

TECHNICAL REPORT

VERIFICATIONS UNDER THE TERMS OF ARTICLE 35 OF THE EURATOM TREATY

Institute of Isotopes, Budapest HUNGARY

6 to 8 March 2012



Reference: HU-12/01

VERIFICATIONS UNDER THE TERMS OF ARTICLE 35 OF THE EURATOM TREATY

FACILITIES: Institute of Isotopes Ltd. in Budapest and parts of the national monitoring

system concerned by the accidental release of I-131 in 2011

DATE: 6 - 8 March 2012

REFERENCE: HU-12/01

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DATE OF REPORT: 16 October 2012

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1 ABBREVIATIONS AND ACRONYMS

BUTE Budapest University of Technology and Economics

CAO FFSD Central Agricultural Office, Food and Feed Safety Directorate
HAS CER Hungarian Academy of Sciences Centre for Energy Research

CRL / NRIRR Central Radiohygiene Laboratory (part of NRIRR)

cpm counts per minute EC European Commission

ECURIE European Community Urgent Radiological Information Exchange

ENER Directorate General Energy of the European Commission

ERO Emergency Response Organisation (of HAEA)

FPP Fine Particle Processing (filter)

Ge(Li) Germanium Lithium-drifted (radiation detector)

GM Geiger Müller (radiation detector)
GMP Good Manufacturing Practice

GOCCB Government Office of the Capital City Budapest (Budapest Főváros

Kormányhivatala in Hungarian)

HAEA Hungarian Atomic Energy Authority (*OAH* in Hungarian)

HAKSER HAtósági Környezeti Sugárvédelmi Ellenőrző Rendszer (JERMS in

English)

HAS Hungarian Academy of Sciences
HEPA High-Efficiency Particulate Air (filter)
HPGe Hyper Pure Germanium (radiation detector)
IAEA International Atomic Energy Agency

ICRP International Commission on Radiological Protection

INT Institute of Nuclear Techniques

IoI Institute of Isotopes Ltd

ISFS Interim Spent Fuel Store at Paks under PURAM ISO International Organization for Standardization

JERMS Joint Environmental Radiation Monitoring System (HAKSER in

Hungarian)

KFKI Hungarian Academy of Sciences KFKI Atomic Energy Research

Institute (AEKI in Hungarian)

LAN Local Area Network
LLD Lower Limit of Detection

LSC Liquid Scintillation Counting/Counter (radiation detection)

MD Ministry of Defense

MDVIEP Middle-Danube-Valley Inspectorate for Environmental Protection,

Nature Conservation and Water Management

MI Ministry of Interior

MHR Ministry of Human Resources

MHS-ES-REWMS Radiation Early Warning, Monitoring and Surveillance System of the

Ministry of Human Resources / Education Sector

MND Ministry of National Development MRD Ministry of Rural Development

MRD/AFS Ministry of Rural Development / Agriculture and Food Sector

MSEA Minister of State for Environmental Affairs

MSH Minister of State for Health

NaI(Tl) Sodium iodide thallium activated (radiation detector)
NDGDM National Directorate General for Disaster Management
NEIAC Nuclear Emergency Information and Analysis Center

NERMS National Environmental Radiation Monitoring System (OKSER in

Hungarian)

NPHMOS National Public Health and Medical Officer Service (*OTH* in Hungarian) NPHMS National Public Health and Medical Service (*NSZSZ* in Hungarian)

NPP Nuclear Power Plant

NREWMS National Radiation Early Warning, Monitoring and Surveillance System NRIRR "Frédéric Joliot-Curie" National Research Institute for Radiobiology and

Radiohygiene (OSSKI in Hungarian)

NRWR National Radioactive Waste Repository under PURAM

NSZSZ Népegészségügyi Szakigazgatási Szerv (NPHMS in English)

OCMO Office of Chief Medical Officer of NPHMOS

OSSKI Országos Frédéric Joliot-Curie Sugárbiológiai és Sugáregészségügyi

Kutató Intézet (NRIRR in English)

PC-CREAM Consequences of Releases to the Environment: Assessment

Methodology; PC version

PERMS NPP Paks Plant Environmental Radiation Monitoring System (ÜKSER

in Hungarian)

PET/CT Positron Emission Tomography – Computed Tomography
PIPS Passivated Implanted Planar Silicon (radiation detection)
PURAM Public Limited Company for Radioactive Waste Management
RAMDAN Radiological Monitoring and Data Acquisition Network (ERMAH in

Hungarian)

RC Radiohygiene Centre

RMN Radioanalytical Monitoring Network of the MRD

RODOS Real-time On-line DecisiOn Support RRL Radioanalytical Reference Laboratory

RWTDF Radioactive Waste Treatment and Disposal Facility in Püspökszilágy

under PURAM

SPECT Single-Photon Emission Computed Tomography

STIENW South Transdanubian Inspectorate for Environment, Nature and Water

TEDA Tri Ethylene Di-Amin (filter)

TLD ThermoLuminescent Dosimetry (radiation detection)

2 INTRODUCTION

Article 35 of the Euratom Treaty requires that each Member State establish the facilities necessary to carry out continuous monitoring of the levels of radioactivity in air, water and soil and to ensure compliance with the Basic Safety Standards¹.

Article 35 also gives the European Commission (EC) the right of access to such facilities in order that it may verify their operation and efficiency.

For the EC, the Directorate-General for Energy (DG ENER), and in particular its Radiation Protection Unit (ENER D.3, at the time of the visit ENER D.4), is responsible for undertaking these verifications.

The main purpose of verifications performed under Article 35 of the Euratom Treaty is to provide an independent assessment of the adequacy of monitoring facilities for:

- Liquid and airborne discharges of radioactivity into the environment by a site (and control thereof).
- Levels of environmental radioactivity at the site perimeter and in the marine, terrestrial and aquatic environment around the site, for all relevant pathways.
- Levels of environmental radioactivity on the territory of the Member State.

In autumn 2011 several monitoring laboratories in EU Member States detected elevated levels of iodine-131 in air that could not be explained by local sources. By applying back-trajectory calculations the source of the contamination could be narrowed to eastern Central Europe. The IAEA was informed and distributed the information. Consequently, Hungary confirmed releases by the Hungarian radioisotope production firm Institute of Isotopes Ltd., Budapest; however, the annual release limit was not surpassed. Although the health consequences for the population (both, in the Budapest area and outside Hungary) can be seen as marginal the event showed 'weaknesses' in communication.

Thus, from 6 to 8 March 2012 a team of three inspectors from DG ENER D.4 visited the site and adjacent areas in order to obtain full information from the operator and from the regulatory authority about the event and the lessons learned. The visit also included verification of the operator's facilities for monitoring liquid discharges, as well as the sampling site for radionuclides in air at the *Országos "Frédéric Joliot-Curie" Sugárbiológiai és Sugáregészségügyi Kutató Intézet (OSSKI*; "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene - NRIRR) in Budapest that forms part of the Hungarian National Environmental Radioactivity Monitoring System (NERMS).

The present report contains the results of the discussions with the operator, measuring laboratory staff and the relevant Hungarian authorities involved in regulatory and control tasks, in particular the Hungarian Atomic Energy Agency (HAEA), as well as results of the verification team's review of some aspects of the environmental surveillance on and around the site in relation to the radiological event. The purpose of the review was to provide full information both from the operator and from the regulator concerning the event and the investigations and countermeasures put in place till now. Monitoring equipment related to the event was verified as well. The verification team witnessed also the production site and received a presentation of improved production methods that are currently being tested.

With regard to general radiological and environmental radioactivity and discharge monitoring aspects the present report is also based on information collected during the 2010 verification in Hungary However, the report does not go into the details of such monitoring as far as it was not verified during this visit.

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Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L-159 of 29/06/1996)

3 PREPARATION AND EXECUTION OF THE VERIFICATION

3.1 PREAMBLE

The Commission's request to execute an Article 35 verification was notified to the Hungarian Permanent Representation to the European Union by letter ENER.D.4 CG/es 6683 dated 4 January 2012.

Subsequently, practical arrangements for the implementation of the verification were made through contacts with the Hungarian Atomic Energy Authority (HAEA).

3.2 PROGRAMME OF THE VISIT

A preliminary programme of verification activities under the terms of Article 35 of the Euratom Treaty was discussed and agreed upon with the Hungarian competent authorities.

The programme encompassed verifications of the radioactive discharges from the Institute of Isotopes in 2011 and 2012 and of selected parts of the Hungarian national environmental radioactivity monitoring programme.

The aim of the verification was to check the operation and efficiency of the facilities for continuous monitoring of the level of radioactivity in air, water and soil at and around the Institute of Isotopes Ltd., including the monitoring of aerial and liquid radioactive discharges into the environment from the institute. The verification activities also encompassed the laboratories in charge of the relevant analyses to be performed in this context, in so far as they were not the object of a verification visit in 2010.

An important part of the programme dealt with verifying the investigations, and the measures taken with a view to avoid similar events in the future (technical and administrative). In particular, the verification touched on communication paths and procedures, in order to see if appropriate improvements were put in place or foreseen. All practical arrangements for the implementation of this mission were made with the designated persons at the HAEA.

The verifications were carried out in accordance with the programme, a summary overview of which is attached as Appendix 1 to this report.

3.3 DOCUMENTATION

In order to facilitate the work of the verification team, a package of information was supplied in advance by the Hungarian authorities. Additional documentation was provided during the visit. All documentation received is listed in Appendix 2. The verification team notes the comprehensiveness of the documentation provided. The information thus provided has been extensively used for drawing up the descriptive sections of this report.

