

Opinion on a notification for Prior Checking received from the Data Protection Officer of the European Commission regarding "Dosimetry Management System at JRC Ispra"

Brussels, 6 February 2008 (Case 2007-505)

<u>1. Procedure</u>

On 3 September 2007, the European Data Protection Supervisor (**EDPS**) received from the Data Protection Officer (**DPO**) of the European Commission a notification for prior checking concerning the Dosimetry Management System at Joint Research Centre (**JRC**) Ispra. The notification was accompanied by the following documents:

- the Radiation Passbook;
- Scheda Personale Dosimetrica (Dosimetry Schedule);
- Points 1.44 1.49 of the Appendix 1 to the International Atomic Energy Agency (IAEA) International Basic Safety Standards for Protection against Ionizing Radiation, Safety Series No 115, 1996;
- "Dosimetry Recording System User Operational Procedure";
- Council Directive 96/29/Euroatom of 13 May 1996 laying down basis safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (**Directive 96/29**);
- Council Directive 90/641/Euroatom of 4 December 1990 on the operational protection of outside workers exposed to the risks of ionising radiation during their activities in controlled areas (Directive 90/641);
- Decreto Legislativo del Governo 17 marzo 1995 n° 230 "Attuazione delle direttive 89/618/Euratom, 90/641/Euratom, 92/3/Euratom e 96/29/Euratom in materia di radiazioni ionizzanti" (**D. Lgs. 230/95**);
- Decreto Legislativo del Governo 26 maggio 2000 n° 241 "Attuazione delle direttiva 96/29/Euratom in materia di protezione sanitaria della popolazione e dei lavoratori contro i rischi derivanti dalle radiazioni ionizzanti" (**D. Lgs. 241/00**);
- Protection of personal data in the Dosimetry Management System (Privacy Statement).

On 28 September 2007, the EDPS sent a request for additional information to the Commission's DPO and the DG JRC Data Protection Coordinator (**DPC**). A partial reply was provided on 7 November 2007. On 28 November 2007, another information request together with draft facts was sent to the respective DPO and DPC. The reply was provided on 16 January 2008. The draft opinion was sent to the Commission's DPO and the DG JRC DPC for comments on 24 January 2008 and these were received on 5 February 2008.

2. Facts

2.1. Context

The present opinion deals with the dosimetry management at the JRC Ispra and covers activities from the handling of personal radiation exposure data coming from measurement of the individual dosimeter to the operation of the Dosimetry Recording System (**DRS**).

The purpose of the processing is to be able to survey and review personal radiation exposure of (internal and external) workers and visitors according to legal and statutory obligations.

The controller of the related data processing operation is the Head of the Unit C1 "Nuclear decommissioning and facilities management" of the JRC.

2.2. Legal requirements in the area of ionising radiation

Legal requirements in the area of protection against the dangers arising from ionising radiation are laid down in IAEA Basic Safety Standards No 115 of 1996 (**IAEA 115/1996**), as well as in the Directives 96/29 and 90/641 as implemented into the Italian Legislative Decrees 230/1995 and 241/00.

Individual monitoring: For exposed category A workers¹, there should be a systematic individual monitoring based on individual measurements established by an approved dosimetric device (Article 25 (1) of the Directive 96/29, Article 6 (d) of the Directive 90/641 - Article 63 and 72 D. Lgs.230/95 and D. Lgs. 241/00).

Monitoring for category B workers shall be at least sufficient to demonstrate that such workers are correctly classified in category B; individual monitoring may be required (Article 25 (2) of the Directive 96/29 - Article 82 and Annex III D. Lgs. 230/95 D. Lgs. 241/00).

The operational protection of apprentices and students aged 18 years and over shall be equivalent to that of exposed workers of category A or B as appropriate. The operational protection of apprentices and students between 16 and 18 years shall be equivalent to that of exposed workers of category B (Article 39 of the Directive 96/29 - Article 82 and Annex III D. Lgs. 230/95 D. Lgs. 241/00).

Accidental and emergency exposure: In the case of accidental exposure, the relevant doses and their distribution to the body shall be assessed (point 1.46 (d) of the Annex 1 to the IAEA 115/1996, Article 26 of the Directive 96/29 - Article 74 and Annex III D. Lgs. 230/95 D. Lgs. 241/00). In the case of emergency exposure, individual monitoring or assessment of the individual doses shall be carried out as appropriate to the circumstances (point 1.46 (d) of the Annex III D. Lgs. 230/95 D. Lgs. 241/00).

