

## **Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Commission on "Occupational radiation exposure data"**

Brussels, 5 November 2008 (Case 2007/383)

### **1. Proceedings**

On 6 June 2007 the EDPS received a notification for prior checking from the Data Protection Officer (DPO) of the European Commission on "Occupational radiation exposure data" at unit H.04 of the Directorate General Energy and Transport of the European Commission (hereinafter as: "DG TREN").

On 11 July 2007 a first request for information was sent to the controller. A further request was made on 4 September 2007 which was answered to on 6 September 2007. Some questions remained unanswered at this stage so the prior checking case remained suspended. A further request was made on 20 December 2007. An answer was provided to the EDPS on 25 September 2008.

The prior check opinion was sent to the controller for comments on 10 October 2008. These were provided on 3 November 2008.

### **2. The facts**

Under the European Union radiation protection legislation, the European Commission is obliged to implement appropriate measures for the radiological control and monitoring of all members of staff who are classified as occupationally exposed to ionising radiation in the course of their work. In order to ensure the legitimate performance of radiological surveillance and the implementation of fundamental principles governing operational protection of exposed workers the DG TREN Health Protection Cell (DG TREN H4) is processing personal data of staff members concerned. The staff members who are occupationally exposed to ionising radiation in the course of their work are the inspectors for nuclear safeguards (nuclear safety and industrial safety), nuclear laboratory staff and safety surveillance staff<sup>1</sup>.

Under special service contracts, approved laboratories deliver the results of occupational protection monitoring concerning staff members classified as occupationally exposed to ionising radiation. Three contractors are involved in the process of radiation monitoring:

- External exposures are evaluated by: LCIE Landauer

---

<sup>1</sup> Persons concerned are also a limited number of AIDCO staff members.

- Internal uptakes of gamma rays emitting radio nuclides are measured by Whole Body Counting performed by FZK medical service
- Internal uptakes of actinide radionuclides are determined by radiotoxicological analysis performed by UK Health Protection Agency.

The FZK medical service sends the Whole Body Counting to the Medical Service of the Commission who then transmits the data to the DG TREN H4. The UK HPA service sends radiotoxicological measurement results to the Medical Service and they forward them to DG TREN H4. Dosimeter readings from LCIE are transmitted to DG TREN H4 and copies are forwarded to Medical Service.

Data from FZK, from HPA and from LCIE Landauer are measurement results associated with an individual person. Only the medical service has the scientific tool for transposing this particular data from FZK and from HPA into medical dose data. For this mathematical transposition, the medical service needs individual personal medical data of the persons concerned which DG TREN H4 does not have.

The results of these calculations, *Effective Dose* and *Committed Effective Dose*, are transmitted to DG TREN H4 for introduction in the passbook only.

For rapid radiological protection measures, the DG TREN H4 receives the FZK and HPA measurement results in order to contact the nuclear operators in cases if any significant intake of radio nuclides by Commission staff is identified.

The results of the dosimeter evaluation from LCIE are transmitted directly to DG TREN H4 because they must be introduced into the passbook without any delay. However, this is a operational quantity *Personal Dose Equivalent Hp* which will be, if necessary, corrected by the medical service into *Effective Dose*. The Medical Service accumulates the monthly dose data for introducing into each individual medical file.

Corrections are only made on request of either Medical Service or DG TREN H4 and are respectively communicated.

The radiological surveillance and occupational monitoring data are entered manually into the Microsoft ACCESS bases Personal Dosimetry database of DG TREN H4. All data are checked before they are entered into the data base in view of technical and administrative correctness. The data base contains data relating to the identification of the person concerned, radiological protection monitoring results and ascertainment of physical fitness as delivered by the Medical Service of the European Commission. Data relevant to the personal radiology protection and surveillance are registered in individual radiation pass books. Following an occupational health examination, the medical service of the Commission submits information (yes/no) concerning the individual physical fitness of the staff members.

The radiation passbook is kept by the data subject like an ordinary passport. The book is presented once a month for updating of dosimetric data and other information. The passbook contains identification data, history of exposure, occupational exposure before employment by the European Commission if available, occupational exposure (external and internal) registered in previous Personal Radiation Passbooks, involvement in any accident and accident dose, radionuclides incorporated, dose assessment of each calendar year, dosimetric data, date of medical examinations and fitness for work, fitness for work in arduous conditions, important addresses and telephone numbers and the medical service references.

