

Opinion on a notification for prior checking received from the Data Protection Officer of the European Commission on "Dosimetry data at JRC-IRMM in Geel"

Brussels, 29 November 2007 (Case 2007-325)

1. Proceedings

1.1. On 21 May 2007, the European Data Protection Supervisor (EDPS) received a consultation on the necessity of prior checking under Article 27(2)(a) of Regulation (EC) 45/2001 ("Regulation") of the personal data processing operations concerning "Dosimetry data at Joint Research Centre (JRC) - Institute for Reference Materials and Measurements (IRMM) in Geel (Belgium)." A completed prior checking notification form and a Privacy Statement were attached to the consultation.

1.2. After examining the submission, on 4 June 2007, the EDPS concluded that the processing operation was indeed subject to prior checking. The EDPS started therefore the prior checking analysis as of 4 June 2007.

1.3. On the same day, the EDPS made an information request to which he received the response on 11 June 2007. On 11 July 2007, the EDPS made a second information request. He received the response on 31 July 2007. On 21 September 2007, the EDPS made a third information request, to which he received the response on 8 October 2007. The EDPS requested further information on 15 October 2007. The next day he received the answer.

On 17 October 2007, the EDPS sent the draft opinion to the DPO for comments and made a request to supply any further information he may find necessary. The EDPS received the comments on 26 November 2007.

2. The facts

2.1. Description of data processing operation

The object of this prior checking opinion is to examine the data processing operations related to the use of the individual dosimeters. It therefore concerns the collection, storing and transfer of information related to ionizing doses received by (i) visitors as well as (ii) individuals working at the Joint Research Centre (JRC) Institute for Reference Materials and Measurements (IRMM) in Geel. The controller is the head of unit of the IRMM Security Service, who is also the head of radioprotection sector.

Two Council Directives lay down the safety standards concerning ionizing radiation.¹ These were implemented on national level in Belgium by a Royal Decree. Council Directive 96/29/EURATOM² concerns the protection of health of workers and Council Directive 90/641/EURATOM³ aims to protect outside workers exposed to the risk of ionizing radiation. Arrêté Royal du 20 juillet 2001 (hereinafter as Royal Decree)⁴ concerns the protection of the population, workers and environment against the danger of ionizing radiation. There is no specific internal rule or decision in the Commission applicable to IRMM in Geel in the field of radiation protection.

Both the Belgian legislation and the Directives set maximum limitation of doses that individuals may receive annually. The rules set an overall annual dose permitted and specific dose limits to certain body parts (lens of the eyes, skin, hand, forearms, feet, ankles) of persons exposed to radiation risks for professional reasons⁵ and for visitors⁶. In order to ensure health protection of workers and visitors, dosimetry monitoring controls the level of ionizing radiation received by persons exposed to such risks. A record containing the results of individual monitoring is made for every worker and visitor exposed to ionizing radiation, and in case the dose limit is exceeded special medical surveillance should be provided.⁷

In certain scenarios workers and external workers may receive higher doses than the limits: A) under special authorisation, B) accidental exposure, C) intervention in case of radiological emergency.

A) Individuals professionally exposed to ionizing radiation can receive higher doses than the limit under special authorisation and under exceptional situations with due respect to the conditions established in the law.⁸ One of these conditions concerns the agreement from the approved physician, who must take into account the age and the health condition of the person concerned.⁹

B) In case, due to an accidental exposure, the workers surpass the annual dose limit, any further exposure is subject to the agreement of the approved physician.¹⁰ All those accidental exposures should be recorded in the medical dossier and the doses should be registered separately.¹¹

C) If an intervention takes place due to radiological emergency, as a main principle the dose limits do not apply. However in case of continuous exposure, the general dose limits apply to workers taking part in the intervention. Derogation is possible with the approval of the Federal Agency of Nuclear Control ("Agence Fédérale de Contrôle Nucléaire" (AFCN)).¹² If

¹ Further standards are laid down by the International Atomic Energy Agency (IAEA) Basic Safety Standards No 115.

² Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the danger arising from ionizing radiation. O.J. L 159, 29/06/1996.

³ Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas. O.J. L 348, 13/12/1990.

⁴ Arrêté Royal du 20 juillet 2001 portant règlement général de la protection de la population, des travailleurs et de l'environnement contre le danger des rayonnements ionisants (Moniteur Belge du 30 août 2001).

⁵ Article 20.1.3 of Royal Decree and Article 9 of Council Directive 96/29/Euratom

⁶ Article 20.1.4 of Royal Decree (limites de dose pour les personnes du public)

⁷ Article 35 of Council Directive 96/29/Euratom

⁸ Article 20.1.6 of Royal Decree

⁹ Paragraph c) of Article 20.1.6 of Royal Decree

¹⁰ Article 20.1. 7 of Royal Decree

¹¹ Article 20.1. 7 of Royal Decree

¹² Paragraph c) of Article 20.2.2 of Royal Decree

due to the emergency exposure, one of the annual dose limits is surpassed, any further exposure is subject to the agreement of the approved physician.¹³ These emergency exposures should be recorded in the medical dossier and the doses should be separately recorded.

The service responsible for Health Physics within the institution and the approved physician who is responsible for the medical control of workers (including external workers) must cooperate and agree in determining the individual doses (including results of internal exposure), accidental exposure and emergency exposures.¹⁴

The controller confirmed that the institute follows the standard procedure required for all dosimetry services in Belgium.

Individual dosimeters are issued to people working in controlled areas. The various types of personal dosimeters and the reading system is subject to prior agreement by the Federal Agency of Nuclear Control ("Agence Fédérale de Contrôle Nucléaire" (AFCN)).¹⁵

Article 30.6 of the Royal Decree lists particularly the requirements of wearing dosimeters for persons exposed to ionising radiation (number of dosimeters to wear, in which part of clothing, in which areas it is obligatory to wear, etc). In case of emergency exposure or exposure under special authorisation a dosimeter is worn with alarm appliance or with direct reading system. All visitors and workers entering the controlled zones should wear the same dosimeters as the workers of that zone.

According to the regular procedure, every month the dosimeters are examined by the dosimetry service of the University of Liège (Belgium), with whom IRMM has a contractual relationship. This examination comprises of the development and reading of the films of the dosimeters. After developing and reading, the film is put in the archive of the University of Liège. The University of Liège matches the dosimetry results with the name of the individual staff member, external worker or visitor. After the reading, an excel file is sent by e-mail to the head of IRMM radioprotection sector. Data are then manually transferred into the dosimetry database.

The life cycle of dosimeters is one month. Individuals receive a new dosimeter every month. The controller noted that there is no need for a more frequent assessment than a monthly read-out because doses are close or equal to background level.

The IRMM Security Service directly hosts, manages and monitors the related information on protected registers and IT system.

2.2. Data subjects concerned

The individuals identified as exposed to ionising radiation are the following: JRC officials, external staff under contract and visitors (who are exposed to ionisation for a short period of time).¹⁶

¹³ Article 20.2.3 of Royal Decree

¹⁴ Paragraph 10 of Article 23.1 of Royal Decree

¹⁵ Article 30.6 of Royal Decree

¹⁶ Apprentices and students below 18 years of age are not authorized in controller areas at IRMM. They therefore cannot be data subjects.

2.3. Personal data involved in the processing operation

The Privacy Statement attached to the notification for prior checking breaks down the data collected into "identification data" and "radiological data". Identification data includes: name, gender, date of birth, starting date at JRC, date of leaving JRC, employer, related company information and related administrative data. Radiological data include: radiation category, dosimeter number and personal radiation exposure.

The dosimetry database also contains the positive results of excretion samples (the excretion samples are obtained by periodic collection of the urine). Positive excretion samples could occur in case of contamination incidents in controlled areas. If a sample is positive, which normally would be an exceptional case, a dose assessment would be undertaken by a physician and medical doctor and the data would be recorded in the database.

The dosimeter has a unique reference number which is linked to the name of the individual.