Recording and reporting of results: A record containing the results of the individual monitoring shall be made for each exposed category A worker. It shall be retained during the working life involving exposure to ionising 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 (points 1.45, 1.46 (a) - (c), 1.49 of

¹ exposed workers who are liable to receive an effective dose greater than 6 mSv per year or an equivalent dose greater than 3/10 of the dose limits for the lens of the eye, skin and hands, forearms, feet and ankles in terms of Article 21 (a) of the Directive 96/29

the Annex 1 to the IAEA 115/1996, Article 28 of the Directive 96/29, Article 6 (f) of the Directive 90/641 - Article 81 and Annex XI D. Lgs. 230/95 D. Lgs. 241/00).

The results of individual monitoring shall be made available to the competent authorities, to the undertaking, to the worker concerned and to the approved medical practitioner or approved occupational health services in order to interpret their implications for human health as provided in Article 31 of the Directive 96/29. In the case of an accidental or emergency exposure, the results of the individual monitoring shall be submitted without delay (point 1.47 (a) and (b) of the Annex 1 to the IAEA 115/1996, Article 29 of the Directive 96/29 - Article 80 D. Lgs. 230/95).

All doses relating to specially authorised exposures of category A workers shall be separately recorded in the medical record referred to in Article 34 of the Directive 96/29 and the individual record referred to in Article 28 of the Directive 96/29 (Article 12 (1) (e) of the Directive 96/29 - Article 74 D. Lgs. 230/95).

Upon request, workers shall have access to the results of their individual monitoring (point 1.47 (a) of the Annex to IAEA 115/1996, Article 38 (2) of the Directive 90/641 - Article 61 D. Lgs. 230/95).

2.3. Description of the processing

The following automatic and manual processing operations were mentioned in the notification form:

- production of a unique reference number to be used as a dosimeter identifier and linked to the name;
- production of a list of monthly dosimeter readings, radio-toxicology data and whole body monitor data;
- production of a list of medical examinations required by the date chosen;
- production of the Dosimetry Schedule;
- production of the report showing all changes made to the database;
- data entry;
- updating of personal data;
- updating of employer data;
- calculation of the personal effective radiation dose from the results of the dosimeter radiation exposure by the Qualified Expert.

Dosimeters: Personal radiation dosimeters are given a unique reference number which is used for identification with an internal or external worker or a visitor.

At the end of the exposure period (generally a month), the dosimeter is measured. From this raw data the Qualified Expert manually calculates the personal radiation exposure over a prescribed limit over a prescribed time period. This information is then put into the DRS software.

DRS software: The DRS is an electronic version of the Dosimetry Schedule. It is composed of several different modules associated with specific duties (data entry, enquiries and reports).

According to the information provided in the document entitled "Dosimetry Recording System User Operational Procedure", the "Data entry" module consists of the following subsections: dosimeter, whole body, radio-toxic, medical examination, other exposure and visitor details. The "Enquiries" module is used to produce a list of medical examination in relation to a particular date, as well as the monthly dosimeter readings, radio-toxicological and whole body monitor data of a particular staff member.

The "Reports" module allows for the printing of the Dosimetry Schedule (with a unique file number) and of the changes made to the database.

Radiation Passbook: Workers performing radiation work on other sites require Radiation Passbook which is an individual radiation monitoring document and medical certificate at the same time. It contains the holder's previous radiation exposure, medical certification and is issued by the JRC. Upon returning to the JRC, the employee must return the document to the Qualified Expert, which enters the data in the Dosimetry Management System.

2.4. Data subjects

Data subjects are those individuals who are occupationally exposed to ionising radiations (members of JRC staff and external staff under contract), apprentices and students, as well as visitors exposed to ionising radiation.

2.5. Categories of data processed

According to the Privacy Statement submitted together with the notification, the following two categories of data are being collected in connection with the dosimetry management:

- identification data: name, gender, date of birth, starting and leaving date, employer, related company information and related administrative data;
- radiological data: radiation category, dosimeter number, personal radiation exposure.

