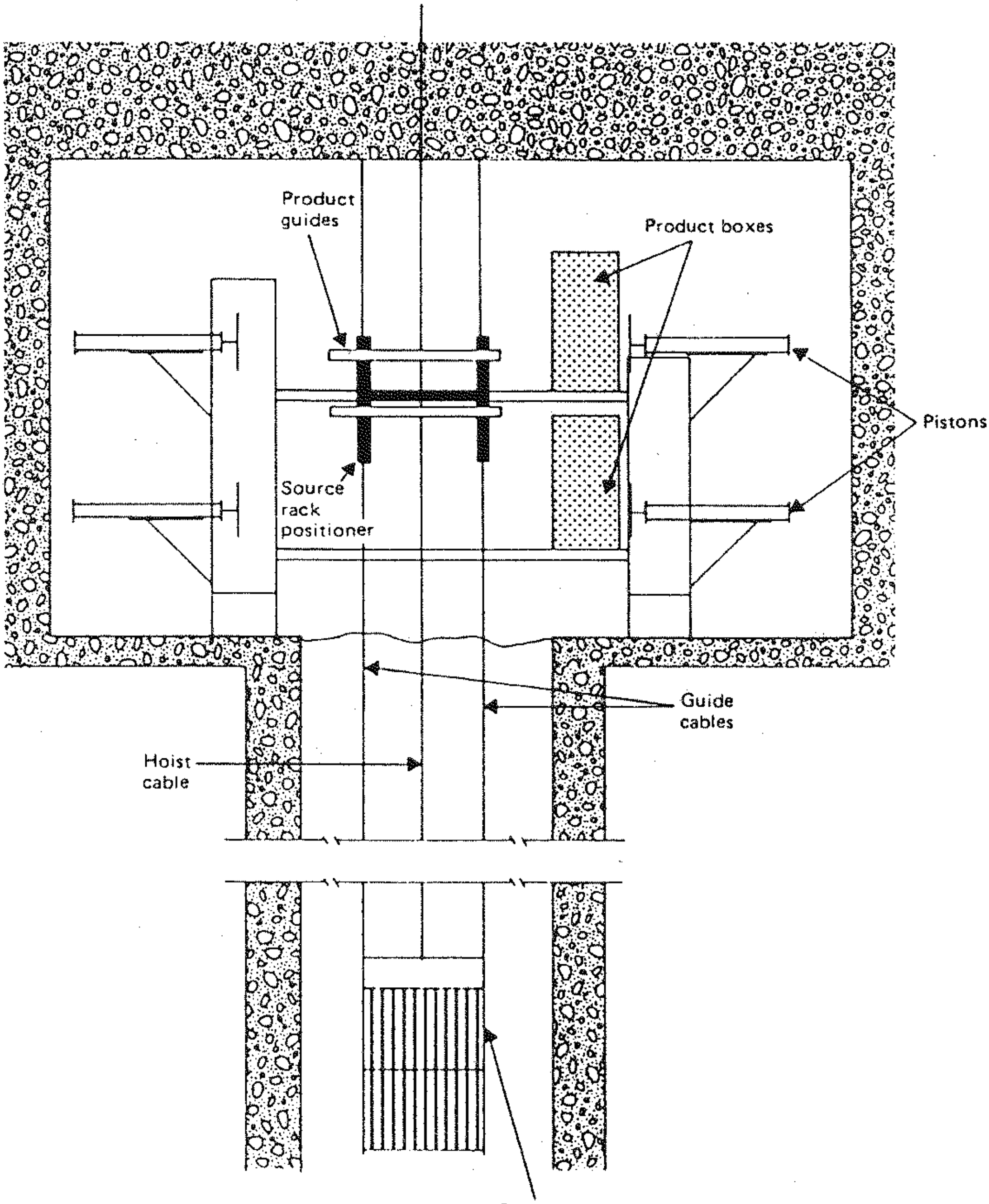

FIG. 6. Cross-sectional diagram of the source rack, hoist mechanism and transport mechanism. (By courtesy of Nordion International Inc.)

serial number engraved on an end cap. Fourteen active source pencils and 40 inactive dummy pencils (stainless steel spacer rods) were loaded into each of two source modules. The source pencils and dummy pencils are held in place in channels at the top and bottom of the source modules. The two source modules are placed one above the other in a flat, vertical source rack to give a uniform radioactivity over an area approximately 0.60 m by 0.90 m. When the source was installed in June 1975 the total radioactivity of the cobalt-60 gamma source was 4.0 PBq (108 kCi). By the time of the accident (5 February 1989) its radioactivity had declined to 0.66 PBq (18 kCi).

3.3. THE SOURCE HOIST MECHANISM

The source rack, when not in use, is stored near the bottom of a 5.5 m deep storage water pool and is raised to the irradiation position by a pneumatic hoist mounted on the roof of the facility above the radiation shield (see Figs 3 and 4). A stainless steel hoist cable attached to the source rack passes through the shield and the roof to two sets of sheaves in the hoist cylinder. When air pressure is applied to the hoist, the sheaves separate and the source rack is lifted. The movement of the source rack is guided by two taut guide cables, one at each end of the rack. In the raised position the source rack (see Fig. 6) actuates a microswitch to indicate that the source is up.

When air is exhausted from the source hoist, the source rack is returned under gravity to the safe storage position in the water pool. The weight of the source rack pulls the sheaves in the hoist cylinder back together, deactuating a microswitch mounted on the hoist cylinder to indicate that the source is down.

3.4. THE PRODUCT TRANSPORT MECHANISM

In the JS6300 irradiator, the products to be sterilized are loaded into fibreglass product boxes 0.40 m square and 0.90 m high. These boxes on stainless steel trays are irradiated in 29 positions, between which they are moved by pistons of the product transport mechanism (see Fig. 7). The boxes are moved backwards and forwards past the source rack along four rows, two on each side of the source rack, on each of two levels (shown schematically in Fig. 8), and are raised from the lower to the upper level by a pneumatic elevator. Steel product guides restrict the movement of the boxes to the path around the source and provide some protection to the source rack. Limit switches monitor the locations of the boxes and control the sequence of operation of the pistons.

The length of time for which a product box remains in each irradiation position (by 5 February 1989, the day of the accident, this had been increased to 140 min) is controlled by a master timer. When the time set on the master timer has elapsed,