3.4 REPRESENTATIVES OF THE COMPETENT AUTHORITIES AND OTHER BODIES

During the verification visit, the following representatives were met:

Hungarian Atomic Energy Authority (HAEA)

Dr. József RÓNAKY Director General

Dr. László KOBLINGER Deputy Director General

Dr. Árpád VINCZE Deputy Head of Dept. of Nuclear and Radiological Materials

Euratom Art. 35-36 coordinator

Zoltán LENGYEL Head of the EU Coordination Department

Dr. Judit SILYE EU Coordinator (EU Coordination Department

"Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene (NRIRR), OSSKI

Dr. Géza SÁFRÁNY Director General

Gyula SZABÓ Head of Division of Public and Environmental Radiohygiene Nándor FÜLÖP Head of Department of Radiohygiene I. Ionizing Radiation

László Béla JUHÁSZ Head of Division of Occupational Radiohygine

Zsolt HOMOKI Researcher Division of Public and Environmental Radiohygiene Ágota UGRON Researcher Division of Public and Environmental Radiohygiene Júlia KÖVENDINÉ KÓNYI Researcher Division of Public and Environmental Radiohygiene

Dr. Lajos BALGH Deputy Director

NPHMOS, Office of Chief Medical Officer (OCMO)

Márta KOVÁCS Head of Department of Public Health

GOCCB (Governmet Office of the Capital City Budapest) PHA (Public Health Administration)

Dr. Attila POLGÁR Head of Radiohygiene Centre

Benedek JOBBÁGY Head of Laboratory

Gábor WINDISCH Physicist

Ministry of the Interior, NDGDM

Dr. Gyula VASS

Head of Department for Dangerous Establishments

Eszter TASKÓ-SZILÁGY

Head of Section for Nuclear Emergency Management

Anita SZEITZ

Analyst, Section for Nuclear Emergency Management

Hungarian Academy of Sciences (HAS)

Zsolt BÁCSI

Hungarian Academy of Sciences Centre for Energy Research (HAS CER)

István VIDOVSZKY expert

<u>Middle-Danube-Valley Inspectorate for Environmental Protection, Nature Conservation and Water Management (KDVKTVF)</u>

Eszter DOLLA Director

Dr. István HUNYU Legal Director

Károly LUKÁCS Department of Complex Environmental Protection

Beáta VARGA expert

South Transdanubian Inspectorate for Environmental Protection, Nature Conservation and Water

Management

Péter VANCSURA expert

Budapest University of Technology and Economics (BUTE)

Dr. Gyorgy PÁTZAY expert

Institute of Isotopes Co., Ltd. (IoI)

Mihály LAKATOS Chief Executive Officer

Lajos TYUKODI Chief Engineer

József KÖRNYEI Director of Research

HAS CER Environmental Monitoring Laboratory

Anikó FÖLDI Head of Laboratory

Péter ZAGYVAI researcher
András KOCSONYA researcher

4 LEGISLATION AND COMPETENT AUTHORITIES

4.1 Primary Legislation and Derived Regulations

4.1.1 Act on Atomic Energy

Nuclear legislation in Hungary is based on the Act on Atomic Energy (Act CXVI 1996) that came into force on 1 June 1997. The Act on Atomic Energy (hereafter referred to as the Act) establishes the basis for the development of a legislative and regulatory system for the safe application of nuclear energy. The Act specifies that the tasks of control and surveillance of the safe application of nuclear energy are the responsibility of the Government.

The Act stipulates that atomic energy can only be used in ways identified by (derived) legal instruments (government and ministerial decrees) and shall be subject to regular supervision by the designated competent authorities. The Act can be downloaded from the HAEA web site (www.haea.gov.hu).

The Act names the following ministers as having major responsibilities (updated to the current political structure):

- The Minister of State for Health (MSH) in the Ministry of Human Resources (MHR) through his National Public Health and Medical Officer Service (NPHMOS) and regional offices located at Government Offices is the national Radiation Protection Authority. The NPHMOS is responsible for inter alia defining dose constraints and carrying out the central collection, processing, recording and evaluation of data related to the national radiation situation (centralisation of the data of the various Hungarian environmental monitoring programmes).
- The Minister of State for Environmental Affairs (MSEA) in the Ministry of Rural Development (MRD) is responsible for inter alia defining the maximum quantity of radioactive materials that may be released to the atmosphere and into water bodies (discharge limits).
- The Minister of State for Food Chain Control Supervision and Agricultural Administration in the Ministry of Rural Development (MRD) is responsible for the inspection of radioactivity in soil, flora, fauna and products of both vegetable and animal origin.

Other ministers and organisations that participate in radiological protection are: the Minister of Interior (particularly with respect to matters of early warning and emergency preparedness in case of radiological incidents), the Minister for National Development, the Minister of Defence, the State Minister of Education within the Ministry of Human Resources, and the Hungarian Mining Office.

4.1.2 Decree of the Minister of Health No. 16/2000 (VI.8)

The Decree of the Minister of Health 16/2000 (VI.8) on the implementation of the provisions of the Act CXVI of 1996 on Atomic Energy introduces basic standards in accordance with international references such as the publication ICRP 60 (International Commission on Radiological Protection) and the IAEA SS-115 (safety standards) and transposes Council Directive 96/29/Euratom into national law. This Decree lays down the basis for radiation protection in Hungary. The competent authority is the National Public Health and Medical Service (NPHMS).

4.2 Environmental radioactivity and foodstuff monitoring

4.2.1 Act CXVI (1996) on Atomic Energy

Article 23 of the Act CXVI (1996) on Atomic Energy requires the minister competent for agriculture to be responsible for controlling the radioactivity in soil, the minister responsible for the food-chain to be responsible for controlling radioactivity in animals, plants and in foodstuffs of animal and non-animal origin, as well as for expert work and for the inspection activity regarding international trade of these products and for issuing certificates.

4.2.2 Act XLVI (2 July 2008)

Act XLVI (2 July 2008) on Food-chain and Its Official Control names the Ministry of Rural Development as responsible for controlling of the food chain.

4.2.3 Governmental Decree No. 274/2006. (XII. 23.)

According to Governmental Decree No. 274/2006. (XII. 23.) on Establishing the Agricultural Office, in compliance with EU legislation 882/2004/EC Article 12, any kind of analysis regarding foodstuffs could be carried out only in dedicated, accredited laboratories.

4.2.4 Governmental Decree No. 275/2002 (XII.21)

The Governmental Decree No. 275/2002 (XII.21) on the monitoring of the national environmental radiation situation and levels of radioactivity describes the legal background and principles of operation of the National Environmental Radiation Monitoring System (NERMS). It defines the structure of the monitoring systems and networks as well as the monitoring and reporting requirements. The decree also stipulates that the radiological surveillance of the food chain for human consumption be within the scope of the monitoring. The national environmental monitoring shall be organised by a steering committee comprising members of all ministries and/or organisations involved and shall be chaired by the HAEA. The decree requires the NRIRR to operate the Information Centre for data collection and evaluation of the system.

This Decree also requires to establish monitoring systems around special installations (e.g. nuclear power plants, training and research reactors, nuclear waste management facilities, grade-A isotope laboratories, etc.); according to this requirement, a separate Joint Environmental Radiation Monitoring System JERMS; (in Hungarian: *HAtósági Környezeti Sugárvédelmi Ellenőrző Rendszer - HAKSER*) is operated within a 30 km radius around the Paks NPP.

4.2.5 Decree of the Minister of Health No. 8/2002 (III.12)

The Decree of the Minister of Health 8/2002 (III.12) on the operation and structure of the RAdiological Monitoring and Data Acquisition Network of the health sector (RAMDAN; in Hungarian: *Egészségügyi Radiológiai Mérő és Adatszolgáltató Hálózat – ERMAH*) describes its legal background and principles of operation. The sampling/monitoring programme focuses on air, surface waters, soil, drinking water, essential components of the food chain for human consumption and the most representative foodstuffs (either from domestic production or imported) consumed by the population. Analytical procedures performed are mainly of gross beta and gamma spectrometric nature. The results are published annually in the "*Egészségtudomány*" (Health Science) journal.

4.3 LEGISLATIVE ACTS REGULATING DISCHARGE MONITORING

4.3.1 Decree of the Minister of Environment and Water No. 15/2001 (VI.6)

The Decree of the Minister of Environment and Water No. 15/2001 (VI.6) on discharges of airborne and liquid radioactivity and their monitoring when using atomic energy (now: Minister of State for Environmental Affairs in the Ministry of Rural Development) specifies that the user of nuclear energy (i.e. the NPP Paks) shall derive its annual limits of discharge of radioactive effluent in accordance with the

methodology (based on dose constraint) as specified by the National Public Health and Medical Officer Service (NPHMOS) of the Health Sector.

This Decree requires the Regional Environmental Inspectorates of the former Ministry of Environment and Water to establish environmental monitoring programmes for special facilities (nuclear power reactors, research reactors, training reactors, uranium mines, radioactive waste depositories, A-level isotope laboratories, interim spent-fuel storage and other areas).

Nuclide specific measuring methods have to be applied to determine activity concentrations in environmental samples. Gross-beta measurement results may only be used for trending purposes. Detection limits shall correspond to international and national quality levels. Only accredited laboratories can be used for regulatory inspection purposes.

4.4 COMPETENT AUTHORITIES

Environmental radioactivity monitoring in Hungary is complex due to the involvement of many ministries with their specific responsibilities and scopes of monitoring programmes.

The National Environmental Radiation Monitoring System (NERMS) currently consists of the following members representing different ministries, authorities and special installations as regulated by the Government Decree 275/2002 (XII.21):

- Ministry of Human Resources (MHR)
- Ministry of Rural Development (MRD)
- Ministry of National Development (MND)
- Ministry of Defence (MD)
- Ministry of Interior (MI)
- Hungarian Academy of Sciences
- Hungarian Atomic Energy Authority (HAEA)
- Nuclear Power Plant Paks (NPP Paks)
- Public Limited Company for Radioactive Waste Management (PURAM)

The activity of NERMS is governed by the NERMS Steering Committee and chaired by the Hungarian Atomic Energy Authority (HAEA). The NERMS Steering Committee approves the annual environmental sampling and measuring programme to be performed by the radiological monitoring networks belonging to the NERMS Members. NERMS Information Centre collects and processes the radiological data measured by the individual monitoring networks, and prepares the annual reports from the results.

The National Public Health and Medical Officer Service (NPHMOS) works under the State Minister of Health and is responsible for carrying out the central collection, processing, recording and evaluation of data related to the national radiation situation (centralisation of the data of the various Hungarian environmental monitoring programmes). Its expert institute is the "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene (NRIRR). NPHMOS operates its own monitoring network RAMDAN.

