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TREN.H.4 – Radiation Protection

Main Findings of the Commission's Article 35 verification in Hungary

Paks nuclear power plant

Date: 8 to 12 November 2004

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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.

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

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 exposure pathways.
- Levels of environmental radioactivity on the territory of the Member State.

For the purpose of such a review a verification team from European Commission visited, from 8 to 12 November 2004:

- The Paks nuclear power plant (hereafter Paks NPP) and its surrounding area.
- The Regional Laboratory of the Radiological Monitoring and Data Acquisition Network of the Ministry of Health, located at Szekszárd (near Paks).
- The Central Radiohygiene Laboratory of the he National Research Institute for Radiobiology and Radiohygiene of the Ministry of Health, located at Budapest.

- The Radiochemistry Laboratory of the National Food Investigation Institute of the Ministry of Agriculture, located at Budapest.
- The Nuclear Emergency Information and Analysis Centre of the National Directorate General for Disaster Management of the Ministry of the Interior, located at Budapest.

With due consideration of the scope of the verification mission and taking into account the relatively short time available for the execution of the programme, emphasis was put on:

- The operator's (Paks NPP) statutory monitoring and control facilities for liquid and airborne discharges of radioactivity into the environment.
- The operator's statutory environmental radioactivity monitoring programme.
- The operator's analytical laboratories for discharge and environmental samples, including aspects of quality assurance and control as well as document control.
- The independent discharge monitoring programme as performed by the competent authority (regulatory control).
- The independent environmental radioactivity monitoring programmes around the Paks site as performed by the competent authorities (check monitoring).
- The competent authorities' analytical laboratories for environmental samples, including aspects of quality assurance and control as well as document control.

The present report gives an overview of the main findings of the verification team and corresponding recommendations.

Recommendations are addressed to the Hungarian Atomic Energy Authority.

MAIN FINDINGS

The proposed verification programme could be completed within the time allocated. In this regard the verification team appreciated the advance information supplied, as well as the additional documentation received during and after the verification.

1. Main findings with respect to the operator's radioactive discharge monitoring programme and related regulatory control

The verification activities performed at the facilities for monitoring and sampling of liquid and airborne discharges of radioactivity into the environment:

1.1 Confirmed the existence and functionality of monitoring and sampling facilities as defined in the regulatory obligations.

1.2 Confirmed that discharges of liquid and airborne radioactivity are monitored and sampled in accordance with regulatory obligations.

1.3 Established that the monitoring and sampling facilities are in general adequate and that the programmes of sampling of liquid and airborne discharges are satisfactory.

1.4 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions.

However,

1.5 With respect to point 1.3 above, for airborne discharges, the verification team noted that, in the central ventilation duct, the position of the primary sampling line nozzles (relative to other components of the system) is such that the representativeness of the sampling may not be fully ensured.

It is recommended that the competent regulatory authority undertakes investigative action and enforces remediation if necessary, so as to be satisfied that the primary sampling line is taking representative airborne discharge samples.

1.6 With respect to point 1.3 above, for airborne discharges, the verification team noted that, at the Dosimetry Control Room, the electronic mimic diagram indicating the operational status of the various components of the primary sampling lines, lacked coherence in the use of colour codes. The verification team was notified that the mimic diagram required some adjustments. Control room staff admitted that, based on the information provided by the mimic diagram in question, they could not have unambiguous knowledge about the actual configuration of the sampling system.

It is recommended that the competent regulatory authority ensures that the mimic diagram indicating the operational status of the various components of the primary sampling lines be overhauled so as to correctly reflect the physical situation present on plant.

1.7 With respect to point 1.3 above, for airborne discharges, the verification team noted that, although present and operational, the sampling devices for H-3 and C-14 belonging to the competent regulatory authority are not yet in use. The verification team was notified that independent check monitoring of H-3 would start in the year 2005. The verification team was also notified that C-14 check monitoring would only be initiated when the authority's laboratory will have obtained accreditation for C-14 measurements (this is expected to occur by the end 2006 - beginning 2007).

It is recommended that the competent regulatory authority takes advantage of its sampling systems for airborne C-14 and H-3 as early as possible.

1.8 With respect to point 1.3 above, for liquid discharges, the verification team noted the absence of facilities that automatically interrupt a discharge in case an activity concentration above set limits is detected. It is generally considered to be good practice to have such an automated discharge control on liquid effluents.

It is recommended that the competent regulatory authority considers the benefit of Paks NPP installing additional means of liquid discharge control. Current provisions are unsatisfactory insofar that the absence of automated emergency closure of discharge tank valves may lead to uncontrolled release of activity into the environment.

