



**EUROPEAN COMMISSION**

DIRECTORATE-GENERAL FOR ENERGY AND TRANSPORT

DIRECTORATE H - Nuclear Energy

**Radiation Protection**

# **TECHNICAL REPORT**

**VERIFICATIONS UNDER THE TERMS OF  
ARTICLE 35 OF THE EURATOM TREATY**

**MALTA**

**25 to 27 April 2006**

**Reference: MT-06/02**

**VERIFICATIONS UNDER THE TERMS OF ARTICLE 35  
OF THE EURATOM TREATY**

**FACILITIES:** Monitoring network for environmental radioactivity in  
Malta.

**LOCATIONS:** St. Luke's Hospital, Guardamangia  
Malta Environment & Planning Authority, Corridino  
Malta National Laboratory Company, San Gwann,  
Public Health Laboratory, Valletta

**DATE:** 25 to 27 April 2006

**REFERENCE:** MT-06/02.

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**DATE OF REPORT:** 19/02/2007

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*signed*

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## **APPENDIX 1      Verification programme**

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**TECHNICAL REPORT**

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**ABBREVIATIONS**

|            |   |
|------------|---|
| ADC        | Analogue to Digital Converter   |
| Commission | European Commission   |
| DG         | Directorate-General   |
| FWHM       | Full Width at Half Maximum  |
| IAEA       | International Atomic Energy Agency                                    |
| ISO        | International Organization for Standardization                        |
| MEPA       | Malta Environment & Planning Authority                                |
| MNL        | Malta National Laboratory   |
| NIM        | Nuclear Instrumentation Module  |
| NORM       | Naturally Occurring Radioactive Materials                             |
| OHSA       | Occupational Health & Safety Authority                                |
| PC         | Personal Computer   |
| PHD        | Public Health Department  |
| PHL        | Public Health Laboratory  |
| QA         | Quality Assurance   |
| REM        | Radioactivity Environmental Monitoring (European Commission database) |
| RPB        | Radiation Protection Board  |
| TREN       | European Commission Directorate-General for Energy and Transport      |

## **1. INTRODUCTION**

Article 35 of the Euratom Treaty requires that each Member State shall establish 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 Standards<sup>1</sup>.

Article 35 also gives the European Commission the right of access to such facilities in order that it may review and verify their operation and efficiency. Within the Commission, the Radiation Protection Unit (TREN.H4) of the Directorate-General for Energy & Transport (DG TREN) is responsible for conducting 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, as far as applicable, in the Member State concerned for:

- Levels of environmental radioactivity on the territory of the Member State;
- Liquid and airborne discharges of radioactivity into the environment from sites, and control of these discharges;
- Levels of environmental radioactivity at site perimeters and in the marine, terrestrial and aquatic environment around sites, for all relevant pathways.

A verification team from DG TREN visited Malta from 25 to 27 April 2006. The team visited facilities which are part of the Maltese national system for monitoring environmental radioactivity. The visit also included meetings with representatives of the Radiation Protection Board, the Ministry of Rural Affairs & Environment, the Ministry of Education Youth and Employment, the Malta Environment and Planning Authority, the Public Health Laboratory, the Malta National Laboratory and St Luke's Hospital. Details of the programme can be found in Section 2.2 below. The verification team acknowledges the excellent co-operation it received from all participating individuals.

The present report contains the results of the verification team's review of relevant aspects of the surveillance of environmental radioactivity on the territory of Malta.

## **2. PREPARATION AND CONDUCT OF THE VERIFICATION**

### **2.1 Introduction**

The Commission's decision to conduct verification under the terms of Article 35 of the Euratom Treaty was notified to the Permanent Representative of Malta to the European Union by a letter bearing the reference TREN/H4/CG/ab/D2006/D/201447. The Maltese Authorities subsequently designated the Radiation Protection Board (RPB) as lead Maltese Agency for preparation of the visit and co-ordination of the Maltese agencies involved.

### **2.2 Programme of the visit**

Prior to the visit, the Commission and the RPB agreed a programme of verification activities, following the modalities for the conduct of Article 35 Verifications as set out in the Commission Communication on Article 35 Verifications<sup>2</sup>.

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<sup>1</sup> Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation. (OJ L-159 of 29/06/1996, page 1).

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The opening meeting was held at the Occupational Health and Safety Authority (OHSA) in Pieta'. The following regulatory bodies made presentations:

- RPB – organizational structure, tasks, relationship to OHSA
- PHD – sampling programme, sample management and analysis
- MEPA – monitoring programme for environmental radioactivity

Slight adjustments were made to the programme during the opening meeting in order to optimise the logistics of the visit. The final programme of verification activities is attached as Appendix 1.