The Radioanalytical Monitoring Network under the responsibility of Ministry of Rural Development (RMN of MRD) works under the umbrella of the Central Agricultural Office (CAO) and the Agricultural Offices of eight counties. The responsibility of the network covers the whole food-chain, including radiological surveillance of food and feed stuffs and surveys connected to the safety of agricultural production. Radioanalytical Reference Laboratory (RRL) of CAO FFSD is responsible for the harmonised methods and database, the quality assurance in the network level and the training of the staff. The nuclide selective methods have priority in the network, alpha-, beta- and gamma-spectrometry often combined with chemical separation. RRL operates a mobile laboratory capable for route monitoring, in-situ and sample measurement by gamma spectrometry.

The environmental inspectorates under the Ministry of Rural Development perform measurements as part of NERMS. Data collected by the inspectorates are integrated and processed to NERMS by the information centre of a designated regional inspectorate, the South Transdanubian Inspectorate for Environment, Nature and Water (STIENW). The inspectorates perform gross-beta measurements of surface waters and sediments. In addition STIENW measures activity concentration of H-3, Sr-90 and gamma-emitting nuclides in surface waters, sediments, fish and algae (except Sr-90 for the latter).

At the Hungarian Academy of Sciences KFKI Atomic Energy Research Institute (KFKI AEKI) campus, the Budapest Research reactor and the Institute of Isotopes Co. Ltd. producing a wide variety of radioactive isotopes are in operation. An environmental monitoring station has been installed to monitor the ambient dose rate and the air contamination. The station is run by the Environmental Protection Service. The measured data is submitted to NERMS. For emergency situations a mobile laboratory is also in service.

For training purposes, since 1971 the Institute of Nuclear Techniques (INT) of the Budapest University of Technology and Economics (BUTE) of the Ministry of Human Resources / Education Sector operates a small pool-type nuclear training reactor. An environmental monitoring system is operated using both continuous and discrete measuring and data collection devices. INT also serves as the data centre for 13 ambient gamma-dose rate measuring stations belonging to the Radiation Early Warning, Monitoring and Surveillance System of the Ministry of Human Resources / Education Sector (MHS-ES-REWMS). The measured data are submitted to NERMS. These stations are also part of the National Radiation Early Warning, Monitoring and Surveillance System (NREWMS).

The National Directorate General for Disaster Management (NDGDM) works under the Ministry of Interior It is the centre of the National Radiation Early Warning, Monitoring and Surveillance System (NREWMS).

The NDGDM Nuclear Emergency Information an Analysis Center (NEIAC) and the HAEA Emergency Response Organization (ERO) are responsible for analysing the situation and predicting the possible consequences of a nuclear and radiological emergency. In case of a nuclear or radiological accident it is the responsibility of the NDGDM NEIAC and the HAEA ERO to give advice to the decision makers on both technology and radiation related issues. As part of the National Nuclear Emergency Response System, NERMS is used to gather information on radiation appearing on the territory of Hungary. HAEA is the international contact point for receiving and sending notifications in any nuclear or radiological emergency at both national and international levels.

The Ministries of Health, of Agriculture and of the Environment, with their independent site-related monitoring systems around the Paks NPP, established the Joint Environmental Radiation Monitoring System (JERMS). The Paks NPP also participates in JERMS by providing its own environmental data. The Plant Environmental Radiation Monitoring System PERMS is the statutory monitoring programme that is implemented by the Paks NPP.

The Public Limited Company for Radioactive Waste Management (PURAM) has three facilities for the short term and long-term storage of radioactive wastes and nuclear fuels, the Radioactive Waste Processing and Disposal Facility (RWTDF) at Püspökszilágy for the disposal of radioactive waste from hospitals etc., the National Radioactive Waste Repository (NRWR) at Bátaapáti for the final disposal of low- and intermediate-level wastes of nuclear power plant origin, and the Interim Spent Fuel Store (ISFS) at Paks for the safe interim storage of the spent fuel assemblies from the nuclear power plant, for a period of 50 years, which is required for technical reasons before disposal. The environmental monitoring data (aerosol, fall-out, soil and plants) of the Radioactive Waste Treatment and Disposal Facility (RWTDF) in Püspökszilágy, and that of the National Radioactive Waste Repository (NRWR) in Bátaapáti is integrated into NERMS. The ISFS and the Paks Nuclear Power Plant are located directly next to each other, therefore the environment monitoring system of the ISFS has been integrated to the system of the nuclear power plant.

All of the Ministries and organisations which constitute the NERMS have some responsibilities in their own field regarding the radiological emergency preparedness according to the National Nuclear Emergency Preparedness Plan as regulated by the Governmental Decree 248/1997 (XII.20) on the National Nuclear Emergency Response System.

4.5 OVERVIEW OF THE ORGANIZATIONAL INFRASTRUCTURE AND FUNCTIONALITY OF THE HEALTH SECTOR AUTHORITY

The particular issues addressed to the Ministry of Human Resources / Health Sector by the current laws and regulations associated with the application of atomic energy and protection against ionising radiation, are delegated to NPHMOS, which maintains the following organizations:

- Office of Chief Medical Officer (OCMO) of the NPHMOS higher authority;
- Radiohygiene Centres (RC) territorial authorities (in cities: Győr, Szekszárd, Budapest, Miskolc, Szeged, Veszprém and Debrecen);
- NRIRR central (national) background institution to support (in Budapest).

From a practical viewpoint and a historical basis, the tasks are grouped and split into three main areas:

- practical tasks to be performed as an authority;
- routine tasks associated with environmental radiological monitoring;
- scientific research and professional support to facilitate and help the legislation, the routine work, and provide the theoretical background for irregular cases.

The practical tasks are delegated to

- RCs as first level authorities;
- OCMO itself, as a higher authority;

while the background support function is delegated to

NRIRR.

The environmental radiological monitoring duties are shared among:

- RCs and
- NRIRR.

The 1st level and higher authority functions – e.g. licensing, inspection, recording etc. – covers the tasks defined in Decree of Minister of Health No. 44/2009. Until 2010, the RCs have been governed by the NPHMOS.

Although the situation of RCs related to their daily operation and financing has been changed according to the Governmental Decree No. 362/2010, they belong to the territorial Government Offices, and NPHMOS co-ordinates the RCs related to their functions summarized above.

NRIRR has no entitlement related to any authority tasks: it provides the general background activity for RCs and NPHMOS, to support their decisions related to specific problems raised due to application of atomic energy and protection against ionising radiation addressed to the Health Sector.

4.5.1 Territorial RCs

The tasks of territorial RCs, as radiohygiene authorities are defined by Decree of the Minister of Health No. 16/2000. The territorial RCs are responsible for radiation protection. Their obligation lies in licensing, supervising and control of workplaces and radiation sources, according to the basic radiation protection regulations.

The tasks related to environmental radiological monitoring are declared by the Decree of the Minister of Health No. 8/2022. According to this Decree, the RCs maintain the territorial laboratories of RAMDAN (see Chapter 5.5.1).

4.5.2 Office of the Chief Medical Officer

The Office of the Chief Medical Officer (OCMO) first of all acts as higher level authority, and in particular cases acts as first level authority. For example, OCMO issues licenses on the first level for the production and distribution of radioactive materials. OCMO as 2nd level authority provides territorial extension of the scope of licenses beyond the territory of competence of the RC on the request of the licensee.

4.5.3 NRIRR

The NRIRR is the basic expert institution for the whole national radio-hygiene system, in the field of occupational radiohygiene.

Taking part in the occupational radiation protection work of the competent authority network as an expert institute and the harmonisation of their activity is the most important, central task of the NRIRR. In general, the product of this activity is an expert opinion, which serves as the basis for the competent authority's decision. The compilation of an expert opinion or report has generally needed on the spot survey, on the spot radiation protection measurements, and countermeasures as well.

Related to radiological monitoring, NRIRR takes responsibility for the maintenance of CRL of RAMDAN, Information Centre of RAMDAN, JERMS and NERMS.

4.6 INTERNATIONAL LEGISLATION AND GUIDANCE DOCUMENTS

- Commission Recommendation of 8 June 2000 on the application of Article 36 of the EURATOM
 Treaty concerning the monitoring of the levels of radioactivity in the environment for the purpose of
 assessing the exposure of the population as a whole, 2000/473/EURATOM.
- IAEA TRS 295: Measurement of radionuclides in food and the environment: A guidebook
- IAEA TECDOC 1092: Generic Procedures for Monitoring in a Nuclear or Radiological Emergency
- IAEA Safety Series 19 (Pub1103): Generic Models for Use in Assessing the Impact of Discharges of Radioactive Substances to the Environment
- IAEA Safety Guide (Pub1216) RS-G-1.8: Environmental and source monitoring for purposes of radiation protection
- IAEA TRS 472_Handbook of Parameter Values for the Prediction of Radionuclide Transfer in Terrestrial and Freshwater Environments
- IAEA TECDOC 1616: Quantification of Radionuclide Transfer in Terrestrial and Freshwater Environments for Radiological Assessments
- ICRP-SG5: Analysis of the Criteria Used by the International Commission on Radiological Protection to Justify the Setting of Numerical Protection Level Values
- ICRP 103: The 2007 Recommendations of the International Commission on Radiological Protection
- EURACHEM Guide: Quantifying uncertainty
- EURACHEM Guide (2007): Use of uncertainty information in compliance assessment
- IAEA TECDOC 1401: Quantifying uncertainty in nuclear analytical measurements
- ISO 11929-3: Determination of detection limit and decision threshold for ionising radiation measurements Part-3

5 THE NATIONAL ENVIRONMENTAL RADIOACTIVITY MONITORING PROGRAMME

5.1 GENERAL DESCRIPTION

In summary the following monitoring programmes/networks exist that are relevant in the context of Article 35 of the Euratom Treaty:

- The Ministry of Human Resources with its Radiological Monitoring and Data Acquisition Network (RAMDAN).

- Radioanalytical Monitoring Network (RMN) of the Ministry of Rural Development.
- Environmental monitoring program of the Environmental Inspectorates of the Ministry of Rural Development
- Regional environmental monitoring program of the South Transdanubian Inspectorate for Environment, Nature and Water (STIENW)
- The National Radiation Early Warning, Monitoring and Surveillance System (NREWMS) under the National Directorate General for Disaster Management of the Ministry of Interior
- The Ministry of Human Resources, and the Ministry of Rural Development with their independent site-related check monitoring around the Paks NPP, called Joint Environmental Radiation Monitoring System (JERMS). Paks NPP participates in JERMS by providing own environmental data.
- The Paks NPP with its statutory Plant Environmental Radiation Monitoring System (PERMS).