1.9 With respect to point 1.4 above, for liquid discharges, the verification team noted that, contrary to the procedural requirements laid down in quality assurance document ELJ-

ÜZVT-03-04 (release rules for contaminated effluents), discharge valve 02TM55S002 was not sealed. Sealing of valves is integral part of the discharge control rules to prevent unauthorised discharges.

It is recommended that the competent regulatory authority, through its inspectorate, ensures that any slackening in the application of the operator's internal quality assurance and control rules for discharges of activity into the environment be promptly detected and remedied.

2. Main findings with respect to the operators' analytical laboratory for discharge samples and related regulatory control

The verification activities performed at the analytical laboratory for liquid and airborne discharges samples:

2.1 Established that the laboratory is well equipped and satisfactorily staffed with adequately trained personnel.

2.2 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions (accreditation NAT-1-1195/2003).

However,

2.3 With respect to point 2.2 above the verification team took note of the procedures applicable to accounting and reporting of measurement results that are below detection limit. In this context the verification team should like to recall that the European Commission issued Recommendation 2004/2/Euratom [(1)] wherein substitution rules for values below the detection limit are presented. Such rules are proposed to avoid unnecessary over- or underestimation of discharged activities. These substitution rules are in line with ISO standard 11929-7:2005.

It is recommended that the competent regulatory authority considers the benefit of revising its regulatory requirements for substitution of analytical results below detection limit by bringing these requirements in line with Commission Recommendation 2004/2/Euratom and ISO standard 11929-7:2005.

2.4 With respect to point 2.2 above the verification team noted that he chain of custody of sample taking, sample preparation and analysis, data handling and document control is well defined and that the responsibilities of individuals are clearly established. However, when performing a vertical audit on a randomly chosen historical sample, the verification team noted that clerical errors are not systematically detected. The team therefore believes that, with respect to quality assurance and control, there is still room for improvement.

It is recommended that the competent regulatory authority advises its on-site inspectorate to submit the quality assurance and control procedures of the Paks NPP Effluent Laboratory to an audit and to require remedial action wherever deemed necessary.

[1] Official Journal L 002, 06/01/2004 P. 0036 - 0046

3. Main findings with respect to the operators' environmental monitoring programme

The verification activities performed at the facilities for monitoring and sampling the environment on and around the Paks NPP site:

3.1 Confirmed the existence and functionality of monitoring and sampling facilities as defined in the regulatory obligations.

3.2 Confirmed that the levels of radioactivity in the environment are monitored and sampled in accordance with regulatory obligations.

3.3 Established that the monitoring and sampling facilities are in general adequate and that the programmes of sampling are satisfactory.

3.4 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions.

The verification activities performed do not give rise to any specific recommendation.

4. Main findings with respect to the operators' analytical laboratory for environmental samples and related regulatory control

The verification activities performed at the analytical laboratory for environmental samples:

4.1 Established that the laboratory is well equipped and satisfactorily staffed with adequately trained personnel.

4.2 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions (accreditation NAT-1-1135/2003).

However,

4.3 With respect to point 4.2 above the verification team noted that the current procedures for quality assurance and control of the gamma spectrometry systems, although accepted by the National Accreditation Board, leave room for improvement. Indeed, control over the stability of the systems can be strengthened (and simplified) through the installation of commercially available software modules. Such software tools allow for an easy follow-up and thus early spotting of any deterioration of detector resolution.

It is recommended that the competent regulatory authority considers the benefit of requiring the operator to strengthen its quality assurance and control capability over gamma spectrometry systems through the acquisition and installation of dedicated software modules.

4.4 With respect to point 4.2 above the verification team noted that sample information and corresponding analytical results are manually transferred into (and between) multiple electronic supports (word processors, spreadsheets, databases). This situation is insofar unsatisfactory as the risk of easily and unwittingly introducing clerical errors is clearly present.

It is recommended that the competent regulatory authority considers the benefit of requiring the operator to enhance its quality assurance and control capability over data handling through the implementation of electronically automated data transmission routines wherever relevant.

4.5 Further to point 4.4 the verification team also noted that the chain of custody for data handling and document control is not fully satisfactory. Members of staff that handle data and generate reports are not nominally registered. Reports are only signed by the laboratory leader. The chain of custody for data handling and subsequent reporting should be kept intact: members of staff that generate reports should sign these before final acceptance and validation (countersignature) by the duly authorised person.

It is recommended that the competent regulatory authority considers the benefit of requiring the operator to improve its quality assurance and control capability with respect to reporting through the implementation of an intact chain of custody, from data handling to final reporting (to the regulator).