The programme included the verification of the control of discharges from St Luke's Hospital as well as the verification of MEPA and PHD's radiological monitoring programmes. In addition a visit was planned to the new Malta National Laboratory (MNL), whose laboratory for making measurements of environmental radioactivity was in the process of being commissioned.

The closing meeting was held on 27 April, in the presence of the responsible Permanent Secretary, Mr. Francis Borg of the Ministry of Education, Youth & Employment. The verification team presented and discussed its verification activities with representatives of the RPB, PHD and the MNL.

### 2.3 Documentation

In order to facilitate the work of the verification team, information was supplied in advance by the RPB, in the form of answers to a questionnaire prepared by the Commission services. Additional documentation and information was provided during and after the verification visit and has been drawn upon extensively in the drafting of the descriptive sections of this report.

### 2.4 Representatives of the Maltese Authorities

#### RPB

|                  |  |
|------------------|--|
| Paul Brejza      | Chairperson Radiation Protection Board                             |
| Albert Tabone    | Radiation Protection Board member from Civil Protection Department |
| Joseph Cremona   | Radiation Protection Board member from OHSA                        |
| Malcolm Micallef | Radiation Protection Board member from Public Health               |
| Louis Vella      | Radiation Protection Board member from Environment                 |

#### Nuclear Medicine Facility, St Luke's Hospital

|                 |   |
|-----------------|---|
| Anthony Samuel  | Director Medical Imaging                      |
| Edward Grupetta | Radiation Protection Unit, St Luke's Hospital |
| Karin Grima     | Radiographer within Nuclear Medicine Unit     |
| Joseph Cassar   | Manager Radiographic Services                 |

(Internet site: [www.slh.gov.mt](http://www.slh.gov.mt) )

#### MEPA

|               |   |
|---------------|---|
| Godwin Cassar | Director-General Malta Environment and Planning Authority |
| Louis Vella   | Assistant Director, Pollution Prevention & Control Unit   |

(Internet site: [www.mepa.org.mt](http://www.mepa.org.mt) )

#### Public Health Directorate

|                  |                                   |
|------------------|-----------------------------------|
| Malcolm Micallef | Director Public Health Department |
|------------------|-----------------------------------|

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<sup>2</sup> Commission Communication on the verification of environmental radioactivity monitoring facilities under the terms of Article 35 of the Euratom Treaty. Practical arrangements for the conduct of verification visits in Member States. (2006/C 155/02).

|                   |   |
|-------------------|---|
| Rose Schembri     | Chief Scientific Officer Public Health Laboratory |
| Raymond Camilleri | Scientific Officer                                |
| Doris Gambin      | Senior Scientific Officer                         |
| Reuben Micallef   | Health Inspector                                  |
| Malcolm Micallef  | Principal Health Inspector                        |
| Simone Zerafa     | Assistant Principal                               |

(Internet site: [www.sahha.gov.mt](http://www.sahha.gov.mt) )

#### Malta National Laboratory

|                  |                             |
|------------------|-----------------------------|
| Edward Xuereb    | Manager - Chemical Division |
| David Farrugia   | Scientist                   |
| David Muscat     | Scientist                   |
| Vanessa Farrugia | Scientist                   |
| Patrick Calleja  | Executive Chairman          |
| Lawrence Attard  | Marketing Executive         |

(Internet site: [www.mnl.com.mt](http://www.mnl.com.mt))

#### Government Representatives

|                  |  |
|------------------|--|
| Francis Borg     | Permanent Secretary Ministry of Education, Youth & Employment            |
| Joseph Degiorgio | Director EU Affairs Ministry of Rural Affairs & Environment              |
| Robert Tabone    | Acting Director EU Affairs Ministry of Education, Youth & Employment     |
| Mario Buttigieg  | Designate Director EU Affairs, Ministry of Education, Youth & Employment |

### **3. LEGAL PROVISIONS FOR ENVIRONMENTAL RADIOACTIVITY MONITORING**

#### **3.1 Introduction**

Malta lies approximately 95 km to the south of Sicily and 300 km to the north of the African coastline and has a total surface area of 316 km<sup>2</sup>. The Maltese archipelago comprises seven islands of which only the three largest, Malta, Gozo, and Comino are inhabited. The main island (Malta) is 27 km long. There are no permanent rivers or lakes and natural water resources are scarce: roughly half of Malta's potable water is supplied from boreholes and half from desalination plants. Malta's proximity to North Africa means that Malta is often affected by dust-laden winds blowing from the Sahara.