The data from the above mentioned radiological environmental monitoring programmes are centralised in the National Environmental Radiation Monitoring System (NERMS) database.

The Radiological Monitoring and Data Acquisition Network (RAMDAN) covers almost the entire territory of Hungary and monitors air, surface waters, soils, drinking waters, vegetation and the major foodstuffs for human consumption. The frequency of sampling and measuring the samples was defined to obtain the best representative information about the specific situation taking into account the Euratom recommendations. The programme is regularly reviewed and, when deemed necessary, adapted to evolving consumption habits and modifications in the country's agricultural structure. For a detailed description see the Technical Report of the verification in 2010 (HU-10/03).

In order to monitor the ambient gamma dose rate around the Paks Nuclear Power Plant, the NRIRR maintains a separate TLD network, consisting of 40 measuring locations within a radius of 30 km around the power plant. The thermoluminescent detectors (TLDs) are exchanged quarterly, thus the NRIRR gets an image every quarter of the ambient dose rate around the Paks NPP.

The NRIRR monitors the vicinity of the site of the Public Limited Company for Radioactive Waste Management at Püspökszilágy every half year. It measures the gross beta activity and H-3 concentration of surface waters, the gross beta activity of the soil and performs a gamma spectrometric analysis of soil and sediment samples.

The NRIRR performs regular environmental monitoring on its own site, too. It measures the ambient dose rate three times a day (on working days), the gross beta activity of aerosol daily, the gross beta activity of fallout monthly and it performs in-situ gamma spectrometric measurements every half year.

Based on the Hungarian national legislation, the environmental sector is in charge of the radiological control of the aquatic environment, 95% of which is surface water. In addition some samples of sediment, fish and aquatic plants are analysed. The analysis mainly consists of gross beta measurements. Radioactive pollution of surface water is insignificant not only in normal conditions but also in the case of accidents. The continuous monitoring of these surface waters is important however, since most of drinking water is of surface water origin.

In the framework of the National Surface Water Quality Programme, laboratories of the regional inspectorates of the Ministry of Environment and Water continuously perform measurements for gross beta activity concentration. As part of the environmental monitoring programme of the Paks Nuclear Power Plant, the Radiological Laboratory at Pécs regularly measures Cs-137 and Sr-90 activity concentrations in the water taken downstream from the Danube.

The South Transdanubian Inspectorate for Environment, Nature and Water is the authority in charge of monitoring radioactive fallout and environmental effects of the nuclear facilities situated in its jurisdiction (NPP Paks and Interim Spent Fuel Storage Facility). In addition, monitoring the long term environmental effects of the re-cultivated areas of the closed uranium mine handled by Mecsek-Öko Environmental Ltd

have been carried out. In the last two years, the tracing and analysing of radioactive emissions from the health institutions of Pécs has also been started.

The Joint Environmental Radiation Monitoring System (JERMS) was established in 1981, based on a decision of the Hungarian Atomic Energy Commission, to perform a regular and independent radiological monitoring of the environment of the Paks Nuclear Power Plant. The operation of JERMS is regulated by the Government Decree 275/2002 (XII.21).

The following ministries (via their organizations and institutions listed) and the nuclear installation itself are involved in the activities of JERMS:

- Ministry of Human Resources:
 - National Public Health and Medical Officer Service (NPHMOS)
 - "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene (NRIRR)
- Ministry of Rural Development (MRD):
 - o Central Agricultural Office Food and Feed Safety Directorate (CAO FFSD)
 - Radioanalytical Monitoring Network of MRD
 - o South Transdanubian Inspectorate for Environment, Nature and Water
- Hungarian Atomic Energy Authority
- Nuclear Power Plant at Paks

The laboratories of the institutions above collect different environmental samples within a 30 km radius of the NPP. The results of the radiological analyses of the samples collected are sent to the Data Processing and Analyzing Centre of JERMS (operated by NRIRR), in order to process the data and determine the radiation burden of the population living around the NPP.

5.2 THE NATIONAL RADIATION EARLY WARNING MONITORING AND SURVEILLANCE SYSTEM (NREWMS)

In Hungary the National Directorate General for Disaster Management is the centre of the National Radiation Early Warning, Monitoring and Surveillance System (NREWMS).

The NREWMS consists of three subsystems:

- Early Warning Telemetric Network (automatic radiological monitoring stations);
- Fixed Radiological Laboratories;
- Mobile Laboratories.

5.2.1 Early Warning Telemetric Network

The telemetric gamma dose rate monitoring network consists of 132 automatic measuring stations. Six principal bodies provide data for the Telemetric Network of the NREWMS:

- Hungarian Army (40 monitoring stations) Ministry of Defence;
- National Meteorological Service (29 monitoring stations) Ministry of Environment and Water;
- Paks Nuclear Power Plant (20 monitoring stations);
- National Directorate General for Disaster Management (26 monitoring stations);
- Ministry of Education and Culture (13 monitoring stations);
- Public Limited Company for Radioactive Waste Management (4 monitoring stations).

The locations of these stations are shown in figure 1.

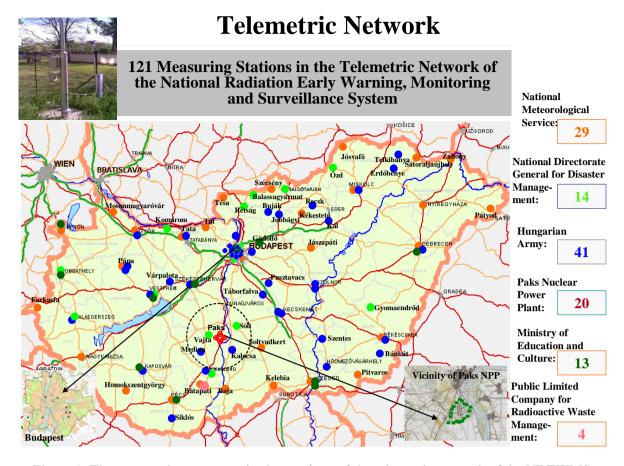


Figure 1: The gamma dose rate monitoring stations of the telemetric network of the NREWMS

The alarm threshold is set at 500 nSv/h; every subsystem sends the data to the national centre (National Directorate General for Disaster Management), where a 24/7 duty service monitors the data. Every subsystem of the NREWMS does the calibration, checking and maintenance according to its own procedures.

For details of this system that was not part of this verification see the report HU-10/03.

5.2.2 Fixed Radiological Laboratories

The following bodies have fixed Radiological Laboratories:

- Ministry of Rural Development
- Ministry of Human Resources ("Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene)
- Paks Nuclear Power Plant
- Hungarian Academy of Sciences
- National Meteorological Service

5.2.3 Mobile Laboratories

The following bodies operate Mobile Laboratories:

- Ministry of Interior (Disaster Management)
- Ministry of Human Resources ("Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene, NRIRR)
- Ministry of Defence (Hungarian Army)
- Ministry of Rural Development

- Paks Nuclear Power Plant
- Hungarian Academy of Sciences (KFKI Atomic Energy Research Institute)

5.3 RAMDAN SAMPLING

5.3.1 Air related programme

There are five air samplers of medium flow rate (150 m³/h, manufacturer: *SENYA OY*, Finland; type: *SENYA JL-150*, *HUNTER*, medium volume air sampler, glass fibre filter, change weekly, leading to LLDs of a few μ Bq/m³ for most gamma emitters) and five air samplers with low flow rate (appr. 2 m³/h, KFKI design, Ø 5 cm *Millipore* membrane filter, change daily, leading to an LLD (after 72 hours) of 1.5 mBq/m³ for gross beta).

The NRIRR has a continuous alpha (natural and artificial) and beta aerosol monitor: *Thermo Electron FHT59Si*. Flow rate about 8 m³/h, detector type: PIPS semiconductor, LAN coupling. Measurement range: 0.1 Bq/m³ – 1 MBq/m³, LLD: 50 mBq/m³ (alpha), 300 mBq/m³ (beta). Alarm thresholds: 80 Bq/m³ (artificial alpha and beta), 150 Bq/m³ (natural alpha).

The filters of the medium flow rate air samplers are analysed by gamma spectrometry (HPGe), those of the low flow rate air samplers are measured for gross beta activity.

RAMDAN has six fallout sampling sites. Their collection areas range from 0.16 to 3 m². The NRIRR has one steel collector (with heater) of 0.2 m², one steel collector (with heater) of 1 m², location: 1 m above ground.

There is monthly exchange of collector canisters. The quantity depends upon the quantity of monthly precipitation. Cleaning is performed with distilled water and a brush.

Gross beta activity and gamma emitting isotopes are assessed, LLD: 1.3 - 6.7 Bq/m² (gross beta), 0.1 - 0.3 Bq/m² (gamma emitters).

5.3.2 Other sampling programmes

Except for air this verification did not touch sampling and monitoring issues. For details of such monitoring see the report HU-10/03.

5.4 RADIOANALYTICAL MONITORING NETWORK UNDER THE RESPONSIBILITY OF THE MINISTRY OF RURAL DEVELOPMENT (RMN OF MRD)

This verification did not involve the Radioanalytical Monitoring Network under the responsibility of the Ministry of Rural Development. For details on this network see the report HU-10/03.

5.5 LABORATORIES PARTICIPATING IN THE NATIONAL ENVIRONMENTAL RADIOACTIVITY MONITORING PROGRAMME

Both, RAMDAN and the RMN of the Ministry of Rural Development operate separate laboratories.

5.5.1 The laboratories of the Radiological Monitoring and Data Acquisition Network (RAMDAN)

The laboratories of the Radiological Monitoring and Data Acquisition Network (RAMDAN) operate under the National Public Health and Medical Officer Service and under the professional coordination of the NRIRR. They send the measurement results to the RAMDAN Information Centre, which is also maintained by the NRIRR. They are responsible to perform the main monitoring programme of RAMDAN.

Altogether, RAMDAN comprises a central and 6 regional laboratories:.