5. Main findings with respect to the Central Radiohygiene Laboratory of the National Research Institute for Radiobiology and Radiohygiene of the Ministry of Health

The verification activities performed at the Central Radiohygiene Laboratory:

5.1 Established that the scope of the national radiological monitoring programme of the Ministry of Health, through the implementation of its Radiological Monitoring and Data Acquisition Network under the lead of the Central Radiohygiene Laboratory, is satisfactory.

5.2 Established that the laboratory is well equipped and satisfactorily staffed with adequately trained personnel.

5.3 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions (accreditation NAT-1-0969/2002).

However,

5.4 With respect to point 5.1 above the verification team noted that the laboratory, and by extension, the whole Radiological Monitoring and Data Acquisition Network is currently not equipped with means to measure C-14 in mixed diet samples. This type of measurement is mentioned in Commission Recommendation 2000/473/Euratom [(2)] on the application of Article 35 of the Euratom Treaty.

It is recommended, taking into consideration Commission Recommendation 2000/473/Euratom, that the competent authority provides the Central Radiohygiene Laboratory of the National Research Institute for Radiobiology and Radiohygiene with the means to implement C-14 measurements on mixed diet samples that are taken within the Radiological Monitoring and Data Acquisition Network.

[2] Official Journal L 191, 27/07/2000 page 37

5.5 With respect to point 5.1 above the verification team noted that the Central Radiohygiene Laboratory voluntarily developed a site-related environmental monitoring programme applicable to the campus of the National Research Institute for Radiobiology and Radiohygiene. This surveillance programme is integral part of the Radiological Monitoring and Data Acquisition Network.

At the time of the visit the team observed that the installed monitoring and sampling facilities were functional. It was noted that the on-line alpha and beta aerosol monitoring system was in a test phase, awaiting approval to replace the outdated low-volume air sampler. This on-line system will become, when approved, one of the monitoring devices of the national 'sparse' network (compliance with Commission Recommendation 2000/473/Euratom on the implementation of Art.36 of the Euratom Treaty). However, it was also noted that back-up power supply is provided by the site's diesel generator that needs a manual start-up and, furthermore, that the system relays alarms to a PC in one of the offices of the laboratory but that these alarms are not transmitted to an on-call member of staff.

It is recommended that the competent authority provides the Central Radiohygiene Laboratory with the means to equip the on-line alpha and beta aerosol monitor (located on the campus of the National Research Institute for Radiobiology and Radiohygiene) with a guaranteed non-interruptible power supply and a 24/24 hour alarm raising capability. Such an upgrade would ensure state-of-the-art continuous monitoring capabilities.

5.6 With respect to point 5.3 above the verification team noted that the Central Radiohygiene Laboratory, in its function as head laboratory of the Radiological Monitoring and Data Acquisition Network, does not submit the environmental data it receives from the regional laboratories to a formal validation. This quality assurance responsibility is left with the regional, non-accredited, laboratories.

It is recommended that the competent authority considers the benefit of requiring the Central Radiohygiene Laboratory of the National Research Institute for Radiobiology and Radiohygiene to put in place, in the framework of general quality assurance and control, a system of formal validation of the environmental monitoring results it receives from its non-accredited regional laboratories.

5.7 With respect to point 5.3 above the verification team noted that the electronic database for the Radiological Monitoring and Data Acquisition Network is a home-made application. The developer of this application is the only member of staff having the knowledge to maintain the tool and to guarantee its operability. Although a highly commendable effort, it would be beneficial, in the long run, to replace the current database with a professional software tool. Such a replacement should, ideally, provide automated data exchange (and validation) facilities between the Central Radiohygiene Laboratory and its depending regional laboratories. Streamlined data exchange with other data providing bodies should also be envisaged. Finally, the database should include automated reporting facilities, at national as well as at international level.

It is recommended that the competent authority, with a view to ensure the durability of the environmental data collected in the framework of the Radiological Monitoring and Data Acquisition Network, provides the Central Radiohygiene Laboratory with the

means to acquire a database using a professional software and with a guarantee of long-term maintenance. It is also recommended to envisage that such a database would become the repository for radiological environmental data from other bodies active in this domain.

6. Main findings with respect to the Regional Laboratory (Tolna County) of the Radiological Monitoring and Data Acquisition Network of the Ministry of Health

Besides being part of the Radiological Monitoring and Data Acquisition Network, the Regional Laboratory also participates in the Paks NPP-related check monitoring programme (within a 30km radius around the Paks NPP).