2.4. Information to data subjects

The Royal Decree lists all items that should be supplied to workers who are likely to be exposed to ionizing radiation before taking up their post. This includes, among others, information on the work related health risks and information on the importance of complying with the medical and technical prescriptions.¹⁷ The information provided should be renewed as needed and at least once a year, and it should be provided to the worker in a written form.

Each individual working on the controlled area is trained on radiation risks.¹⁸ Part of this training concerns dosimetry and dose recording. The Royal Decree requires that such training should be given at the moment of taking up the service, in the case of transfer or change of the function and at the introduction of a new working tool or new technology.¹⁹

The head of the institution should ensure that individuals other than workers who can be exposed to ionizing radiation possess the necessary information and training. If the individuals have not received such a training or information, the head of the institution should organise it.²⁰ According to the information received from the controller, visitors are always escorted when authorised to enter controlled areas.

The Privacy Statement is available for data subjects on the IRMM services (internal) website. It contains the following information: description of processing operation; identity of controller; reference to the Regulation; types of personal data collected and the purposes of collecting such data; mentioning technical means used by the IRMM Security Service; general list of individuals who have access to the personal information or to whom data are disclosed; protection and safeguarding of information; the procedure to verify, modify or delete information; retention period; contact information of DG JRC data protection coordinator, and the Commission's Data Protection Officer; and the possibility of recourse to the European Data Protection Supervisor.

The contact information of the EDPS is not updated, and there is no contact data of the controller (e.g functional mailbox).

¹⁷ Article 25 of Royal Decree

¹⁸ Article 25 of Royal Decree further specifies the items that individuals should be supplied with.

¹⁹ Article 25 of Royal Decree

²⁰ Article 25 of Royal Decree

In case anybody was positively irradiated,²¹ it is communicated in an email internally to the person concerned. This direct information supplied to employees was introduced at IRMM at the request of the staff committee. The controller noted that legally it would be sufficient that the staff members receive the information at their own request (e.g. during the medical examination). There is a general duty of the employer to inform staff members on health and safety issues (labour safety regulation "Codex"). It is however not stipulated with regard to doses how it is done. As the controller noted, the most practical way to comply with the legal requirement is to foresee the possibility to inform the staff member at least during the medical visit. Providing direct information to the staff members at IRMM is a supplementary measure.

In the case of external workers, a positive irradiation would be immediately communicated to the external company. Moreover, an exposure sheet is sent to the external company, which informs the external workers about positive irradiation. The controller noted that it is the responsibility of the external company how the results are communicated to their workers. Article 26(3) of Arrêté Royal du 25 avril 1997 specifies that external workers are informed about positive irradiation indirectly via their company.

It has also been noted by the controller that as nearly all doses for external workers are "background doses" (0 doses) there is no need for a monthly transmission of information, and results are communicated annually. The external company however could request explicitly a monthly transmission by IRMM.

The exposure sheet for external workers contains the following information: the calendar year, name and date of birth of individual, dosimeter number, national ID, external exposure (by month, total, partial) and internal exposure (body organ, contamination agent and expected amount) remarks, stamp and signature from physician.

Measures are taken to ensure that visitors entering the controlled areas should not be exposed to ionising radiation (meaning no dose above the background). Should a visitor ever receive a dose above the background level, the same procedure would apply for him/her as for external workers.

2.5. Rights of data subjects

- *Right of access:*

Article 38(2) of Council Directive 96/29/EURATOM stipulates that Member States should require that workers have *access at their request* to the results of their individual monitoring, including the results of measurements which may have been used in estimating them, or of the assessments of their doses made as a result of workplace measurements.

According to the Royal Decree, each worker has access to the results of his/her individual dosimeter. This includes access to the results of measurement which are used for evaluating the individual doses and also access to the evaluation of the doses the individual received in the workplace.²²

The Privacy Statement specifies that in case data subjects want to verify which of their personal data are stored by the IRMM Security Service, or they want to modify, correct or delete the data, they have to contact the Controller.

²¹ A positive irradiation is a dose above the background level.