In principle, when receiving the completed passbook, the data subject receives all data from the database. There is no additional/different information stored in any data base by DG TREN H4. The data subject may copy the book, if wanted.

Personal data are shown in the personal radiation pass book of the individuals and therefore is accessible for the data subjects at any time. The right to correct and verify data administrative data (name, address, telephone numbers, etc) may be exercised orally or in a written form addressed to DG TREN H4 or to the Medical Service of the European Commission. Data subjects are obliged to inform the medical service about any change of their health situation (in case of pregnancy, injury, epidemiological decease, etc).

Data subjects receive information in a written notice titled "Note to European Commission Staff Classified as Occupationally Exposed to Ionising Radiation"<sup>2</sup>. Each data subject receives the note electronically via the e-mail system and in written form together with the radiation passbook. The note contains information on the purpose of the processing of personal data by DG TREN H4; the type of data collected and processed; the period of conservation of the data; the implementation of appropriate security measures to protect the data; the right of access and rectification of the data for the data subjects under specific circumstances; and the right to contact the controller or delegated controller identified as such.

The data are transmitted, as explained above, to the Medical Service of the Commission. If necessary, personal data will be exchanged between DG TREN H4 and the radiation protection or medical service of the nuclear operators in the Member states. These external services are also bound by strict confidentiality rules.

Under European Radiation protection legislation, data on individual dose is retained during the working life of the person and afterwards until the individual data subjects have/or would have attained the age of 75 years. In any case, the data has to be retained for not less than 30 years from the termination of the work period classified as occupationally exposed.

[...].

### **3. Legal aspects**

#### **3.1. Prior checking**

The notification relates to the processing of personal data ("any information relating to an identified or identifiable natural person" – Article 2(a) of the Regulation). Because in the present case dosimetry data can be linked to an identified person it can be considered as personal data. The data processing in question is carried out by an institution (DG TREN of European Commission) in the exercise of activities which fall within the scope of Community law (Article 3(1) of the Regulation).

Some aspects of the processing operations are manual (for example, dosimetry results are entered manually into the Personal dosimetry database and into the individual radiation pass). In the dosimetry database the processing operation is automated. Article 3(2) of the Regulation is thus applicable in this case.

The processing therefore falls within the scope of the Regulation.

---

<sup>2</sup> TREN-CPS/KS D(2007)

The scope of the prior checking analysis is restricted to the processing operations related to the occupational radiation exposure data. This opinion does not cover the medical surveillance of workers exposed to the risks of ionizing radiation, which otherwise is a requirement of occupational medicine in general and which is performed by the Commission Medical Service<sup>3</sup>.

Article 27(1) of the Regulation requires prior checking by the EDPS of all "processing operations likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes". Article 27(2) of the Regulation contains a list of processing operations that are likely to present such risks, among those "processing of data related to health" (Article 27(2)(a) of the Regulation). Information on ionising doses received by individuals clearly relates to their health; therefore the processing operation falls under the scope of Article 27(2)(a) of the Regulation.

Since prior checking is designed to address situations that are likely to present certain risks, the opinion of the EDPS should be given prior to the start of the processing operation. In this case however the processing operation has already been established. This is not a serious problem in that any recommendations made by the EDPS may still be adopted accordingly.

The notification for prior checking was received on 6 June 2007. According to Article 27(4) of the Regulation the present opinion must be delivered within a period of two months. Taking into account the periods of suspension for comments and information requests, plus the month of August, the opinion must be adopted no later than 14 November 2008.

### **3.2. Lawfulness of the processing**

The lawfulness of the processing operations must be examined in the light of Article 5 of the Regulation. The notification for prior checking referred to Article 5(a) to justify the lawfulness of the processing operation. However, the EDPS considers that although there is a "grey zone" between Article 5(a) and Article 5(b) of the Regulation, in this case where the legal obligation is very specific as regards the processing of personal data, it is Article 5(b) that applies, which stipulates that: "*personal data may be processed only if the processing is necessary for compliance with a legal obligation to which the controller is subject.*" Indeed, the controller of the processing operation is subject to a specific legal obligation under Luxemburg national law implementing two Council Directives for the protection of the health of workers.