The verification activities performed at the Regional Laboratory:

6.1 Established that the laboratory is well equipped and staffed with adequately trained personnel.

6.2 Established that quality assurance and control documentation (written procedures and working instructions) is under development, with the aim to obtain accreditation. The verification team endorses the efforts made by the Regional Laboratory to achieve this.

6.3 Established that the programme of activities performed by the laboratory, in the framework of the Radiological Monitoring and Data Acquisition Network and the check monitoring programme around the Paks NPP, is satisfactory.

However,

6.4 With respect to points 6.1 and 6.2 above the verification team, observing that the obtention of accreditation generates a significant additional workload, took note of the relative understaffing of the laboratory.

It is recommended that the competent authority provides the Regional Laboratory with the means (staff and budget) to achieve accreditation within reasonable delays, especially since this laboratory is not only responsible for regional environmental monitoring (within the Radiological Monitoring and Data Acquisition Network) but also participates in the check monitoring programme around the Paks NPP.

7. Main findings with respect to the Radiochemistry Laboratory of the National Food Investigation Institute of the Ministry of Agriculture

The verification activities performed at the Radiochemistry Laboratory:

7.1 Established that the scope of the national radiological monitoring programme of the Ministry of Agriculture, through the implementation of its Monitoring Network for Radioactivity in Food and Environment, under the lead of the Radiochemistry Laboratory, is satisfactory.

7.2 Established that the laboratory is well equipped and staffed with adequately trained personnel.

7.3 Established that quality assurance and control is implemented through a compilation of written procedures and working instructions (accreditation NAT-1-1160/2003).

However,

7.4 With respect to point 7.2 above the verification team noted that the number of staff is reduced to its strict minimum. In case of absence of one member of staff the Radiochemistry Laboratory is at risk of losing its continuity of measurement capability, systems maintenance and data management.

It is recommended that the competent authority provides the Radiochemistry Laboratory with sufficient means to ensure permanent availability of such competence that is necessary to fully implement the laboratory's statutory sample analysis programme at any time.

7.5 With respect to point 7.2 above the verification team noted that the single member of staff that is responsible for liquid scintillation counting, performs manual parameter setting of the counting device. The verification team believes that this practice, while fully acknowledging the expertise of the said member of staff, may lead to mistakes. Also, because subjective parameters are involved in spectrum analysis, this may lead to insufficient reproducibility of the results obtained.

It is recommended, in the general framework of quality assurance and control, that the competent authority provides the Radiochemistry Laboratory with the means to acquire dedicated software for gamma and liquid scintillation spectrum analysis.

8. Main findings with respect to the Nuclear Emergency Information and Analysis Centre of the National Directorate General for Disaster Management of the Ministry of the Interior

The verification team received an extensive briefing about the emergency preparedness and response capabilities that are in place in Hungary.

The information received does not give rise to any specific observation.

9. Other recommendations

9.1 With respect to general aspects of quality assurance and control at the Paks NPP

The verification team received, during and after its mission in Hungary a large number of documents. These documents were of various types such as source documents, explicative notes, reports; but also copies of quality assured documents and documents explaining regulatory requirements.

When studying the quality assured documentation it received, i.e. excerpts of the Quality Handbook, the team noted that the information provided therein was not always consistent. Such inconsistencies occur between the various departments of the plant that are at the origin of the documents. Examples of such inconsistencies can be found with respect to technical characteristics of monitoring and sampling equipment. This seems to indicate that the management of quality assurance and control documentation is not fully mastered. The

team, although acknowledging that the monitoring and sampling provisions are in a transition phase - and thus require overhaul of the quality assurance and control documentation - takes the point of view that quality assurance and control management at the Paks NPP, with regard to discharge control, environmental monitoring and respective laboratories, is not sufficiently robust.

These findings, in conjunction with the remarks and recommendations made under sections 1, 2 and 3 above, leads to the following:

> *It is recommended that the competent regulatory authority undertakes the necessary steps to enforce the Paks NPP to strengthen its control over - and improve its management of - internal quality assurance and quality control procedures and related documentation.*

9.2 With respect to the organisation of the Radiological Monitoring and Data Acquisition Network of the Ministry of Health

The Central Radiohygiene Laboratory of the National Research Institute for Radiobiology and Radiohygiene, as top level laboratory of the Radiological Monitoring and Data Acquisition Network, is an accredited laboratory. The Regional Laboratory at Tolna County is trying to obtain accreditation but faces staffing budgetary problems that slow down this process. The verification team endorses the efforts made to obtain accreditation, all the more since the Tolna County laboratory not only has statutory duties within the Radiological Monitoring and Data Acquisition Network, but also plays a major role in the independent check monitoring around the Paks NPP.