²² Article 30.6 of Royal Decree

- *Right of rectification:*

Personal data are modified in the database within two weeks following a justified and legitimate request by the data subject or the controller.

2.6. Storage and blocking or erasure of personal data

The Royal Decree requires that arrangements are made so that the results of the dosimeter measurement can be conserved in the archives together with the documents ensuring undisputable identification of the concerned person.²³

Article 28 of Council Directive 96/29/EURATOM requires that a record containing the results of the individual monitoring should be made and provides a list of information that should be retained during the working life of the worker exposed to ionizing radiation and until the individual has or would have attained the age of 75 years. As a minimum period the record should be kept for 30 years from the termination of the work involving exposure.

The list of information that should be retained concerns:

- (a) individual dose records of exposure measured or estimated (on specially authorised exposure, general individual monitoring, accidental exposure and emergency exposure),
- (b) in the case of accidental or emergency exposure, the report relating to the circumstances and the action taken,
- (c) the results of workplace monitoring used to assess individual doses where necessary.

In practice, records are kept in the archive of IRMM for not less than 30 years after the termination of the work or from the date of the last visit.

The recorded data are also printed on paper for each individual on a yearly basis. The Health Physics service keeps this printed information in the archive at least for 30 years according to their legal obligation.

2.7. Recipients of personal data

According to paragraphs (1) and (3) of Article 29 of Council Directive 96/29/EURATOM the results of individual monitoring should be

- (a) made available to competent authorities and to the undertaking, and
- (b) submitted to the approved medical practitioner or approved occupational health services in order to interpret their implications for human health. In the case of accidental or emergency exposure, the results of individual monitoring shall be submitted without delay.

The notification for prior checking lists the following recipients: Medical Service (DG ADMIN of the European Commission), Health Physics Service (IRMM SHES sector (see below) and Belgian Federal Service for Labour (Federal Overheidsdienst Tewerstelling en Arbeid- België). Similarly, the Privacy Statement stipulates that personal data can be disclosed to "qualified and experienced radiation protection and medical officers." Health Physics Experts and Medical Officers are those identified in European Directive 96/29 and Belgian Legislation ARBIS (Royal Decree of 20/07/2001).

The IRMM SHES sector is the Safety, Health, Environment and Security sector, which includes the health physics (HP) service. This HP is described in Article 23 of the Royal Decree.

²³ Article 30.6 of Royal Decree

The qualified expert in health physics is defined by the Royal Decree as a person who has the necessary knowledge and training to carry out physical, technical and radio-chemical examinations to assess the doses and to give advice to ensure an effective protection of the individuals and a correct functioning of the protection means according to Article 23 of the Royal Decree.²⁴

The Belgian Federal Service for Labour receives the results of radiation doses after a calendar year. These results concern the radiation doses received by each and every staff member, visitor and external worker. This also means that their names are included in the communication.

Further, accidental radiation exposure should be sent as soon as possible but at the latest within 30 calendar days to the Federal Agency of Nuclear Control ("Agence Fédérale de Contrôl Nucléaire" (AFCN)), to the Hygienic Administration ("Administration de l'Hygiène") and to the Physician of the Work and Employment Minister ("Médecine du Travail du Ministère de l'Emploi et du Travail"). The communication should mention among others the circumstances of the exposure, the doses received and the persons concerned.²⁵

In practice, the competent authorities receive this information, including personal data, in the form of one sheet per individual. These data are transferred by mail.

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). The data processing in question is carried out by an institution 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 into the dosimetry database manually and the exposure sheet is also filled in manually). Recorded data are also printed on paper for each individual on a yearly basis, which is kept by the Health Physics Service in the archive. These data clearly form part of a filing system. 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.

The scope of the prior checking analysis is restricted to the processing operations related to data collected via the individual dosimeter.²⁶ 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. Nevertheless, the EDPS finds it necessary that all processing operations covering occupation health risks should be submitted for his prior checking.