In terms of the other explicative documents submitted, the processed data can be categorised as follows:

- \rightarrow data contained in the **Dosimetry Schedule**:
- name, sex, place and date of birth and fiscal code of the worker;
- identification and seat of the employer;
- reason why the schedule was issued;
- history of exposure: from to, employer, external and internal radiation: partial/global organ, radiation, dose equivalent, *equivalente di dose totale globale*, notes;
- exceptional radiation (agreed not agreed), internal contamination, remarks;
- occupational data: from to, tasks, type of radiation (global/partial/external/internal), classification (A/B/not-applicable), signature of the Qualified Expert;
- other ionising radiation related activities: from to, employer/self-employed, type of radiation, signature of the worker;
- dose assessment during the calendar year: month, external, internal and total exposition; other employer/self-employed, signature of the Qualified Expert; remarks;
- dose assessment for the calendar year: effective dose, equivalent dose, organ or body part;
- effective dose accumulated over life;

 \rightarrow data contained in the "Data Entry" module of the **Dosimetry Recording System**:

- dosimeter: "First part of the form allows all readings to be set to zero for the period, second part of the form allows for any non-zero readings to be recorded. The effective dose refers to the whole body dose measured by the monthly thermo luminescent dosimetry (TLD) badge. Under the Dosimetry Schedule the dose equivalent is reported for extremities (hands, feet), skin and lens of the eye. The body/organ reported only needs to be hand/foot, skin or lens). The notes can be used to record the number of the dosimeter used to measure dose equivalent."

- whole body: date of measurement, institution, dose equivalent;
- radio-toxic: date of measurement, institution, dose equivalent;
- medical examination: date of medical examination, valid until, fitness for work;
- other exposure: date, effective dose, dose equivalent, organ or body;
- visitor details: dosimeter number, date, effective dose, location;

\rightarrow data contained in the **Radiation Passbook**:

- personnel number, name, sex, date and place of birth, as well as address and phone number of the passbook holder;
- inspector's card number, record number, date of issue, list of approved compliers (name, signature)²;
- history of exposure: occupational exposure before employment by the European Commission, registered in previous Personal Radiation Records, involvement in any accident (yes/no), date of accident, accident dose;
- radio-nuclides incorporated;
- remarks;
- dose assessment for the calendar year: year, month, partial body dose, effective dose;
- estimated doses in another employer's controlled areas: from to, institution, partial body dose, effective dose;
- whole body counter: date of control, institution, radio-nuclides, activity, committed dose equivalent;
- radio-toxicological monitoring: date of control, institution, sample, activity, committed dose equivalent;
- medical examination: date, fitness for work with radiation exposure;
- fitness for work under arduous conditions (e.g. respiratory equipment): date, valid until, remarks;
- radiation protection training: course title, institution, date;
- important addresses and phone numbers: headquarters, Medical Service, Health Physics Officer.

2.6. Recipients

According to the information provided in the notification (including its attachments), the data can be disclosed to the following recipients:

- JRC Qualified Nuclear Physicists Experts / suitably qualified and experienced radiation protection staff / Qualified Experts as identified in the Directive 96/29 (Article 1)³ and the D.Lgs. 230/1995 (*Capo VIII, Allegato XI*);
- JRC approved medical practitioners as identified in Articles 87 and 88 D. Lgs. 230/95;
- Heads of Human Resources Units and the Hierarchy (Directors) of the respective data subjects;
- employer of the external workers (Qualified Experts, approved medical practitioners and Human Resources);
- competent authorities (ANPA, ISPESL, ASL, *Ministero del Lavoro e della Previdenza sociale* as referred to in D. Lgs. 230/1995 (*Capo VIII, Allegato XI*));

² persons authorised by the Qualified expert to insert data into the radiation passbook

³ persons having the knowledge and training needed to carry out physical, technical or radiochemical tests enabling doses to be assessed, and to give advice in order to ensure effective protection of individuals and the correct operation of protective equipment, whose capacity to act as a qualified expert is recognised by the competent authorities, A qualified expert may be assigned the technical responsibility for the tasks of radiation protection of workers and members of the public.

The employer is ultimately responsible for the employees' safety at work and therefore needs access to appropriate information (administrative, medical and professional risks' exposure data) in order to make an informed decision about work resulting in exposure to ionising radiation.

2.7. Data retention

The individual dosimetry records shall be retained 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 (points 1.45, 1.46 (a) - (c), 1.49 of the Annex 1 to the IAEA 115/1996 and Article 81 and Annex XI D. Lgs. 230/95 D. Lgs. 241/00).

The data stored for further statistical purposes are kept in anonymous form.