The National Research Institute for Radiobiology and Radiohygiene, and through it the competent authority, centrally regulates and finances the number and type of analytical equipment the various laboratories of the Radiological Monitoring and Data Acquisition Network must possess. This centralised management expresses itself also where it concerns the scope of the Radiological Monitoring and Data Acquisition Network: the monitoring and sampling programme is reviewed each year and must be validated by the competent authority before the tasks can be distributed to the various laboratories that are part of the network.

Taking into consideration Article 36 of the Euratom Treaty, the implementation of which seems to devolve to the National Research Institute for Radiobiology and Radiohygiene, the verification team would like to encourage the competent authority to consider whether it should not also centralise quality assurance and control for the whole Radiological Monitoring and Data Acquisition Network.

The verification team takes the point of view that it would be beneficial should the National Research Institute for Radiobiology and Radiohygiene take the responsibility to ensure that sampling and analysis methodologies as well as the related quality assurance and control documentation would be unified throughout the network.

These findings, in conjunction with the remarks and recommendations made under sections 5 and 6 above, leads to the following:

> *It is recommended that the competent authority, taking into account that the monitoring programme and laboratory equipment are already centrally managed,*

should investigate whether it would not be beneficial for the Radiological Monitoring and Data Acquisition Network if sampling and analysis methodologies as well as related quality assurance and control documentation would be unified and centrally managed.

9.3 With respect to the National Environmental Radiation Monitoring System (NERMS)

NERMS (Decree 275/2002 (XII.21) Korm on the monitoring of the national environmental radiation situation and levels of radioactivity) is a legally based project that aims at integrating the data of the various Hungarian environmental monitoring networks into a single, consolidated database. Such integration is necessary to efficiently comply with Commission Recommendation 2000/473/Euratom on the application of Article 36 of the Euratom Treaty.

Article 36 of the Euratom Treaty stipulates that "The appropriate authorities shall periodically communicate information on the checks referred to in Article 35 to the Commission so that it is kept informed of the level of radioactivity to which the public is exposed." It is understood that the Ministry of Health, through the National Research Institute for Radiobiology and Radiohygiene, should become the designated body that will discharge Hungary from this responsibility.

However, in order to successfully perform the above task, the National Research Institute for Radiobiology and Radiohygiene will become heavily reliant on relevant information it must receive from other (regulatory) bodies that operate under various ministries having their own and specific monitoring programmes. This transmission of information is essential because the Ministry of Health's existing monitoring programme, the Radiological Monitoring and Data Acquisition Network, does not cover all the topics that are listed in Recommendation 2000/473/Euratom.

It is noted that the various environmental monitoring programmes that are currently implemented in Hungary are in many cases overlapping if not partially redundant. The ministries involved are thus sometimes unnecessarily duplicating efforts. The means that Hungary devolves to radiological monitoring of the environment are thus not optimally put into effect. In this context it does not seem appropriate to require that the Radiological Monitoring and Data Acquisition Network be developed and extended to cover the full scope of Recommendation 2000/473/Euratom, because in doing so it will add to the duplication of effort.

It is also understood that the role the Hungarian Atomic Energy Authority (HAEA) can play in the integration process is limited. Decree 114/2003 (VII.29) Korm stipulates that the HAEA should act as co-ordinator in these matters, without however explicitly providing the HAEA with the necessary powers to enforce such an integration. The success of the integration will therefore more or less depend on the goodwill of the ministries that are currently involved in environmental monitoring.

Therefore:

It is recommended that the Hungarian Government addresses the current complexity of ministerial responsibilities in the area of radiological environmental surveillance related to Articles 35 and 36 of the Euratom Treaty.

CONCLUSIONS

10.1 The verification visit was successful and the objectives of the review were met. Within the remit of verification activities under Article 35 of the Euratom Treaty it has been demonstrated that the facilities necessary to carry out continuous monitoring of levels of radioactivity in the air, water and soil around the Paks NPP site and on the territory of Hungary are adequate. The Commission could verify the operation and efficiency of these facilities.

10.2 However, some shortcomings were noted and lead to recommendations by the Commission to the Hungarian competent authorities with the aim to achieve improvements. It should be noted that these recommendations do not discredit the fact that radiological environmental monitoring in Hungary is in conformity with the provisions laid down in Article 35 of the Euratom Treaty.

10.3 The Commission would appreciate being kept informed about the actions the Hungarian competent authority may undertake in the framework of the recommendations made.

10.4 Finally, the verification team acknowledges the excellent co-operation it received from all persons involved.

[signed]

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