- NPHMOS NRIRR Central Radiohygiene Laboratory (CRL)
- Government Office for Borsod-Abaúj-Zemplén County NPHMS RC(Miskolc)
- Government Office for Csongrád County NPHMS RC (Szeged)
- GOCCB NPHMS RC (Budapest)
- Government Office for Győr-Moson-Sopron County NPHMS RC (Győr)
- Government Office for Hajdú-Bihar County NPHMS RC (Debrencen)
- Government Office for Tolna County NPHMS RC (Szekszárd)

Furthermore the environmental Radiohygiene Laboratory of the Government Office for Central Transdanubian Regional Institute of NPHMS RC has not been established yet.

Only the Central Radiohygiene Laboratory of NRIRR is accredited according to MSZ EN ISO/IEC 17025:2001.

With the exception of air monitoring at NRIRR this verification did not include the laboratories. For details on this see the report HU-10/03.

5.5.1.1 NRIRR laboratory - verification of 2010

The following is a direct transcription of the relevant part of the report HU-10/03. The specific 2012 verification is covered in Chapter 7.2.1.

The verification team performed an in depth verification at the NPHMOS NRIRR – Central Radiohygiene Laboratory (CRL), also known as the Frédéric Joliot Curie Institute. Founded in 1957 the Institute employs 80 staff, mainly scientists.

The laboratory has ISO 17025/2000 accreditation for over 70 methods, valid until 23 March 2014.

Samples arriving at the laboratory are registered in a ledger with the following information recorded:

- Central number (consecutive)
- Division number (each division starts with 10, 20, 30 etc. followed by a consecutive number, e.g. 10491)
- Type of sample
- Date of order
- Date of sampling
- Sampling location
- Name of sampler
- Name of sample receiver
- Person responsible for measurement

A further column shows the date when the results were prepared and is completed after measurement.

The laboratories are fully equipped to undertake drying, ashing and milling as appropriate when preparing samples for analysis.

Records have been kept since 2001 when accreditation started and were readily accessible. A number of samples were selected and staffs were quickly able to retrieve all documents relating to sample receipt, measurement and results.

In addition to the paper records all data relating to sampling and results is input to the NERMS database which uses Microsoft Access. Each individual laboratory can see all data but only modify their own records. NRIRR can modify all records.

Radon measurements are taken on site. In addition one assistant has taken the initiative to establish a small weather station with a view to relating the radon measurements to the prevailing weather conditions.

Regular gamma dose rate measurements are taken at the same point in the garden since the 1970's.

The verification team visited the individual laboratories within the Institute and received valuable explanations from the staff regarding the instruments and methods used. The principal areas visited were the following:

Tritium and caesium measurement

A background measurement is undertaken before each sample measurement. H3 concentration is increased by electrolysis with the possibility to handle 12 samples per 5 day week. Around 500-600 analyses are carried out yearly. Typical concentrations are of the order of < 2Bq/litre for water from the river Danube and $< 0.2 \, MBq/litre$ for well water.

A Julabo evaporator is used for the concentration of surface water, 100 litres at the outset are reduced to 1 litre for the measurement of Cs 137, the activity of which is generally very low in water taken from the river Danube.

Gamma spectrometry

In addition to the some 250 analyses undertaken as part of the environmental monitoring programme the laboratory undertakes about 200 additional measurements for the construction industry and other interested parties.

The bulk of the accredited methods are undertaken in this lab with a wide range of calibrations from 0.8ml to 1 litre sizes covering trays, bottles and Marinelli beakers.

Though the laboratory has a number of detectors at it's disposal generally only 1 detector is used on a regular basis due to cooling costs.

Multi detector measurement was not possible at the time of the visit due to problems with the Procount 2000 software, though a repair was due to be undertaken.

In the past the laboratory took part in PROCORAD inter-comparisons but this has been discontinued due to the high cost. Very good results were obtained and delivery of overall results was quite quick. The laboratory continues to take part in other inter-comparison exercises, particularly where participation is free of charge.

Alpha spectrometry

A Canberra Alpha analyst system is used for measurements of Am, Pu, U and Th, with accreditation held for the Am methods. This machine has been found to give good results for Polonium-210 and radium but the methods are not accredited. However it is envisaged to try and obtain accreditation. Around 150 samples are analysed annually.

TLD measurements

The TLD system which dates from 1976 uses $CaSO_4$: Tm powder, heated to 220 °C in a nitrogen atmosphere to avoid oxygen "burning". The laboratory has the necessary equipment to manufacture the TLD capsules, in addition to being able to read the results. The national network consists of 115 volunteers spread throughout the country.

Radon measurements

In addition to a Durridge RAD 7 radon monitor the laboratory operates a RADOSYS system which incorporates CR-39 particle registration material, an etching unit using a sodium hydroxide solution and an automatic track counting microscope using RADOSYS 2000 application software.

Overall

Owing to the prevailing weather conditions at the time of the visit it was not feasible to visit sampling points and gamma measurement stations in the countryside. The team were shown the measurements taken in the grounds of the Institute. Gamma dose rate has been measured since the 1970's on a regular basis at the same point in the garden using a portable gamma spectrometer. Nearby radon measurements are made inside a small "house". There is a small weather station which allows to relate radon content to the weather conditions.

Two fallout samplers are located near the main building, both of which are heated in winter. The larger for dry measurements is 1m * 1m, whilst the wet sampler is 0.2m². Both are emptied monthly, or more frequently, particularly in the case of the larger sampler.

Three aerosol samplers are also installed. A homemade device with a capacity of +/- 100 m³ per day, the volume being measured by a gas meter has the filter placed in the top of the intake tube. The filter is changed every morning, 7 days a week and the gross beta activity measured without any preparation. A JL 150 Hunter air sampler is used for gross gamma measurements on the filter which is changed weekly. The device incorporates an auto stop if the filter is "full", i.e. there is a drop in pressure. The third device, a Thermo Eberline FHT 59 was out of order due to a software problem at the time of the visit. This allows the automatic measurement of alpha and beta separately with the results being sent directly to the main building. The flow rate is 7-8 m³ per hour.

The verifications do not give rise to specific remarks.

Some areas, e.g. with regard to accreditation, have been improved since that verification.

5.5.2 Laboratories of the Radioanalytical Monitoring Network under the responsibility of the Ministry of Rural Development

The 2012 verification did not touch upon this network and its laboratories. For details of this see the report HU-10/03.

6 MEDICAL FACILITIES USING RADIOISOTOPES

In Hungary, the establishment of a nuclear medicine facility as a medical isotope laboratory requires an authorisation issued by the State Public Health and Medical Officer's Service. The licence covers import, purchase, processing, and application of radioactive substances.

Nuclear medicine departments are designed and constructed as specific radionuclide laboratories with one controlled personnel entrance and controlled active rooms: the hot laboratory in which radionuclide sources are stored, handled and prepared for use, the administration room, the radioactive waste storage room, and the examination rooms. Waiting areas for active and inactive patients are separated. Separate toilet facilities are available for active patients.

The following medical radioisotopes and applications are being used in Hungary: For in vivo diagnostics Tc-99m is with $\geq 80\%$ by far the most applied radionuclide, but there is also Ga-67, Tl-201, In-111, I-131, I-123, F-18, etc. For in vitro diagnostics, I-125 is used (helicobacter pylori: C-14). I-131 is used for isotope therapy of the thyroid, in case of hyperthyroidism the applied I-131 activity stays below 550 MBq per patient, and the patient can leave the hospital after application. In case of cancer metastases treatment, 550 MBq - 5 GBq are applied to a patient, which requires hospitalization of the patient in a specially designed, controlled "isotope" ward. For bone palliation therapy, the radionuclides Sr-89, Sm-153, Re-186, etc. are used. The patient can leave the hospital after treatment. Immobilization in "normal" hospital bedrooms is required after application of Y-90, Re-186, Er-169, and Dy-165.

According to data from the latest yearbook of the Hungarian College of Nuclear Medicine (2007), there are 48 nuclear medicine departments in Hungarian hospitals. Furthermore, there are 4 PET/CT centres, two of which have a medical cyclotron to produce isotopes, 43 planar cameras, 36 SPECT (single or dual head), and 17 thyroid cameras.

In 2010, the verification team selected two hospitals in Budapest which were visited during the verification mission: the nuclear medicine department of the State Health Centre and the Pozitron-Diagnosztika Ltd diagnostic centre, running a PET/CT and its own cyclotron with a radiopharmaceutical production facility. Details are given in report HU-10/03.

7 EVENT AT THE INSTITUTE OF ISOTOPES, LTD.

7.1 HISTORICAL OVERVIEW

7.1.1 First information of Commission services

In autumn 2011 several monitoring laboratories in EU Member States detected elevated levels of iodine-131 in air that could not be explained by local sources. Within the so-called 'ring of five' (an unofficial communication platform between radiological laboratories in central Europe) the Austrian AGES (*Agentur für Gesundheit und Ernährungssicherheit*) laboratory in Vienna first contacted the laboratories in the neighbouring countries to inform them about the event. Laboratories in the Czech Republic confirmed such measurements. By applying back-trajectory calculations the source of the contamination could be narrowed to the east of the two countries. Since no official information about a radiological release was available rumours about potential sources (that included accidental releases at the Japanese reactor site of Fukushima, the Armenian NPP Metsamor, as well as accidents in nuclear submarines) spread in the media. Finally, the IAEA was informed by the Czech authorities and in turn distributed the information, including to the European Commission. Only then Hungary confirmed releases by the Hungarian radioisotope production firm Institute of Isotopes Ltd., Budapest; however, the annual release limit of 1600 GBq for iodine-131 for that firm was not surpassed. (Having an on-line connection to relevant data from the Hungarian NPP Paks, HAEA immediately realised that the power plant could not be the source for the iodine-131 levels.)

Although the health consequences for the population (both, in the Budapest area and outside Hungary) can be seen as marginal the event caused considerable irritation and concern. Unfortunately the existing possibility of sending an 'information' message via the European Community Urgent Radiological Information Exchange (ECURIE) system for clarification was not used by the Hungarian authorities, pointing to 'weaknesses' in communication.

7.1.2 Description of events

7.1.2.1 Institute of Isotopes Ltd.

The Institute of Isotopes Ltd. (IoI) is a company dealing with research, development and production of a wide variety of radioactive isotopes and other products for a broad range of application areas, especially healthcare, research and industry. The company operates at the KFKI Campus site (at the same site as the Budapest Research Reactor) (29-33 Konkoly Thege Miklós út, 1121 Budapest, Hungary).