²⁴ Article 2 "Definitions" of the Royal Decree. Qualified experts are approved by the Agence Fédérale de Contrôl Nucléaire" (AFCN))

²⁵ Article 20.1.7 of Royal Decree

²⁶ As it is suggested by the name and the description of the processing operation as submitted in the prior checking notification, and as it is pointed out in the Privacy Statement annexed to the notification form.

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.

On 21 May 2007, the EDPS received a consultation on the matter. He concluded on 4 June 2007 that the processing operation falls under the scope of prior checking and launched the prior checking procedure on the same day. According to Article 27(4) of the Regulation the present opinion must be delivered within a period of two months that is no later than 5 August 2007. The procedure was suspended due to information requests for a period of 85 days (7 + 20 + 17 days + 1 day + 40 days for comments on draft opinion) and for August 2007. The opinion should therefore be delivered no later than 29 November 2007.

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 Belgian 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 Belgium by Arrêté Royal du 20 juillet 2001 (referred to as Royal Decree) 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 Belgian 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 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"²⁷.

²⁷ 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.

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 Belgian law referred to by the controller 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.

1) 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;

(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.

2) Article 6 of Council Directive 90/641/EURATOM specifies with regard to the obligation of the operator towards external workers that:

1. The operator of a controlled area in which outside workers perform activities shall be responsible, either directly or through contractual agreements, for the operational aspects of their radiological protection which are directly related to the nature of the controlled area and of the activities.

2. In particular, for each outside worker performing activities in a controlled area, the operator must:

(a) check that the worker concerned has been passed as medically fit for the activities to be assigned to him;

(b) ensure that, in addition to the basic training in radiation protection referred to in Article 5 (1) (b), he has received specific training in connection with the characteristics of both the controlled area and the activities;

(c) ensure that he has been issued with the necessary personal protective equipment;

(d) also ensure that he receives individual exposure monitoring appropriate to the nature of the activities, and any operational dosimetric monitoring that may be necessary;

(e) ensure compliance with the general principles and limitation of doses referred to in Articles 6 to 11 of Directive 80/836/Euratom;

(f) ensure or take all appropriate steps to ensure that after every activity the radiological data of individual exposure monitoring of each outside worker within the meaning of Annex I, Part III, are recorded.

3) Article 30.6 of the Royal Decree stipulates the dose measurement in more detail:

- the situations where the wearing of a dosimeter (or more dosimeters) is obligatory,
- the obligation to conserve the dosimeter results in the archive.²⁸

4) Article 26 of Arrêté Royal (Royal Decree) of 25 April 1997 concerning the protection of workers against the risks resulting from ionizing radiation specifies the mission of the physical control service,²⁹ in stipulating that the service is responsible for organising the dosimeter follow-up of each external worker during their intervention (Article 26(2)), and for transmitting the individual doses to the head of the company where the external worker is employed and if that is the case to the chosen physician of the independent external worker (Article 26(3)).

The EDPS further concludes that the collection and follow-up of ionising doses received by workers, external workers and visitors and the processing of those data is ***necessary in order to comply with the legal obligation of the controller.***

²⁸ "Les dispositions sont prises pour que les résultats des mesures effectuées soient conservés en archives avec les documents assurant une identification indiscutable des personnes intéressées."

²⁹ service de contrôle physique

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 EDPS insists that it must be ensured that the procedure under examination guarantees the quality of the data.

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.

The EDPS finds that many of the measures put in place to ensure data accuracy are appropriate. This is the case concerning the fact that the University of Liège already matches the dosimeter results with the name of the individual concerned (staff member, external worker or visitor) because it reduces the risk of inaccurate data matching when data are entered manually into the dosimetry database at the JRC institute. The fact that the dosimeter has a unique reference number which is linked to the name of the individual and to the dosimeter itself contributes to the correct and accurate linkage of the respective personal data. Data accuracy is also ensured by the technical arrangement that new individual dosimeters are issued every month.

The legal requirement in the Royal Decree that the archive should contain the results of the measurement and other documents ensuring the undisputable identification of the individual concerned also contributes to data accuracy.