2.8. Rights of data subjects

The data subjects' rights (access, rectification, blocking and erasure) can be exercised upon a request to the controller. To this aim, the following functional mailbox can be used: <u>jrc-ispra-dosimetry@ec.europa.eu</u>. Following a justified and legitimate request by the data subject, the personal data will be modified in the DRS database within 14 days.

2.9. Information given to data subjects

A **Privacy Statement** will be available at the distribution boards of the dosimeters in each building entrance, as well as on the Unit C1 webpage on the new JRC Intranet.

The Privacy Statement submitted for review provides for the following information: identity of the controller, certain categories of data collected, certain data recipients, the existence of the rights of access and rectification, time-limits for storing of the data, the contact details of the Commission DPO and the DG JRC DPC, as well as the right to send a complaint to the EDPS.

Notification of the data subjects: There is an immediate notification of a high dose and a regular notification of normal radiation exposure to the individual and the employer.

2.10. Security measures

(...)

3. Legal Aspects

3.1. Prior checking

Applicability of the Regulation: The present notification relates to the processing of personal data (*"any information relating to an identified or identifiable natural person"* - Article 2 (a) of the Regulation) carried out in the exercise of activities falling within the scope of Community law (Article 3 (1) of the Regulation). The processing is partly automatic (the DRS database) and the personal data processed manually are kept in structured files (individual dosimetry records; Article 3 (2) of the Regulation). Therefore, the Regulation (EC) 45/2001 is applicable.

The scope of the prior checking analysis is restricted to the processing of dosimetry data. The medical surveillance of workers exposed to ionising radiation at DG JRC Ispra has been analysed in a separate opinion⁴.

Grounds for prior checking: Article 27 (1) of Regulation (EC) No 45/2001 subjects to prior checking by the EDPS 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. This list includes "*processing of data relating to health*" (Article 27 (2) (a) of the Regulation). Processing of dosimetry data clearly concerns health related data and thus needs to be subjected to prior checking.

Ex-post prior checking: 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. In any case, this is not a serious problem in that any recommendations made by the EDPS may still be adopted accordingly.

Deadlines: The present notification was received on 3 September 2007. According to Article 27 (4) of the Regulation, the EDPS opinion must be delivered within a period of two months. The procedure was suspended for a total of 101 days (40 + 49 + 12). Consequently, the present opinion must be delivered no later than on 13 February 2008.

3.2. Lawfulness of the processing

The lawfulness of the processing operations must be examined in light of Article 5 of Regulation 45/2001. The notification for prior checking stated that the processing is necessary according to Article 5 (a) of the Regulation. Although there is a "grey zone" between Articles 5 (a) and (b) of the Regulation, the EDPS considers that in the present case, Article 5 (b) of the Regulation allowing for *"processing necessary for compliance with a legal obligation to which the controller is subject"* is applicable. Indeed, the controller of the processing operation is subject to very specific legal obligations laid down in the Italian Legislative Decrees 230/95 and 241/00 implementing the Directives 96/26 and 90/641⁵ (cf. point 2.2. above).

3.3. Processing of special categories of data

Pursuant to Article 10 (1) of the Regulation, the processing of health related data is prohibited except in specific predefined circumstances, such as when the processing is "necessary for the purposes of complying with the specific rights and obligations of the controller in the field of employment law insofar as it is authorised by the Treaties establishing the EC or other legal instruments adopted on the basis thereof" in terms of Article 10 (2) (b) of the Regulation or

⁴ cf. EDPS opinion **2007-329** (Individual Medical Files at DG JRC Ispra et Seville)

⁵ As to the applicability of the Italian Legislative Decrees within the DG JRC of the European Commission, it has to be recalled that in line with the established ECJ jurisprudence, national law applies within EU institutions insofar as it does not run counter to the smooth functioning of these institutions. In fact, the privileges and immunities granted to the Communities on a basis of Article 291 of the Treaty, as implemented in the 1965 Protocol *"have a purely functional character, inasmuch as they are intended to avoid any interference with the functioning and independence of the Communities"* - ECJ, 1/88, SA Générale de Banque/ Commission [1989] ECR 857, §9; ECJ, C-2/88 Zwartveld and Others [1990] ECR I-3365, §§ 19 and 20; CFI, T-80/91 Campogrande/ Commission [1992] ECR II-2459, §42

"necessary to protect the vital interests of the data subject" in terms of Article 10 (2) (c) of the Regulation.