I-131 is primarily produced by IoI for thyroid diagnosis and treatment purposes by neutron irradiation of TeO₂ targets in the core of the Budapest Research Reactor. Iodine is separated from the irradiated target in a special hood by dry distillation at an elevated temperature. The NaI solution produced is further processed in other hoods of the clean laboratory. Because of the high volatility of iodine, the hood is equipped with an air ventilation systems and the air filter system is equipped with charcoal filters. The activity concentration of I-131 in the stack and the discharged volume of air are determined in the stack. Since the research reactor (that uses the same stack) under normal conditions does not have any discharges of I-131 all such releases are assumed to be caused by IoI. It is very likely that the main source of the emission was due to the dry distillation process.

Monitoring by the operator showed that in autumn 2010 released activities increased slightly. Thus, an exchange of the active carbon filters of the hoods located on the operator side was decided. Thus, in May 2011, the production of I-131 was stopped. Due to a shortage of high quality active carbon filter material this change could be only done in summer 2011; the FPP filters were not renewed. Also the air ventilation of the hood was modified.

Radioiodine production resumed in early September 2011, however, iodine releases still were higher than expected. Production continued until 16 November 2011. According to an official press release of the Institute of Isotopes Ltd., issued on 17 November 2011, an enhanced level of I-131 release occurred during the production of I-131 medical products in this time period. The total amount of activity of I-131 released during this period was 324 GBq, while the cumulative release from 1 January to 16 November was 624 GBq, which is 39% of the annual discharge limit (1600 GBq) and thus more than the limit for obligatory reporting to the competent authority (set at 30% of the annual limit). (The annual discharge limit was derived for this practice from the dose constraint determined by the National Public Health and Medical Officer Service (NPHMOS) as the national competent authority.) During the verification IoI admitted that with regard to the 30% 'rule' for releases it 'was an error' not to report caused by bad information flow: weekly data were sent to the reactor that operates the discharge data base, but the values were not summarised; thus, IoI did not realise immediately the elevated release (only when it reached 39%).

A concerted inspection by all the involved supervisory authorities took place on the IoI premises on 21 November 2011. As a result, the competent authority suspended production of iodine-131 using the dry distillation method. On the other hand, for the following period I-131 radiopharmaceuticals were continuously produced by using imported bulk I-131 sodium iodide solution. Releases of iodine-131 were significantly lower during that time. Extrapolation of the release values to 52 weeks would give an annual release of about 0.61% of the allowed yearly release limit (1600 GBq). IoI states that further reconstruction of the filtering as well as of the ventilation system may contribute to further decrease of the release.

At the time of the visit there was no production since the authorities had not allowed its resumption, the explanation for the releases still being unsatisfactory.

7.1.2.2 Regional monitoring results and dispersion

The monitoring station closest to the point of release (release height: 80 m) belonging to the national network NERMS is operated by the Frédéric Joliot-Curie National Research Institute for Radiobiology and Radiohygiene, Budapest, Hungary (NRIRR). The I-131 content in the air is measured offline using weekly sampling periods. The background level of I-131 iodine has not exceeded $10 \,\mu\text{Bq/m}^3$ in the air of Budapest; the minimal detectable activity concentration of I-131 in aerosols for the station is in the range of 1-3 $\mu\text{Bq/m}^3$.

During the Fukushima accident in spring 2011 increased iodine levels up to 3020 $\mu Bq/m^3$ were detected at that station. After 20 May, 2011 the iodine level went back to normal levels.

Starting from 1 September, 2011, the station detected slightly increased iodine levels (see figure 2). The highest iodine level was on 26 September at 173 $\mu Bq/m^3$.

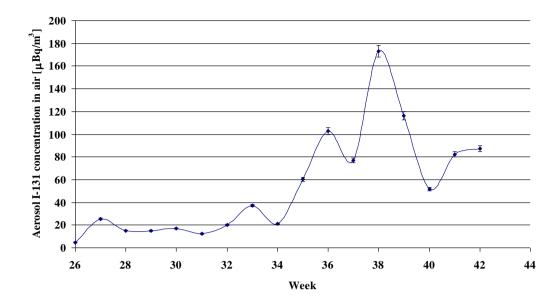
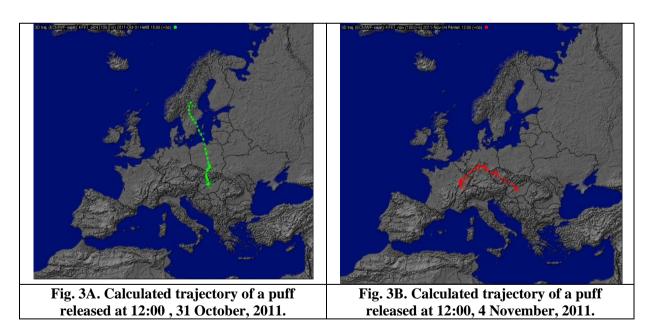


Figure 2: Aerosol bound I-131 activity concentration in air measured by the station of the Frédéric Joliot-Curie National Research Institute for Radiobiology and Radiohygiene, NRIRR, Budapest, in 2011.

Since elevated level of radioactive iodine measured in Europe were reported at beginning of November 2011, trajectories for this period were calculated to see which countries could have been affected by the release. As an illustration, trajectories corresponding to a release of a puff at 12:00 on 31 October and 12:00 on 4 November 2011 are shown in figures 3A and 3B, respectively. The trajectories were calculated using the ALADIN program based on actual measured meteorological data.



The trajectory of the 31 October release shown in figure 3A follows a northerly direction reaching Slovakia, Poland and Sweden. The release of the 4 November, shown in figure 2B, is directed to the West, reaching Austria, the Czech Republic, Germany and France.

24 hour dispersion calculations were also performed by the RODOS system for releases on 31 October 2011 (10:00 - 15:00, release of 16 GBq I-131), and 4 November 2011 (10:00 - 15:00, release of 15 GBq I-131). The RODOS results showed that after 24 hours the total radioactive concentration of I-131 in air at a distance of 300 km from the release point was in the range of 100-300 μ Bq/m³.

Determination of the initial distribution of I-131 activity among aerosol, elemental and organic forms would allow to compare model predictions to actual measurement results.

7.1.2.3 Initial response measures

The Institute of Isotopes Ltd. suspended I-131 production until the cause of the event could be fully investigated and the necessary technical modifications carried out. Clarification of the technological reason for the enhanced release will lead to significant changes in the production method. IoI realised that it had made a mistake by not reporting the event to the authority as foreseen in the authorisation (releases of more than 30% of the annual limit had to be immediately reported. The release amounts were only transmitted to the on-site system that deals with emissions of the whole site). The verification team was informed that subsequently, the reporting procedures were changed (internal communications regulation) and the new procedures were accepted by the competent authority.

The Hungarian Atomic Energy Authority (HAEA), the Hungarian contact point for the IAEA, is the competent authority for licensing and surveillance of nuclear facilities only. The laboratories using radioisotopes are in the hands of the National Public Health and Medical Office Service (NPHMO). The communication problems that were faced in the wake of the event have called the Hungarian Government's attention to the necessity for improvement and simplification of the regulatory system. Meetings of the competent authority and the stakeholders addressed this problem and lead to procedural changes.

The production license is still suspended until the cause for the higher-than-design-level releases is found. Technical studies to identify this cause (one by the Hungarian Academy of Sciences, the other one by HAEA) are ongoing.

7.2 VERIFICATION ACTIVITIES

The verification was performed in order to receive a clear picture of the event and the consequences that were taken or are foreseen.

A first discussion with the authorities involved gave an overview of the current knowledge about the event and the immediate measures taken (in particular those on the level of the involved authorities). A visit of the laboratory that detected the impact on Hungarian territory and made first analyses, as well as a visit of the production site itself (including the on-site monitoring facilities and the new production approaches that were tested on laboratory scale) allowed a closer insight. A final discussion with the authorities focussed on the lessons learned and improvements at various levels.

7.2.1 NRIRR

This chapter only covers the verification of 2012 that focussed on the radioiodine releases from the Institute of Isotopes and thus on the facilities for detecting radioiodine in air. With regard to the general verification of the NRIRR we refer to the one performed in 2010 and the relevant report HU-10/03.

NRIRR ("Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene; in Hungarian *OSSKI - Országos Frédéric Joliot-Curie Sugárbiológiai és Sugáregészségügyi Kutató Intézet*) is located at 1221 Budapest, XXII. Ker. (Budafok) Anna u. 5, some 8 km SSW of the site of IoI where the emissions took place.

In an introductory meeting the verification team received presentations on the National Environment Radiation Monitoring System (NERMS) in general, the Radiological Monitoring and Data Acquisition Network (RAMDAN, the Ministry of Health system), and in particular with regard to the iodine event, a presentation on "Monitoring of Special Installations - Health Sector" (NPP, nuclear research reactor, radioactive waste disposal, isotope production). The latter covered the activities by NRIRR and the Radiohygiene Centre (RC) of Budapest ('Capital RC').

Capital RC is responsible for monitoring of KFKI (i.e. the Budapest Research reactor and IoI). Two common sampling locations are operated at Csillebérc (some 8 km from the KFKI site, mainly a recreational park area

in the hills). Sampling (soil, grass/hay – 1 location close to fence, 1 some 1 km downwind from the site) is monthly from spring to autumn, the samples being analysed by gross beta measurement, gamma spectrometry and (vegetation samples) atomic emission spectrometry (for potassium). Samples are taken by GOCCB NPHMS RC staff.

Realising some problems with data reporting by the Radiohygiene Centres new procedures were set up within the 'Electronic Public Administration Operative Programme' (EKOP) including strict deadlines. This new system was well accepted by the staff of the involved Hungarian bodies.