The islands are for the most part composed of marine sedimentary rocks, principally limestone. Therefore elevated levels of natural radioactivity and radon would not be expected and indeed levels of natural background radiation are low, of the order of 100 nSv/h or less.

There are no nuclear power plants, or other installations of the nuclear fuel cycle in Malta. The nearest large nuclear power plants and nuclear fuel cycle installations are situated more than 1200 km away, in the south of France. Malta was not significantly affected by the radioactive fall-out from the Chernobyl accident.

Malta has no producers of radioisotopes or significant NORM industries such as fertilizer production. The main applications of ionising radiation are unsealed sources used for medical purposes and sealed sources used for industrial non-destructive testing and industrial nuclear gauges. The unsealed medical sources represent the only source of planned discharges of radioactivity to the environment in Malta.

As a result of its recent accession to the European Union, Malta has brought its legal framework and procedures addressing radioactivity and nuclear issues into line with the EURATOM *acquis*, including provisions in relation to the monitoring of environmental

radioactivity, and has made efforts to establish and operate the necessary system for environmental radioactivity monitoring as per the EURATOM *acquis*.

## **3.2 Authorities involved in monitoring of environmental radioactivity**

### *3.2.1 The Radiation Protection Board*

The Radiation Protection Board (RPB) acts as the national co-ordinator for all matters concerning environmental radioactivity and radiation protection, including co-ordination of implementation of the Euratom *acquis* of primary and secondary legislation. It is responsible for reporting to the EU and international institutions in accordance with Malta's obligations. The RPB is appointed by the Prime Minister under the provisions of the Nuclear Safety and Radiation Protection Regulations (LN44/03).

The RPB is composed of representatives from four agencies:

- The Occupational Health and Safety Authority (OHSA);
- The Environment Protection Directorate of the Malta Environment and Planning Authority (MEPA);
- The Superintendent of Public Health;
- The Civil Protection Department.

Each member agency nominates one member of the Board. OHSA nominates the Chairperson of the Board (with an executive capacity), thus making OHSA the lead authority on the Board. Figure 1 below summarises the bodies represented within the RPB, their parent ministries, and their respective responsibilities as regards the environmental monitoring programme.

In the field of radiation protection, the OHSA is normally the lead Maltese agency for operational contacts to the Commission and to the IAEA. OHSA possesses a number of portable and hand-held instruments for monitoring contamination, and alpha, beta, and gamma radiation. The OHSA does not possess its own laboratory equipped for radiation measurements.