Council Directive 96/29/EURATOM and Council Directive 90/641/EURATOM, implemented in *Règlement Grand Ducal 14 Decembre 2000 concernant la protection de la population contre les dangers résultants des rayonnements ionisants* constitute ***the legal basis for the processing operation.***

From the available information, the EDPS considers that there is a legal vacuum in the EU institutions concerning the protection of workers exposed to the risks of ionizing radiation. The Council Directives are addressed to the Member States. No similar regulation exists for the protection of workers of EU institutions, other than those specified in the national law. According to Article 291 of the EC Treaty "*The Community shall enjoy in the territories of the Member States such privileges and immunities as are necessary for the performance of its tasks, under the conditions laid down in the Protocol of 8 April 1965 on the privileges and immunities of the European Communities. (...)*". Although the institutions and bodies are granted a special status in the Member states, the Protocol on privileges and immunities does not grant absolute

---

<sup>3</sup> See EDPS Opinion 2004-0225 on Medical files (yet to be adopted)

immunity. As the Court of Justice has held, the privileges and immunities which the Protocol grants to the Communities "have a purely functional character, inasmuch as they are intended to avoid any interference with the functioning and independence of the Communities"<sup>4</sup>. National law therefore applies within the EU institutions and bodies in so far as it does not run counter the smooth functioning of these bodies. The Luxemburg Regulation referred to above does not run counter the smooth running of the institution; therefore the EDPS concludes that the legislation invoked by the controller indeed serves as an adequate legal basis for the processing operation.

Articles 25-28 of Council Directive 96/29/EURATOM set out the following obligations:

● **Monitoring - General**

*Article 25*

*1. Individual monitoring shall be systematic for exposed category A workers. This monitoring shall be based on individual measurements which are established by an approved dosimetric service. In cases where category A workers are liable to receive significant internal contamination an adequate system for monitoring should be set up; the competent authorities may provide general guidance for identifying such workers.*

*2. Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B. Member States may require individual monitoring and if necessary individual measurements, established by an approved dosimetric service, for category B workers.*

*3. In cases where individual measurements are impossible or inadequate, the individual monitoring shall be based on an estimate arrived at either from individual measurements made on other exposed workers or from the results of the surveillance of the workplace provided for in Article 24.*

● **Monitoring in the case of accidental or emergency exposure**

*Article 26: In the case of accidental exposure the relevant doses and their distribution in the body shall be assessed.*

*Article 27: In the case of emergency exposure, individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances.*

● **Recording and reporting of results**

*Article 28*

*1. A record containing the results of the individual monitoring shall be made for each exposed category A worker.*

*2. For the purposes of paragraph 1 the following shall be retained during the working life involving exposure to ionizing radiation of exposed workers, and afterwards until the individual has or would have attained the age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure:*

*(a) a record of the exposures measured or estimated, as the case may be, of individual doses pursuant to Articles 12, 25, 26 and 27;*

---

<sup>4</sup> See Case 1/88 SA SA Générale de Banque v Commission [1989] ECR 857, paragraph 9, Case C-2/88 Imm. Zwartfeld and Others [1990] ECR I-3365, paragraphs 19 and 20, and the judgment in Case T-80/91 Campogrande v Commission [1992] ECR II-2459, paragraph 42.

*(b) in the case of exposures referred to in Articles 26 and 27, the reports relating to the circumstances and the action taken;*

*(c) the results of workplace monitoring used to assess individual doses where necessary.*

*3. Exposure referred to in Articles 12, 26 and 27 shall be recorded separately in the dose record referred to in paragraph 1.*

As mentioned above, these obligations have been implemented in national Luxembourg law. The EDPS therefore considers that the collection and follow up of ionising doses of workers exposed to radiation is a processing operation necessary in order to comply with a legal obligation of the controller in accordance with Article 5b of Regulation (EC) 45/2001.

### **3.3. Processing of special categories of data**

The processing of special categories of personal data such as data concerning health in principle is prohibited under Article 10(1) of the Regulation. An exception from the main principle can be found in Article 10(2)(b) of the Regulation, which stipulates that "*paragraph 1 shall not apply where the processing is necessary for the purposes of complying with the specific rights and obligations of the controller in the fields of employment law insofar as it is authorised by the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof (...)*". Since the controller is clearly subject to obligatory rules (as described above) in the field of employment law, the EDPS concludes that data on ionizing radiation collected by dosimeters can lawfully be processed by the controller.

### **3.4. Data Quality**

Data must be adequate, relevant and not excessive in relation to the purposes for which collected and/or further processed (Article 4(1)(c) of the Regulation) and must be accurate and where necessary kept up to date (Article 4(1)(d) of the Regulation).