NRIRR has ISO 17025 accreditation for gamma spectrometry; the 'other' RCs don't, but make every effort to apply accredited methods, with NRIRR having a supervisory role (e.g. 2-3 times training and discussion meetings at NRIRR). The RCs have p-type HPGe detectors, NRIRR also a 25% n-type (also usable for low energy gamma ray detection), all using *Canberra Genie 2000* as gamma spectrometry system. For aerosol sampling, three RCs use old *Senya Hunter* devices. A few years ago NRIRR developed a special calibration method for the detection of I-125. Analysis of I-125 in air started in 2008, using glass fibre filters. Due to a malfunction of the *Hunter* air sampler, no gamma spectrometric analysis could be performed from ca. 2008 to 2010, leaving a large data gap. During the current mission, the measuring devices were not verified; they were covered during the last visit in 2010.

The team was told that after the Fukushima reactor accident in Japan in March 2011 the institute detected peaks of I-131 and I-125 in surface air (September 2011) and immediately linked this to 'problems' at IoI; Thorough analysis of available data showed that also during the time of Fukushima a second effect (besides Fukushima) was influencing radioiodine levels at the station; thus, e.g. a release event at IoI could be deduced for May 2011.

The team verified the 'HiVol' air sampler (*Senya Hunter 150*; 3000 m³/d), installed near the laboratory building. The glass fibre filters are usually changed on Mondays; the verification on Tuesday already showed a relatively large amount of filter covering due to household wood burning and the influence of a not too distant oil refinery.

The filters are compressed for measurement using a hydraulic press; they are weighed for determination of dust concentration (generally ca. $12 \mu g/m^3$).

Currently, an adaptation of the device is in progress with a view to allow sampling also of organic iodine: below the glass fibre filter an activated carbon filter will be installed, with a lower, adjusted flow rate.

Formerly, in the space above the glass fibre filter, an IR lamp was installed for heating and thus decreasing filter clogging effects, in particular in autumn and winter. The team was told that this device was removed in order to have the same method as the other stations at RCs.

Besides the high volume sampler a low volume air sampler (flow rate 18 m/d) is installed, using cellulose filter material, for daily sampling. This device has heating for winter.

The verification team encourages putting the new procedures with regard to communication also on the appropriate international level.

The verification team encourages the installation of an iodine specific sampling device in the JL-150 air sampler. It recommends equipping all samplers of this kind that are included in the RCs of the RAMDAN system with heating devices, so as to have the same systems available at all stations with the same property of avoiding filter clogging due to aerial pollution e.g. from household wood burning.

7.2.2 Institute of Isotopes, Ltd.; KFKI campus

7.2.2.1 General

The Institute of Isotopes (IoI) is located on the KFKI (Hungarian Academy of Sciences Atomic Energy Research Institute) campus, Budapest, 1121 Konkoly Thege M. út 29-33, in the hills NW of the centre of Budapest.

The whole campus is fenced, with guards controlling access and registration procedures for personal control. At the campus entrance barrier two gamma dose rate probes are installed.

In a first discussion the verification team received a presentation of the company and the company's view on the events. IoI was established in 1959 by the Hungarian Atomic Energy Committee; it currently employs 195 persons and covers an area of some 10000 m². It has ISO-9001:2008 certification, is audited according to the ISO 13485 standard, and is Good Manufacturing Practice (GMP) audited according to EU regulations. It can apply the CE marking ('Conformité européenne') for medical devices according to EU legislation. The business areas reach from radiopharmaceutical production (e.g. I-131, I-125, Y-90, Sm-153, Ho-166) and immuno assays to radiation technics instruments production and irradiator design, development and installation. The most important markets for its produce besides the EU are the Far East (India and Japan), with the IAEA being the main partner for distribution to 3rd world countries.

The team was given a description of the (former) production process for I-131 and an overview of the filtering and monitoring system. IoI admitted that when it had detected elevated discharge levels (leading to an aggregated release larger than 30% of the annual limit) and it thus had the obligation to report them to the authority it only reported the values internally to the KFKI discharge data system.

The team was informed that the annual limit of 1600~GBq for aerial releases of iodine-131 is based on a dose restriction of $50~\mu\text{S}v/\text{yr}$. The limit was defined in the 'common past with the research reactor' (the research reactor having no iodine-131 releases to air all was attributed to IoI). Such an authorisation was given by the health and environmental authority. A study in 2001, which forms the basis for this limit, looked at three possible critical groups, all outside the fence (the residential area is about one km from the stack). Cow's milk was not taken into account, since there are no cows in the area and an according pathway would have led to a contribution of less than 10% anyway. Sheep milk was not taken into account because sheep are not allowed in the area. As a fourth group non-professional radiation workers at the campus site were taken up. Generally, noble gases from the reactor are the main dose criterion. For first calculations the computer programme PC-CREAM (Consequences of Releases to the Environment: Assessment Methodology; PC version) was used; a recent check showed an even lower effect on potential population doses.

7.2.2.2 I-131 production system

The production process for iodine-131 using a dry distillation system was introduced in the middle of the '80s.

Solid tellurium dioxide targets are irradiated by neutrons in the reactor. One of the nuclear reaction products is I-131. Iodine is distilled from the target at a temperature above 750°C. The distillation system consists of a ceramic vessel, an electric furnace, and a quartz bridge tube fitted to the top of the ceramic vessel and to the acidic scrubber containing sulphuric acid. The acidic scrubber is connected to three absorbers containing a sodium hydroxide solution. The 3rd absorber (safety vessel) is connected to the vacuum-pump, which ensures regulated I-131 flow during distillation from the target to the absorbers. Vacuum adjustment is controlled by visual observation (web-camera), resulting in continuous bubbling.

The radiation level developing in the 1st absorber is monitored as a function of time. The distillation process is accomplished when the activity in the 1st absorber attains a plateau (after ca. 2 hours). The I-131 bulk solutions can be taken from the 1st and 2nd absorbers. A complete distillation cycle lasts for about 3 hours.

The dry distillation system is located in a hot cell of the grade-A isotope laboratory hot cell line. The hot cells are under continuous depression, not only during distillation but also at rest. Depression in the hot cells

is maintained by the air ventilation system equipped with filters. The filter system consists of various filters: pre-filters, main filters and post-filters. Two kinds of filter materials are included in the system: FPP (Fine Particle Processing – polymeric fibrous material) for aerosols and activated carbon of high specific surface for capturing elemental as well as organic iodine. The air - sucked by the vacuum-pump from the distillation system - also flows through this filter system.

The air coming from the overall ventilation system serving all hot cells is released through the chimney-stack at 80 metre altitude relative to ground level. The stack is used by both, the research reactor and IoI, a 7 m high wall in the chimney separating the two stack input lines. On the IoI side of the wall, at 3.2 m altitude a tube allows air to be pumped to the sampling place in the ventilation engine-house situated just beside the chimney-stack. There are five sampling spots in the sampling line of which three are used. For measurement a NaI(Tl) detector is installed with a single channel analyser set at the energy range of I-131, however not efficiency calibrated. At the same time, for validation of the measurement, the background corrected cpm values collected in the single channel in the measurement of I-131 samples of known activities were checked during a period of 2 years.

The team was told that IoI realised in early 2011 that the old I-131 production method had to be replaced by a new method. Thus, in parallel with the 'old' production, developments in this direction were started.

7.2.2.3 Campus on-site and discharge monitoring

With regard to on-site monitoring, 18 gamma probes are installed on the campus (two of them inside of the building). The team received a presentation of the system including the data management and display options on screen. The detectors consist of two commercial GM probes (one more, one less sensitive); measuring intervals are a few seconds; data are stored locally and uploaded every 10 minutes using a web-based application. The data presentation system is accessible by the public. An alarm system is set at 200 nGy/hr for checking the reason of such elevated values (this happens for example during transports of radioactive material between buildings); IoI is informed when at times of reactor releases. A test using an external source with a probe permanently installed in the office led to an immediate optical and acoustic alarm. The team verified the presence of several of the probes, generally mounted ca. 2 m above ground, with TLDs mounted in a box; data communication to the data centre is performed by telephone line.

Four basic 'stations' are set-up on site with sampling equipment for air and precipitation (fallout), covering the four wind directions. At station 1 (which is fenced and has locked access) the team verified a continuous iodine air monitor that is also connected to the central data collection system.

Station no 6, which is fenced with locked access contains a fallout collector of ca. 50 cm diameter, an air sampler (aerosol, elemental iodine, organic iodine), and a TLD.

Filter material is glass fibre for aerosol sampling whereas for elemental iodine the filters are activated carbon impregnated with silver.

In addition to its own devices the KFKI campus houses the 'NPP Paks reference station' which is part of the NPP Paks monitoring system. It is installed in a separate fenced and locked area, within a locked container. The system houses:

- a high volume air sampler (with 3 component filter: aerosols, elemental I with 'PACI' filter of 95-98% efficiency, organic I with TEDA impregnated carbon filter) with side channel blower;
- a low volume continuous monitor for emergency: with plastic scintillator (aerosol and elemental iodine filters) and NaI(Tl) detector (Marinelli geometry; for organic I); data handling: *Advantech industrial computer 610*, data storage and transmission to NPP by radio;
- dose rate monitor Bitt RS03 232/H.

Laboratory in the IoI building

The team verified the measuring laboratory in the IoI building where samples from the sampling stations are analysed (wet fallout with weekly change; aerosols daily change). For gamma spectrometric analysis a 20% HPGe detector (*Canberra*) with a 5 cm Pb shield with Cu liner is used; no cling film is used for

contamination prevention. The laboratory also has an old Ge(Li) detector available. For aerosol samples normally a gross beta measurement is performed using a *Berthold LB770* device; in case of increased values the sample is also analysed by gamma spectrometry.

Aerosol samples from the HiVol sampler with weekly sample change are analysed by gamma spectrometry using a 30% *Canberra* HPGe in a low level steel container (15 cm steel, 1 mm Cu; Fe coming from a bridge destroyed during WWII). NIM electronics is used, spectrum management and analysis software is *Canberra Genie 2000*. Measuring times are overnight, cling film protection is applied for contamination prevention. The LLD achieved with the system is ca. 20 μ Bq/m³ for I-131 and Cs-137. The calibration sources from the Czech Metrological Institute are certified. Background determinations are performed monthly, as well as calibration checks.

For LSC an old *Packard TriCarb 4530* is available. IoI also has a mobile lab (for in situ gamma spectrometry).