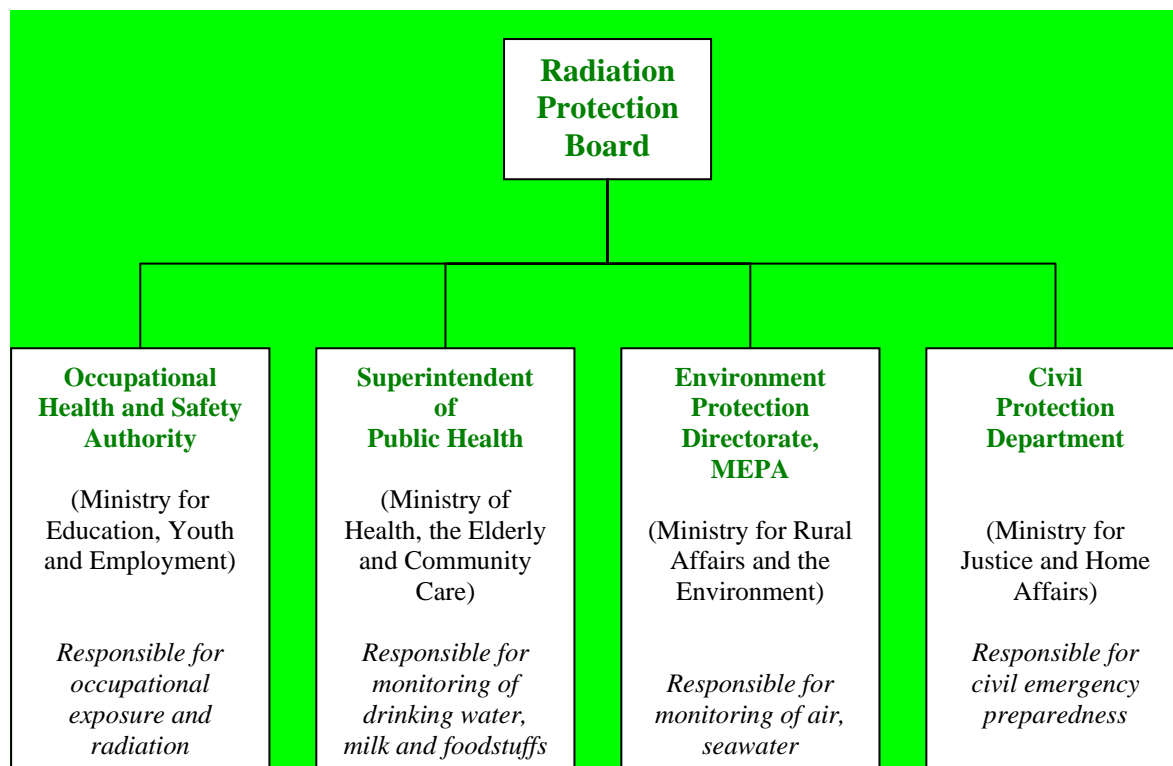


Figure 1: The Radiation Protection Board of Malta

### 3.2.2 Statutory responsibilities

The statutory responsibilities of OHSA relevant to the Euratom *acquis* are:

- Protection of workers from the risks arising from the use of ionising radiation;
- Management of the personal dosimetry data of radiation workers;
- Inspection of installations handling radioactive materials in the medical, industrial, research, and educational sectors;
- Licensing of occupational applications of ionising radiation in the industrial, research and educational sectors;
- Implementation of IAEA and Euratom Safeguards on nuclear materials;
- Licensing of import, export, transport, storage, use and disposal of nuclear materials, sealed sources and other radioactive materials;
- Licensing of the import and use of radiation producing equipment;
- Education and training of radiation workers on radiation protection issues;
- Reporting environmental monitoring data to the Commission in accordance with Euratom Article 36.

The main areas of activity of the Malta Environment and Planning Authority (MEPA) are environmental protection and development planning. The operation of Malta's environmental monitoring network, including the monitoring of radioactivity in air, soil, rainwater and seawater, falls within the remit of the Pollution Prevention and Control unit of MEPA's Environmental Protection Directorate.

The Ministry of Health, the Elderly, and Community Care is responsible for the areas which its title suggests, including Public Health. Amongst its various responsibilities, the Public Health Department (PHD) is responsible for verifying and controlling the levels of

radioactivity in drinking water, foodstuffs and milk. The execution of these responsibilities is entrusted to the Public Health Laboratory and the Health Inspectorate.

The Civil Protection Department of the Ministry of Justice and Home Affairs is responsible for preparedness and response in the event of civil emergencies, including emergencies involving radioactivity.

### 3.3 Legal framework

The legal basis for control of radioactive materials, radiation protection and monitoring of environmental radioactivity in Malta consists of:

- The EURATOM Treaty and its derived legislation;
- A number of ratified or signed conventions, agreements and other legal instruments;
- National legislation, including national legislation transposing relevant Community directives:
  - Nuclear Safety and Radiation Protection Regulations (LN44/03);
  - Sewer Discharge Control Regulations (LN139/02);
  - Importation Control Regulations (LN242/04);
  - Public Health Act (Cap. 465);
  - Food Safety Act (Cap. 449);
  - Quality of Water Intended for Human Consumption (LN23/04).

In addition a number of pieces of international guidance are applied in Malta to monitoring and control of radioactivity in the environment and in foodstuffs as follows:

- Commission Recommendation<sup>3</sup> on the application of Article 36 of the Euratom Treaty;
- IAEA Tecdoc 1000, Clearance of Materials resulting from the use of Radionuclides in Medicine, Industry and Research;
- IAEA WS/G/2.3 Regulatory Control of Radioactive Discharges to the Environment;
- IAEA Safety Report Series Generic Models for use in the Control of Radioactive Discharges to the Environment;
- Reports of IAEA Expert Missions performed in 2005 and 2006.