The purpose of the present processing operation is to collect health related personal data by the means of individual dosimeters concerning individuals occupationally exposed to ionising radiation, and to keep a database on those results for meeting the legal obligation of the controller in the field of employment law. The personal data collected for the purpose are identification and radiological data (radiation category, dosimeter number and personal radiation exposure, positive results of excretion samples). These data satisfy the requirement of being adequate, relevant and not excessive for the purposes of the processing operation.

As to the accuracy and up to date nature of the data, as mentioned above, the radiological surveillance and occupational monitoring data are entered manually into the Microsoft ACCESS bases Personal Dosimetry database. All data are checked before it is entered into the data base in view of technical and administrative correctness. The fact that individual radiation passbook is detained by the person concerned serves to guarantee the quality of the data (see below 3.7. Right of access and rectification).

The data must be processed *fairly and lawfully* (Article 4(1)(a) of the Regulation). The lawfulness has already been examined in Section 3.2 above. Fairness requires special attention because of the sensitive context: it is related to the information that should be supplied to the person concerned (see Section 3.8).

### **3.5. Conservation of data**

Article 4(1)(e) of the Regulation provides that data may only be kept in a form which permits the identification of data subjects for as long as it is necessary for the purpose for which the data were collected and/or further processed. Personal data may be stored for longer periods notably for scientific or statistical purposes providing it is kept in anonymous form.

As mentioned above, data on individual dose are retained during the working life of the person and afterwards until the individual data subjects have/or would have attained the age of 75 years. In any case, the data have to be retained for not less than 30 years from the termination of the work period classified as occupationally exposed. This conservation period is established in accordance with national legislation applicable.

Considering that the storage of accurate data on ionizing radiation dose may have significant relevance later in the context of medical treatment of the individual, and/or in view of possible claims even after several years for alleged occupational disease, the EDPS finds reasonable the time limit prescribed by law for which the personal data are kept.

### **3.6. Transfer of data**

In the present case personal data are transferred within the Commission and to recipients other than Community institutions and bodies, and therefore, both Articles 7 and 8 of the Regulation may apply in the present case.

#### ***Data transfers based on Article 7 of the Regulation***

Article 7(1) of the Regulation stipulates that "*without prejudice to Articles 4, 5, 6 and 10 personal data shall only be transferred within (...) Community institutions or bodies if the data are necessary for the legitimate performance of tasks covered by the competence of the recipient.*"

The Medical Service of the European Commission receives radiation dose related personal data. In principle, it can be seen that the personal data transferred are necessary for the legitimate performance of their tasks covered by their competence (Article 7(1) of the Regulation). Considering that medical follow-up of the workers is necessary in the context of occupational radiation protection, the data transfers to medical service can be regarded as legitimate.

#### ***Data transfers based on Article 8 of the Regulation***

Transfers of personal data to recipients other than Community institutions and bodies and which are subject to Directive 95/46/EC are possible "*if the recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority*" (Article 8(a) of the Regulation).

A number of the radiation protection or medical services of the nuclear operators in the Member states may receive personal data and health-related data of the individuals concerned.

These authorities in principle are subject to Luxemburg legislation implementing Directive 95/46/EC, and they are recipients who are subject to the exercise of public authority under Article 8(a) of the Regulation. They are entitled to receive these data in the frame of the exercise of this authority. Article 8 is therefore respected.

### **3.7. Right of access and rectification**

According to Article 13 of the Regulation: "*the data subject shall have the right to obtain without constraint and at any time within three months from the receipt of the request and free of charge from the controller information at least as to the purposes of the processing operation, the categories of data concerned, the recipients to whom the data are disclosed and communication in an intelligible form of the data undergoing processing and of any available information as to their source*". Article 14 provides: "*the data subject shall have the right to obtain from the controller the rectification without delay of inaccurate or incomplete personal data*".

The right of access to the personal data of the individuals concerned is laid down in Article 38(2) of Council Directive 96/29/EURATOM. The notification for prior checking and the note to staff annexed to the notification specify that data subjects can exercise their right of access and rectification under "*specific circumstances*".

The EDPS underlines that Article 13 of the Regulation provides for an unconditional right of access to the data for the person concerned. Restrictions to this right are provided for in Article 20, but these are not applicable a priori in this case. The right of access must therefore be granted to those concerned even in those cases in which there are no "*specific circumstances*". This must be reflected in the information given to data subjects (see below Section 3.8).