As explained above, the purpose of the processing in question is the compliance with the mandatory rules imposed on the controller with respect to the protection of occupationally exposed persons as laid down in the Italian Legislative Decrees 230/95 and 241/00 implementing the Directives 92/26 and 90/641. In any case, the processing of health-related data of visitors accessing controlled areas could be justified with respect to the necessity to protect their life and health. Article 10 of the Regulation is therefore fully complied with.

3.4. Data Quality

The data quality principles enshrined in Article 4 (1) (a), (c) and (d) of the Regulation require that the data are "processed fairly and lawfully", they are "adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed", as well as "accurate and, when necessary, kept up to date".

Fairness and lawfulness: Lawfulness has already been discussed (cf. point 3.2) and fairness will be dealt with in relation to information provided to data subjects (cf. point 3.9).

Adequacy, relevance and proportionality: The data processed in connection with dosimetry management at JRC Ispra are of administrative and medical nature. The EDPS is of the opinion that the processing of the data subject's fiscal code (within the Dosimetry Schedule) cannot be deemed necessary for the surveillance of persons occupationally exposed to ionising radiation. Therefore, he recommends that the fiscal code should not be processed in this context, unless the necessity of its processing can be reasonably explained.

Accuracy: The EDPS notes that several measures are put in place in order to comply with this data quality principle, ranging from the attribution of a unique identification number to each professionally exposed person to the possibility to request rectification of inaccurate or incomplete data processed (cf. also point 3.8). Article 4 (1) (d) of the Regulation is therefore duly complied with.

3.5. Data retention

Article 4 (1) (e) of the Regulation states that personal data must be "kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed". In addition, "the personal data which are to be stored for longer periods for statistical purposes should be kept either in anonymous form only, or if that is not possible, only with the identity of the data subject encrypted" and "shall not be used for any other purpose".

As indicated above, the individual dosimetry records are being kept for at least 30 years from the termination of the work involving exposure to ionising radiation and are in any case deleted 75 years after the birth of the data subject (points 1.45, 1.46 (a) - (c), 1.49 of the Annex 1 to the IAEA 115/1996 and Article 81 and Annex XI D. Lgs. 230/95 D. Lgs. 241/00). In addition, the data stored for further statistical purposes are kept in anonymous form.

Considering that the storage of accurate dosimetry data may have significant relevance later in the context of medical treatment of the person concerned and/or in view of possible occupational diseases' related claims, the EDPS considers the legally prescribed time limit as reasonable. Article 4 (1) (e) of the Regulation is thus fully respected.

3.6. Transfer of data

Articles 7, 8 and 9 of Regulation (EC) No 45/2001 set out certain obligations that apply when the processed data are being transferred to third parties. The rules differ depending on whether the transfer is made to or within a Community institution or a body (based on Article 7), to recipients subject to Directive 95/46/EC (based on Article 8), or to other types of recipients (based on Article 9).

As indicated above, the data may be transferred to the following recipients:

- JRC Qualified Experts, JRC approved medical practitioners, JRC Heads of Human Resources Units and the Hierarchy (Directors);
- employer of the external workers (Qualified Experts, approved medical practitioners and Human Resources);
- competent authorities.

Internal transfers: The transfers within JRC Ispra shall be examined in light of Article 7 of the Regulation 45/2001. This Article provides that "personal data can be transferred within or to other Community institutions or bodies if the data are necessary for the legitimate performance of the tasks covered by the competence of the recipient" (paragraph 1) and that "the recipient can process the data only for the purposes for which they were transmitted" (paragraph 3).

The EDPS notes that the internal transfers fall within the legitimate performance of the tasks covered by the competence of the respective recipient. In fact, in their quality as employer, the JRC Human Resources and Directors have to ensure adequate protection of JRC staff occupationally exposed to ionising radiation at JRC Ispra, such as to ensure that only medically fit workers are exposed to the respective health risks. The JRC Qualified Experts are entrusted with the specific radiation protection tasks, whereas the JRC approved medical practitioners are responsible for the medical surveillance of the professionally exposed workers.

In order to ensure full compliance with Article 7 of the Regulation, the EDPS recommends that all internal recipients are reminded of their obligation to process the data only for the purpose for which they were actually transmitted.

Transfer to recipients subject to Directive 95/46/EC: The data transfers to the Italian supervisory authorities, as well as the transfers of external workers' data to their employer established in the EU shall be examined in light of Article 8 of the Regulation. This Article allows for transfers to recipients subject to (the national law adopted for the implementation of) Directive 95/46/EC *"if the recipient establishes that the data are necessary for the performance of a task carried out in a public interest or subject to the exercise of public authority"* (Article 8 (a) of the Regulation).