## 4. ENVIRONMENTAL RADIOACTIVITY MONITORING IN MALTA

### 4.1 Introduction

Because of its small size, the Maltese Authorities consider Malta to constitute a single region for the purposes of assessing radiological exposure in line with Recommendation 2000/473/Euratom. At the time of the visit there was no single national monitoring plan as MEPA was responsible for drawing up the monitoring programme relative to environmental radioactivity whilst the PHD was responsible for drawing up the programme for monitoring of radioactivity in foodstuffs, milk and drinking water. MEPA had issued a monitoring plan covering the period 2006 to 2008 whereas the Public Health Directorate's monitoring plan for food, milk and water is issued internally on an annual basis. The verification team observed

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<sup>3</sup> 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).

that the number of samples taken under the latter sampling plan varies significantly from year to year and that the sampling plan is distributed to all concerned staff through an official email.

*In view of the small number of actors involved in the Maltese programme, the verification team suggests that a single monitoring plan be produced.*

*The verification team recommends that all sampling plans be broadly consistent from year to year.*

#### **4.2 External ambient gamma dose rate**

MEPA has procured a multifunction gamma monitor; model number MFM203, manufactured by AMES of Slovenia, for continuous monitoring of the external ambient gamma dose rate. The instrument is located at the MEPA's Corridino premises. It has a measuring range of 10nSv/h to 10Sv/h and is scheduled to enter operational service early May 2006. The verification team was able to examine the instrument and the installation location.

The MEPA's 2006-2008 Environmental Monitoring Programme plans for the purchase of a second instrument, for installation on the island of Gozo.

*The verification team endorses the stated intention to install a second instrument on Gozo.*

#### **4.3 Airborne radioactivity**

The MEPA environmental monitoring plan provides for the acquisition of a high-volume air sampler, for installation at the Corridino premises, with an air throughput of 200 m<sup>3</sup>/h, twice-monthly filter change and analysis of the filters at the Malta National Laboratory. However MEPA is experiencing difficulties in drawing up technical specifications due to Malta's dry climate and its proximity to North Africa which often leads to Malta experiencing very dusty winds, blowing from the Sahara.

The Civil Protection Directorate has a low-volume air sampler available but this equipment has not been used for continuous air sampling. At the time of the verification there were no air-sampling instruments installed for continuous monitoring of radioactivity on the territory of Malta.

*The verification team recommends that the MEPA rapidly establish technical contacts with their counterparts in Member States having similar climatic conditions in order to specify suitable equipment for monitoring airborne particulates.*

*The verification team recommends that high priority be accorded to expediting the operation of the monitoring arrangements for airborne particulates as described in the MEPA's environmental monitoring plan.*

#### **4.4 Other Environmental Sampling**

The Environmental Protection Directorate is responsible for monitoring of non-potable waters. Malta has no permanent surface waters and on this basis the MEPA monitoring plan makes no provision for sampling of surface waters.

The plan also provides for limited sampling of coastal waters and soil, but at the time of the verification such samples had yet to be taken.

*The verification team recommends that MEPA bring its sampling activities into line with its declared environmental monitoring plan.*

The climate in Malta is dry and the annual rainfall is about 50 cm/year. Summer is normally rainless, precipitation normally occurs during winter (November-April) and then mostly as heavy showers. The authorities therefore consider precipitation sampling more appropriate for an emergency situation than part of a programme of continuous environmental monitoring.

#### **4.5 Monitoring of Drinking Water**

The PHD is responsible for monitoring of potable water. The verification team found that sampling and analysis of drinking water had been carried out during 2004 and 2006, but not during 2005. Samples are taken from the normal piped supply of drinking water at various locations on Malta and Gozo and are measured for gross gamma in the Public Health Laboratory. As Malta's drinking water needs are met almost equally by production from boreholes and desalination plants, it is important that both types of production are systematically sampled with roughly equal sampling frequency. Maltese competent authorities intend to include in the future national environmental monitoring plan the analysis of water samples from both boreholes and desalination plants.

*The verification team endorses the stated intention to monitor drinking water in such a way that it reflects the relative contributions of both types of water supply.*

During 2006 water samples were also sent to an accredited laboratory in another Member State for tritium, total alpha, total beta, and Sr-90 analysis. Measurement results are transmitted by PHD to the OHSA for forwarding to the Commission for inclusion in the REM database.

#### **4.6 Monitoring of milk**

Like the sampling plans for potable water, sampling plans for milk vary from year to year (see recommendation made under 4.1 above). Indeed no milk samples were taken during 2004. The 2005 samples, covering both imported and domestic milk production, were analysed in the Public Health Laboratory.

#### **4.7 Foodstuffs – mixed diet**

One sample per year of mixed diet is taken from St Luke's Hospital and from Gozo General Hospital. The 2005 samples were analysed for gross gamma in the Public Health Laboratory and the 2006 samples were sent to an accredited laboratory in another Member State.