The EDPS notes that the right to rectification can be somewhat limited because of the nature of the processing operation. It clearly applies to the updating of administrative data of the individual entered in the database. It is however more difficult to guarantee this right concerning radiation doses. Having said this, in principle, it cannot be excluded that an individual concerned requests another medical or radiation protection expert's review of his/her state and requests that information should be entered in the dosimetry database with a view of making his/her data up-to-date. In the present case, this could be a means to exercise the right to rectify radiation dose related data, and under the Regulation such an exercise of the right should be granted.

### **3.8. Information to the data subject**

Articles 11 and 12 of the Regulation provide a list of information that should be supplied to the person concerned and specify the moment of providing that information.

The EDPS considers that it is Article 12 on information to be supplied to the data subject where the *data have not been obtained from the data subject directly* that applies mainly in this case, because the information is obtained from the various parties involved in the process.

As it has been described in the facts part above, the Privacy Statement contains most of the information required by Article 12 of the Regulation. However, information is lacking on the categories of recipients and right to have recourse to EDPS at any time. Furthermore, as mentioned above, the right of access and rectification should not be subject to "*specific circumstances*".

As to the means of supplying the information, the EDPS is satisfied that this information is provided electronically to all data subjects via the email system and in written form together with the radiation pass book.

Article 12 of the Regulation describes the moment when the information should be supplied to the data subject: where the data are not obtained directly from the data subject, the controller should inform the data subject *at the time of undertaking the recording of personal data*, or if a disclosure to a third party is envisaged, *no later than the time when the data are first disclosed*.



In order to provide personalised information about the processing operation, the individuals should receive the information listed in Article 12 (privacy statement) before the processing operation is launched.

### **3.9. Processing data on behalf of controllers**

Where a processing operation is carried out on its behalf, the controller is required to choose a processor providing sufficient guarantees in respect of technical and organisational security measures. The controller must also draw up a contract or legal act stipulating in particular that the processor shall act only on instructions from the controller (Article 2(e) and 23 of the Regulation).

LCIE Landauer, FZK medical service and the UK Health Protection Agency act as processors on behalf of DG TREN H4. Even though they are only processing radiation or radiotoxicological analysis, these are still considered as personal data<sup>5</sup>. The contract (or other legal act binding the processor) must specify therefore that the processor shall act only on the instructions of DG TREN H4. Moreover, these processors are subject to national law transposing Directive 95/46/EC and therefore, the processor is bound by the obligations of security and confidentiality as laid down by national law.

### **3.10. Security measures**

Article 22 of the Regulation requires that *"the controller shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected"*.

The EDPS considers that the security measures adopted by DG TREN-H4 are adequate in the light of Article 22 provided that measures are put in place to ensure the confidentiality of personal data concerned.

Medical officers and physicians dealing with radiation-dose-related personal data are subject to professional secrecy. In this regard the confidentiality requirement is met. The controller should however ensure that the confidentiality and security of communications is guaranteed when information is transferred between subcontractors and the DG TREN-H4, and between DG TREN-H4 and the national competent authorities. In this respect, the EDPS recommends that, as an appropriate measure and good practice, the envelopes containing health related information should be marked as "CONFIDENTIAL" and "TO BE OPENED BY XY ONLY", or in case of email communication, the emails are made secure.

### **Conclusion:**

There is no reason to believe that there is a breach of the provisions of the Regulation provided that the above considerations are fully taken into account. In particular:

---

<sup>5</sup> See definition of personal data in Opinion of Working Group 29 4/2007 on concept of personal data, WP 136.

- The right of access and rectification of personal data of the persons concerned should not be conditioned to "specific circumstances"; this should be reflected in the data protection notice;
- It cannot be excluded that an individual concerned requests another medical or radiation protection expert's review of his/her state and requests that information should be entered in the dosimetry database with a view of making his/her data up-to-date;
- Information is provided on the categories of recipients and right to have recourse to EDPS at any time;
- Individuals receive the information listed in Article 12 (privacy statement) before the processing operation is launched;
- The confidentiality and security of communications should be guaranteed when information is transferred between subcontractors and the DG TREN-H4, and between DG TREN-H4 and the national competent authorities.

Done at Brussels, 5 November 2008

(signed)

Joaquín BAYO DELGADO  
Assistant European Data Protection Supervisor