The EDPS however expresses his concern that data accuracy might be jeopardised during the procedure of informing external workers about eventual higher doses they might have received during the performance of their activities at the JRC institute in Geel. According to the description of the controller, external workers are informed *via the company* they work for of their own radiation exposure in case a dose limit was exceeded. External workers do not receive the information about positive irradiation directly. As there can be potential conflict of interest between those of the external worker and the company he/she works for, the transmission of accurate data may be endangered. Therefore, the EDPS would find it more appropriate from a data protection perspective that apart from informing the external company

of the positive irradiation, the external worker (or his/her chosen physician) should also receive that information directly from the JRC institute in Geel. (This is also a requirement under the right to supply appropriate information to the data subject concerning the specific circumstances of the processing operation. See, Section 3.8 of the Opinion).

The data subjects have the right to access and the right to rectify their own personal data, which ensures that the information in the dosimetry database can be as complete as possible. This also contributes to ensuring the quality of data (see Section 3.7 of the opinion).

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 of the Opinion).

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 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 it has been described above in the facts, the IRMM keeps the records in its archive for not less than 30 years after the termination of the work or from the date of the last visit. The recorded data are also printed on paper for each individual on a yearly basis. The Health Physics service keeps this printed information in the archive at least for 30 years according to their legal obligation.

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 and the Health Physics Service (IRMM SHES sector) can receive 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 occupation disease prevention, the data transfers to medical officers and health physics expert *in abstracto* can be regarded as legitimate. It needs to be noted, however, that in contrast to medical officers, health physics

experts are not necessarily physicians, and thus they are not bound by the rules of professional secrecy of the physicians with regard to the health-related data they receive. Also, other persons than physicians may have access to the health related data of workers at the Medical Service (e.g. nurses). The requirements of Article 7(3) of the Regulation should therefore be respected: *"the recipient shall process the personal data only for the purposes for which they were transmitted."* Health physics experts and persons working at the Medical Service with access rights should be made aware of this rule.

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 authorities must receive personal data and health-related data of the individuals concerned according to the Belgian national legislation: the Belgian Federal Service for labour, the Federal Agency of Nuclear Control, the Hygienic Administration, and the physician of the Work and Employment Minister. These authorities in principle are subject to Belgian 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. The need for transfer is stated in the applicable national legislation. Moreover, personal data are transferred to the University of Liège with whom IRMM has contractual relation for the purpose of developing dosimeter films and matching the results to the name of the individuals concerned. In this case Article 8(a) of the Regulation also applies as the University acts on behalf of the controller in fulfilling a public task. As to the necessity of the transfer, it is established jointly by the sender and the recipient.

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 and in Article 30.6 of the Belgian Royal Decree. The notification for prior checking and the Privacy Statement annexed to the notification specify that data subjects can exercise their right of access and rectification by contacting the controller. This procedure in principle meets the data protection requirements.

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. 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. This could be a means in the present case 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 (dose results are recorded by dosimeters, films are developed by the University of Liège, physicians examining excretion samples, etc).

Substance of the information provided:

The EDPS is satisfied that workers and individuals who are likely to be exposed to ionising radiation receive general information related to the health risks and on the importance of complying with the medical and technical prescriptions. The training on health risks includes dosimetry and dose recording.

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. Nevertheless, the contact information of the EDPS is not updated, and there is no contact data of the controller (e.g functional mailbox). The EDPS therefore requests the controller to provide particular contact information of the controller and update the email address of the EDPS: edps@edps.europa.eu in the Privacy Statement.

In addition, the EDPS considers that due to the sensitivity of the present processing operation as it concerns radiation doses in the context of occupational risks, it would be a good practice if the controller would provide the information on positive irradiation to the data subjects without a specific request from the data subjects in the exercise of their right of access. Thus, any positive irradiation should be directly communicated to the data subjects concerned (see below in "Moment of supplying the information" part). The EDPS welcomes the good practice at IRMM that, pursuant to the request of the staff committee, in case any staff member is positively irradiated, it is communicated to the person concerned through an internal email. This procedure guarantees fair processing in respect of the data subject and takes into regard the specific nature of the present processing operation. This information should however be also communicated to external workers and visitors (see below).