### **5. LABORATORIES INVOLVED IN MALTA'S ENVIRONMENTAL MONITORING PROGRAMME**

#### **5.1 Public Health Laboratory**

The Public Health Department is responsible for the surveillance of the safety of food in Malta. The Public Health Laboratory (PHL) is one of the five sections of the Department of Public Health. The laboratory is located in Valletta and is equipped to test water and food for chemical and bacteriological analysis. PHL also performs measurement of samples in a laboratory in St. Lukes Hospital, Guardamangia in which gamma spectrometry of foodstuffs and drinking water can be carried out. This laboratory was created in the wake of the Chernobyl accident.

Some samples are also sent for analysis in accredited laboratories in other member states because the low demand for measurements of certain types of radioactivity does not justify the laboratory having its own facilities. In addition, samples may also be sent for analysis abroad as part of the laboratory's quality control measures.

The only instrument at the PHL for measurements of environmental radioactivity is a gamma spectrometry system composed of a Canberra model GC-2518 coaxial Ge detector mounted inside a lead/copper low background shielding, cooled by a Canberra model 7500SL low background cryostat and connected to a NIM rack containing the power supply, amplifier, and ADC. Spectrum analysis is carried out using the proprietary Genie 2000 package. Almost the only use made of the instrument is for making gross gamma measurements of food, milk and water samples from the PHD's environmental monitoring programme. Other measurements, for example tritium or gross alpha, are performed at a laboratory, outside Malta, which has been ISO 17025 accredited for the measurements in question.

## **5.2 Malta National Laboratory Co. Ltd.**

As part of the Malta's preparations for EU membership the Malta National Laboratory Co. Ltd (MNL) was set up in 1999, financed through pre-accession funding from the European Union. It was established as a largely self-financing, independent, non-profit making body, to provide scientific testing services to the Maltese public and private sectors.

MNL is in the process of being accredited by the National Accreditation Board of Malta against ISO 17025. In the future, it is intended to include radioactivity measurements in the scope of the accreditation, but work on this has not yet begun.

The measurement and testing services of MNL are organised into four divisions: Chemical, Biological, Forensic, and Engineering. Radioactivity analysis is part of the Chemical division, which has four graduate scientists, of whom two are trained for analysis of radioactivity.

MNL cooperates extensively with the IAEA. In the frame of a Technical Cooperation Project (MAT/9/003) MNL receives equipment and training from the IAEA.

The chemical laboratory has sections dealing with sample registration, sample preparation and measurements. The analytical equipment for measurements of radioactivity includes:

- One Ortec high performance Ge-detector running Ortec's GammaVision® software;
- One liquid scintillation counter (Perkin Elmer 3170TR/SL) with Perkin Elmer QuantaSmart® software for gross beta, Sr-90 and Tritium determination;
- Eight planar silicone detectors (ORTEC Octetes) with ORTEC AlphaVision® software for alpha analysis.

The laboratory is in the process of developing methods for analysing samples of soil, drinking water, sea water, and filters from air samplers.

Although MNL has contacts with MEPA, at the time of the verification, no contracts were in place between MNL and the Maltese Government's services concerning involvement in the Maltese environmental monitoring programme.

## **6. VERIFICATION ACTIVITIES - ENVIRONMENTAL MONITORING**

### **6.1 St. Lukes's Hospital, Guardamangia – Nuclear Medicine Facility**

Commission verifications according to Article 35 may extend to all facilities with the potential for discharging radioactivity to the environment. The only such facilities in Malta are hospitals.

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Therapeutic nuclear medicine is carried out at Sir Paul Boffa Hospital in the Oncology Department, mostly involving the use of I-131 for the treatment of hyperthyroidism and differentiated thyroid cancer.

Diagnostic nuclear medicine is carried out in the Department of Medical Imaging of St Luke's Hospital. This department is currently equipped with one single-headed gamma camera and has its own shielded facilities where radiopharmaceuticals are prepared daily. 2500 procedures are performed annually in this unit using Tc-99m, I-131, Ga-67 and Tl-201. Bone and cardiac scintigraphy are the most commonly performed procedures but a comprehensive range of diagnostic procedures is available including central nervous system imaging, lymphoscintigraphy and parathyroid imaging.

St. Luke's Hospital in Guardamangia was selected for verification of the system established for controlling discharges of radioactivity to the environment. A fraction of the administered doses are passed as urine in the facility's toilets, the discharges from which are collected in decay holding tanks prior to discharge to the public sewer.