Lab building 416 (*Sugárvédelmi laboratórium*)

The laboratory operates a large gamma spectrometry system, housed in a low level shield (based on Fe from an old bridge, with Cu liner and with ventilation system for Rn reduction). It also houses a whole body counter with three detectors (2 NaI(Tl), 1 HPGe) that is used for the routine annual inspections of workers at the campus. Per year some 100 measurements are performed, measuring time is 20 min/person; various geometries are calibrated using phantoms. The system uses *Canberra* NIM, a *Canberra Series 85* MCA and a PC for analysis.

With regard to a potential exposure pathway by mushroom consumption the team was told that staff do collect and measure mushrooms in the woody campus area.

Liquid discharge (water) sampling/monitoring station

The team verified the water sampling station located at the waste water exit for the whole site.

For sampling a few drops are collected each minute in a 201 container. Analysis is for H-3; a 100 ml sample is evaporated for daily gross beta analysis; in case of an event gamma spectrometry is additionally performed. For immediate sampling 2 boxes are available that are switched automatically; manual switching from the central unit is possible.

A continuous gamma monitor based on a 3"x3" NaI(Tl) detector, mounted upside down in a basin allows for quick detection of significant liquid releases.

Aerial discharges

For aerial discharges the reactor and IoI use a common stack, separated by a wall. In the stack 4 pumps are available (three running).

For sampling the team verified two vacuum pumps (*Leybold Trivac*); one system is on-line (1 filter, NaI(Tl) detector in upside down Marinelli geometry, not calibrated), one is off line (3 filters). A gas counter (*metrix*) serves for flow rate determination for each line.

7.2.2.4 Production site visit

The verification team visited the iodine-131 production site including the hot cells formerly used. The team was also shown a demonstration set-up of the system that may also be used for testing improved production methods using dry distillation.

The hot cell line is currently under reconstruction. New manipulators (at the time of the visit in store) were available for installation at the new distillation location. Apparently the hot cell ventilation system that should build up a pressure difference did not work well, also before the time of the event (this could have

even let to a contamination of the air in working areas, but that never happened). The (differential) pressure was 20 Pa (instead of 150 Pa); it "was low" for several years and the authorities demanded a new system.

A short visit was paid to a second production line used for further processing of the NaI solutions produced or imported (no radio-iodine production) with clean room and hot cells partly under reconstruction; here a smaller filtering system is in place.

The team visited the radioiodine production filter area which is located in a locked part of the basement of the production building. Air from the hot cells passes a pre-filter (FPP plus powder), followed by 3 units of active carbon (1 if no production, the additional ones for production). After a post filter (FPP plus active carbon) a long pipe leads to the ventilation station, where filters (FPP plus active carbon) are installed. Non-radioactive substances currently are not filtered; this is foreseen for the future.

The verification team encourages the implementation of the new administrative and technical procedures foreseen in continuous contact with the relevant authorities and urgently recommends setting up an efficient communication system with the competent authorities.

7.2.3 Lessons learned

IoI:

During discussions and the visit of the production site the verification team was informed about several ideas that should lead to a considerable improvement and enhanced safety of the iodine production process.

In general, Radiation Protection Rules were renewed and a new internal 'Rule of Communication of IoI' has been enacted. The latter states that in extraordinary situations – besides e.g. the owner – first of all the 10 involved authorities (including HAEA) have to be informed.

With regard to FPP filter renewal, discussions with the subcontractor begun. Replacement is foreseen by November 2012. Changing the filtering approach also will include installation of 'PACI' filters for elemental iodine.

To improve the efficiency and reliability of the system it was redesigned after the event. The new system provides a measuring possibility also for the authority (i.e., the environmental inspectorate); in a first phase this has been done already. In a 2^{nd} phase a specialist for air flow from the Budapest Technical University will be involved to improve the system design. In the new system high resolution gamma measurement using a semi-conductor detector is foreseen, providing the possibility to determine also other γ -emitters besides I-131.

The team received an explanation of several new ideas for improving the production system, such as installing separate ventilation for the furnace plus bridge and the 1st absorber with adequate control of local filters etc. The process will stay the same but control will be improved. IoI says that for technical reasons it will not be possible to keep the system 100% tight. However, a detector above the furnace will allow for quick detection of any leaks. In addition filtering will be improved. Better vacuum pumps will be installed and, for the case of a failure, a computer controlled alarm system will be put in place.

With regard to communication, in future information about releases will be transmitted quickly (until now: only some days later); it will also contain information on local filters.

The release path is planned to be changed in such a way that radionuclides will not go to the larger filters or to the stack, but the production process will be stopped.

The team was told that the new system will be ready by November 2012 or by early 2013.

IoI tries to have the same new monitoring system as the research reactor (for more efficiency). This could include one server at the research centre containing all data with access by 'everybody'.

Authorities:

As an example of the actions taken by the Hungarian authorities, since January 2012, a new act provides for more complex inspections of IoI. <u>As a result of such inspections the collaboration between the involved authorities was significantly improved.</u>

With regard to disaster management and the inspection system for IoI, changes were already put in place (e.g. new Disaster Management Act; inspectorates put up on national and local level). This touches industrial safety, transport of critical goods and critical infrastructure protection. Hazardous material incl. nuclear and radiological are only involved if emergency situation occurs, including countermeasures. The new act provides a possibility to lead complex inspections in emergency situations. Disaster management deals with organisation of inspections and collects data; it involves fire brigades, health authorities, etc..

Although in the investigated case the level of the safety of the population was not decreased and no emergency situation was declared, two such complex inspections were performed and revealed shortcomings. A follow-up proved efficient collaboration between the authorities.

The verification team encourages the implementation of all new techniques and procedures foreseen, in particular with regard to efficient communication among the authorities involved and to the European level.

8 CONCLUSIONS

All verifications that had been planned by the verification team were completed successfully. The team wishes to indicate its appreciation of the quality and the comprehensiveness of the information supplied to it before and during the visit.

At a number of points in the report reference is made to the sampling programme and specific measures in place in Hungary in general and with regard to the Paks NPP in particular. This information is provided to give an 'overall' view of the situation in Hungary and was not the object of verification. Earlier reports, references HU-10/03 and HU-04/4, deal with these aspects in greater detail.

The information provided and the verification findings led to the following observations:

- (1) The verification team received detailed information about the event both from the operator and the relevant Hungarian authorities. This information pointed to several shortcomings of the site operator, particularly with regard to reporting. The verification team took note of the shortcomings.
- (2) The programmes set up in response to the event by the site operator and by the Hungarian authorities seem sound and effective. The team witnessed a part of the monitoring arrangements and verified administrative, operative and quality control measures. The information provided and the results presented to the Commission team were appreciated and the control and monitoring systems to be put in place are considered to be appropriate.
- (3) The verification team identified a lack of communication between the operator, the competent authority, within involved authorities in Hungary and at international level.
- (4) The different radioactivity monitoring systems in place seem to be efficient and effective. However, procedures for systematic control of the results have to be urgently established.
- (5) The measures introduced by the authorities and the site operator after the event are in line with the provisions laid down under Article 35 of the Euratom Treaty.
- (6) The Commission services request from the Hungarian Competent Authorities to be kept fully informed about the results of the studies to explain the event in detail, as well as about any future findings relative to the event at the Institute of Isotopes.
- (7) Finally, the verification team acknowledges the excellent co-operation it received from all persons involved in the activities it performed.

APPENDIX 1

THE VERIFICATION PROGRAMME – SUMMARY OVERVIEW

Monday 5/3

1. EC team travels to Budapest

Tuesday 6/3

- 2. 09:00 10:00: Opening meeting (Budapest, HAEA)
- 3. 10:00 11:00: Meeting with representatives of the National Public Health and Medical Office Service (Ministry of National Resources/Health Sector), the Government Office of the Capital City Budapest National Public Health and Medical Service (Ministry of Public Administration and Justice) and the "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene (NRIRR). (Budapest, HAEA)
- 4. 11:00 11:30: Meeting with representatives of the Middle-Danube-Valley Inspectorate for Environmental Protection, Nature Conservation and Water Management (Ministry of Rural Development/Environment Sector) (Budapest, HAEA)
- 5. 14:00 17:00: Verification activities at locations of the national monitoring system for environmental radioactivity in the vicinity of the Institute of Isotopes, Ltd. (e.g. those operated by the "Frédéric Joliot-Curie" National Research Institute for Radiobiology and Radiohygiene) (Budapest, NRIRR, XXII. Ker. Anna u. 5., 1221 Budapest).

Wednesday 7/3

6. 09:00 – 17:00: Verification activities at the Institute of Isotopes, Ltd., 29-33 Konkoly Thege Miklós út, 1121 Budapest: discharge monitoring, environmental monitoring

Thursday 8/3

- 7. 09:00 12:00: Verification activities at the Institute of Isotopes, Ltd., Budapest: measuring laboratory
- 8. 13:30 15:00: Closing meeting (Budapest, HAEA)
- 9. Return of EC team to Luxembourg

EC team: Constant Gitzinger, Eberhardt Henrich, Alan Ryan

Team leader: Constant Gitzinger

APPENDIX 2

DOCUMENTATION RECEIVED

Note:

The list does not include various other documents that were asked for (and received) during the verification activities such as calibration certificates, standard operation procedures, quality assurance procedures, source records and measurement results, technical drawings, legislative texts, reports.

Ministry of the Environment:

• Decree of the Minister of Environment No. 15/2001. (VI.6.) on Radioactive Releases to the Atmosphere and into Waters in the Course of Using Atomic Energy and their Monitoring

HAEA:

- I-131 release at the Institute of Isotopes Ltd., Budapest from 8 September to 16 November, 2011, Information from HAEA, 23 November 2011
- OKSER 2010, az országos környezeti sugárvédelmi ellenörző rendszer (OKSER) 2010. évi jelentése

NRIRR:

- Background information on duties of the radiohygiene authority and environmental monitoring systems involving the Health Sector in Hungary
- HAKSER 2010, a hatósági környezeti sugárvédelmi ellenörző rendszer (HAKSER), 2010. évi jelentése

Institute of Isotopes:

- Report to the European Committee about the I-131 isotope release to the air, at the Institute of Isotopes Co. Ltd., Budapest, Hungary
- Institute of Isotopes Co. Ltd. Communication Regulation

KFKI, Environmental Protection Services:

• Study on establishing the emission limits for the activities of the Institute of Isotopes Co. Ltd., Budapest, 30 November 2001