Means of providing the information:

The EDPS considers that placing the Privacy Statement on the internal website of IRMM is a positive step to ensure transparency of the processing operation and to provide more information to the data subjects. The EDPS is nevertheless concerned that not all data subjects have access to the internal website of IRMM. This is the case regarding external workers and visitors. Therefore, the EDPS recommends placing the Privacy Statement to those parts of the building where it can be well perceived by non-staff members (for example at the entrances of the building or where individuals receive the dosimeters).

Moment of supplying the information:

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. For example, staff members could receive the privacy statement (or a link to accessing it on the intranet website) during their mandatory training, visitors and external workers could receive it at the time of their first visit at IRMM before performing their activities.

In the case of external workers, the information on positive irradiation would be immediately communicated to the external company. Moreover, an exposure sheet is sent to the external company, which inform the external workers about positive irradiation. The controller noted that it is the responsibility of the external company how the results are communicated to their workers. The same procedure would apply with regard to visitors, in case they would ever receive a dose above the background level.

The EDPS is concerned that external workers and visitors may not receive the information so relevant for their health status directly when it is already available for IRMM, rather they would receive it with delay via an external party. The language of the Regulation is clear: the controller should provide the information to the data subject no later than the time when the data are first disclosed if a disclosure to a third party is envisaged. Although the external company should be seen as an intermediary to pass the information from IRMM to the person concerned, this can also be seen as a first disclosure of information, which implies that the person concerned should receive the information at the same time. The EDPS thus requests that a procedure is put in place ensuring that external workers and visitors receive the information directly from IRMM about positive irradiation.

Even if the legal bases referred to by the controller do not make it an obligation for the controller to communicate positive irradiation to staff members, external workers and visitors directly, in any event, they cannot prejudice the more advanced information right for the concerned data subjects available under the Regulation.

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).

IRMM has contractual relation with the University of Liège which in the present case acts as processor on behalf of IRMM while it develops the dosimeter films, performs the read-out and matches the results to the names and transfers that information to IRMM. The contract (or other legal act binding the processor) must specify therefore that the processor shall act only on the instructions of the IRMM. Moreover, the University is subject to Belgian national law transposing Directive 95/46/EC, and therefore, the processor is bound by the obligations of

security and confidentiality as laid down by Belgian law. The controller should ensure that these requirements of Article 23 are included in the contract.

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 IRMM 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 of communications is guaranteed when information is transferred between the University of Liège and IRMM, and between IRMM and the Belgian 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, IRMM should:

- ensure that the concerned external workers and visitors receive information about positive irradiation directly from the JRC institute in Geel,
- make sure that any member of the Health Physics Service and the Medical Service receiving and processing the data is aware of the rule that they may not use the data for other purposes.
- revise the privacy statement to provide the contact information of the controller and update the email address of the EDPS: edps@edps.europa.eu,
- place the privacy statement for visible places for external workers and visitors,
- provide personalised information about the processing operation under Article 12 of the Regulation before the processing operation is launched. For example, staff members could receive the privacy statement (or a link to accessing it on the intranet website) during their mandatory training, visitors and external workers could receive it at the time of their first visit at IRMM before performing their activities.
- ensure that the contract between IRMM and the dosimetry service (currently the University of Liège) specifies that the service acts only on the instructions of the IRMM, and that the service is subject to Belgian national law transposing the security and confidentiality requirement of Directive 95/46/EC.

- ensure that the confidentiality of communications is guaranteed when information is transferred between the dosimetry service and IRMM, and between IRMM and the Belgian competent authorities. In this regard email communications should be secured and mail communication should have appropriate note on the envelope (for example: "Confidential" or "To be opened only by XY").

In addition, all processing of personnel data related to occupation risks of workers exposed to ionizing radiation (such as medical control and surveillance) should be notified for prior checking by the EDPS.

Done at Brussels, 29 November 2007

Peter HUSTINX
European Data Protection Supervisor