The second waste stream consists of solid wastes including Tc-99m generators, empty source vials, contaminated tubing and so forth. Solid wastes are held in the storage bunker pending decay to the clearance levels set out in the Nuclear Safety and Radiation Protection Regulations of 2003.

St. Luke's certificate of authorisation for accumulating and discharging radioactive waste from unsealed sources (reference M7/AD01/01) was issued by the RPB in accordance with the Nuclear Safety and Radiation Protection Regulations of 2003. It covers the clearance of solid wastes and the discharge of aqueous solutions to the public drain. OHSa carries out environment and radio-protection inspections of the Nuclear Medicine Facility.

The principal component of the solid waste produced by the facility is spent technetium generators. These are held in the facility's shielded storage bunker whilst radioactivity levels decay down to clearance levels. Each technetium generator is numbered. The arrival date and the reference date of the generator are recorded. The dismantling procedure requires that the generators be kept for a minimum of 13 weeks before dismantling. The team noted that the dismantling procedure pre-dates the certificate of authorisation and is in need of updating to be consistent with the certificate of authorisation. The radioactivity measurements are made with a Geiger-Müller probe, which was not subject to periodic re-calibration.

*The verification team suggests that the dismantling procedure be updated to ensure consistency with actual practice and the certificate of authorisation for accumulating and discharging radioactive materials, and to ensure that the measurement probe is recalibrated periodically.*

The principal component of the facility's liquid waste discharges consists of the discharges from the patients' toilets, supplemented by discharges of excess or unused radiopharmaceuticals. The outflow from the patients' toilets is collected in one of two decay tanks where it is typically held for 14 days before discharge to the public drain. Discharges are made in the presence of the Health Physicist. However, no measurement or estimate is made of the actual radionuclide inventory of the tank before discharge. Instead compliance with the discharge authorisation is ensured by estimating the fraction of the administered radionuclide activity which would have been passed in the patients' toilets.

*The verification team recommends that discharge procedure for the liquid waste decay tanks be reviewed to ensure direct compliance with the discharge authorisation.*

## 6.2 Public Health Laboratory in Valetta and laboratory facility at St. Luke's Hospital, Guardamangia

The verification team visited both the Public Health Laboratory in Valetta and the laboratory facility at St. Luke's hospital where gamma spectrometry is performed.

### 6.2.1 Sampling, registration, archiving and reporting at PHL in Valletta

The PHD's Inspectors sample milk, drinking water and mixed food diet in accordance with the annual programme issued by PHD. The samples are taken to the PHL in Valetta where they are registered and given an identification number, which follows the sample throughout the measurement procedure. Samples which require mechanical treatment such as homogenisation are treated in the Sample Preparation Area at the PHL in Valletta, although at the time of the verification visit this facility was closed for refurbishment, and therefore operations there could not be verified.

Depending upon the analyses to be performed samples are either sent to the laboratory at St Luke's for gamma measurements or sent to a laboratory outside Malta if other analyses are to be performed. The results of the measurements are recorded on the sample request form and then taken to Valetta for entry in the food-stuffs database or water database as appropriate. The databases are on the Government server and are backed up every night. After verification by the Chief Scientific Officer of the PHL, the results are transmitted to the OHSa for forwarding to the Commission's Joint Research Centre in Ispra.

The PHD applies to the samples taken for measuring radioactivity in water and food-stuffs the same management system that it uses for other types of sample taken within its remit, such as samples for environmental health purposes. As the results of measurements of the latter may be used in prosecutions and may thus be challenged in court, the management system applied must be robust. The verification team followed the "paper trail" left by imported skimmed milk sampled by the PHD's Inspectors in 2005, from sample taking through to final reporting. Based upon this, sample management within the PHD appears well controlled, although the version of the result reporting form in use at the time of the visit did not make provision for recording authorisations.

*The verification activities with respect to sample management by the PHD do not give rise to any particular remarks.*

### 6.2.2 PHL facilities at St. Luke's Hospital

The verification team visited the PHL facilities for analysis of radioactivity at St Luke's hospital and verified the presence and operability of the instruments.

The laboratory is equipped with a Canberra gamma spectrometry system as described in Section 5.1 above. Five members of the PHL staff have received training sponsored by PHD from an IAEA consultant on the use of the instrument. The system is only used infrequently for measurements of samples. Nonetheless, it is kept in an operational state throughout the year by weekly filling of the instrument's dewar flask and roughly monthly checks on the instrument's energy calibration using a Co-60 source. Samples are weighed into 500 ml or 1000 ml Marinelli beakers for measurements. When samples are being measured, an air blank measurement is also performed as a check on the instrument's operation. There is a written procedure covering sample preparation and gamma spectrometric measurements. However, the procedure concentrates on how to run the software and makes no mention of quality related matters such as checks on the spectrum, e.g. FWHM of a peak, blanks, calibration.

Calibration is performed every six month using a standard multi-energy source from Amersham, the manufacturer's certificate of which was verified by the team. Calibrations are recorded by the spectrometer's software. The verification team was able to satisfy itself that calibrations had taken place in January 2004 and March 2006.

The Public Health Laboratory has begun work on implementing a formal Quality Management system in accordance with ISO 17025 which it hopes to have accredited by the Malta Standards Authority and it is intended to include the gamma testing within the scope of this laboratory-wide Quality Management System. The laboratory has participated in international inter-laboratory comparison exercises, including one such exercise for powdered milk organised by the European Commission's Institute for Reference Materials and Measurements.

*The verification team endorses the stated intention of introducing an accredited, ISO 17025 Quality Management System, which would address the quality issues identified above.*

### 6.2.3 Mixed food diet sampling at St Luke's hospital

The verification team witnessed food sampling at St. Luke's Hospital performed by a Health Inspector from the PHD. The Public Health Inspectors apply the same sampling protocols to sampling food for analysis of its radioactivity as they apply to sampling food for chemical or bacteriological analysis, thereby affording the radioactivity samples the same degree of protection and traceability as food samples taken for fitness for consumption. The origin of the food sampled is traceable through the purchasing records of the hospital's stores.

For mixed food diet, one ward is selected and the Inspector takes samples from the meals served for breakfast, lunch and dinner, ensuring that the meals do not represent a special diet. Samples of water are taken from the hospital's drinking water supply. Sub-samples are packed together in a temperature controlled package, a numbered seal is applied, and the package is then transferred to the PHL in Valletta for registration.

*Verification activities did not give rise to any particular remarks.*

## 7. CONCLUSIONS

All verifications that had been planned by the verification team were completed successfully. In this regard, the information supplied in advance of the visit, as well as the additional documentation received before the start and during the verification, was useful. The information provided and the outcome of the verification activities led to the following observations:

- (1) The verification activities that were performed demonstrated that some of the monitoring devices necessary to carry out continuous monitoring of levels of radioactivity in the air, water and soil in Malta are newly installed or in an advanced phase of planning.
- (2) The team noted that current monitoring campaigns are not yet part of a well established routine programme, and it strongly encourages the efforts undertaken to consolidate such a routine programme.
- (3) A number of recommendations have been formulated. These recommendations aim at improving some aspects of environmental surveillance in Malta. The



recommendations do not detract from the fact that environmental monitoring in Malta is soon expected to be in conformity with the provisions laid down under Article 35 of the Euratom Treaty.

- (4) The verification findings and ensuing recommendations are compiled in the ‘Main Findings’ document that is addressed to the competent authority in Malta through the Permanent Representative of Malta to the European Union.
- (5) The present Technical Report is to be enclosed with the Main Findings.
- (6) The Commission Services ask the Maltese competent authority to inform them of any implementation achievements with regard to the situation at the time of the verification. The full implementation of a routine environmental radioactivity monitoring programme, including the installation and functionality of all projected new equipment and of the recommendations issued by the verification team, shall be confirmed by 2008.

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**APPENDIX 1**

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| <p><b>VERIFICATION PROGRAMME</b></p> |
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**Tuesday 25 April**

1. Opening meeting: introduction and presentations at OHSA premises in Pieta<sup>(4)</sup>
2. Verification activities: visit to Nuclear Medicine facility to evaluate management of environmental discharges, St Lukes Hospital, in Guardamangia.
3. Visit to facilities for measuring ambient gamma, in Corradino

**Wednesday 26 April**

4. Continuation of verification activities: visit the Public Health ( food and drinking water sampling) at the St Lukes Hospital, Post Natal Ward
5. Continuation of verification activities: visit Public Health Laboratory, at Valletta

**Thursday 27 April**

6. Continuation of verification activities: visit Malta National Laboratory Company, at San Gwann
7. Closing meeting with the Maltese authorities at OHSA premises, in Pieta. Presentation of preliminary conclusions.

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<sup>4</sup> By those ministries and/or institutions that have statutory obligations with respect to national radiation monitoring and to site surveillance.

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