The EDPS considers that these transfers are necessary for the exercise of public authority and/or for the exercise of a public interest task in the area of protection against ionising radiation in accordance with the applicable national legislation. The necessity of the actual transfer is established jointly by the sender and the recipient.

Transfers to recipients <u>not</u> subject to Directive 95/46/EC: The transfers of external workers' data to their employer not established in the EU, as well as the transfers of data of third countries nationals to the respective third countries national authorities shall be

examined in light of Article 9 of the Regulation. In principle, transfers to recipients not subject to Directive 95/46/EC may occur only "if an adequate level of protection is ensured in the country of the recipient or within the recipient international organisation and the data are transferred solely to allow tasks covered by the competence of the controller to be carried out" (paragraph 1), unless "the controller adduces adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals and as regards the exercise of the corresponding rights, resulting - in particular - from appropriate contractual clauses⁶" (paragraph 7) or unless one of the exceptions defined in paragraph 6 is applicable. In the present case, paragraph 6, (a), (d) or (e) of the Regulation (transfer based on "the unambiguous consent of the data subject", "necessary or legally required on important public interest grounds", or "necessary in order to protect the vital interests of the data subject") may be applicable.

3.7. Processing of personal number

Article 10 (6) of the Regulation provides that "the EDPS determines the conditions under which a personal number or other identifier of general application may be processed by a Community institution or body".

The EDPS notes that the personal number of the data subject is being processed in connection with dosimetry management at JRC Ispra (cf. Radiation Passbook). He considers that the personal number can be used in this context since it allows for the identification of the respective staff member and facilitates the follow-up in an appropriate way. There is no reason to determine any further conditions in this case.

3.8. Rights of access and rectification

Right of access: Pursuant to Article 13 of the Regulation, "the data subject shall have the right to obtain, without constraint, 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".

The right of access to the regular individual dosimetry results is enshrined in Article 61 D. Lgs. 230/95. It is specified in the Privacy Statement that the access request should be sent to the controller's functional mailbox. Article 13 of the Regulation is therefore fully respected.

Right of rectification: Article 14 of the Regulation provides that "the data subjects shall have the right to obtain from the controller the rectification without delay of inaccurate or incomplete information".

The EDPS notes that the right of rectification can be somewhat limited because of the nature of the processing operation in question. It clearly applies to the updating of administrative data contained in the Dosimetry Schedule, Dosimetry Recording System and Radiation Passbook. Nevertheless, it is more difficult to guarantee this right with respect to medical data

http://ec.europa.eu/justice_home/fsj/privacy/modelcontracts/index_en.htm

⁶ To this respect, cf. the Commission Decision 2001/497 of 15 June 2001 on standard contractual clauses for the transfer of personal data to third countries, under Directive 95/46/EC as amended by Commission Decision 2004/915/EC of 27 December 2004 concerning the introduction of an alternative set of standard contractual clauses for the transfer of personal data to third countries -

processed. In principle, it cannot be excluded that the person concerned requests a review by an external radioprotection expert. It could be a good practice to include a reference to such an expert opinion into the respective dosimetry documents and software in order to make the processed data complete.

3.9. Information to the data subject

In order to ensure transparency and fairness of the processing of personal data, Articles 11 and 12 of Regulation 45/2001 provide for certain information to be supplied to the data subjects. The provision of Article 11 is applicable in case "*the data have been obtained from the data subject*", the provision of Article 12 in case the data have been obtained from other source. In the present case, both Articles are applicable since the data processed are being obtained from the person concerned, as well as from the two JRC Units involved in the processing.

As indicated above, the Privacy Statement posted at the dosimeters' distribution boards in each building entrance, as well as on the Unit C1 webpage on the new JRC Intranet contains the following information:

- identity of the controller,
- certain categories of data collected,
- certain data recipients ("Qualified Experts and Medical Officers as identified in the Directive 96/29 and D. Lgs. 230/95"),
- the existence of the rights of access and rectification,
- time-limits for storing of the data,
- contact details of the Commission DPO and the DG JRC DPC,
- right to send a complaint to the EDPS (to <u>edps@edps.eu.int</u>).

In addition, in case of overexposure, all data subjects (including visitors) are being informed about the received dose without delay (Article 80 D. Lgs. 230/95).

In order to ensure the full compliance with Articles 11 and 12 of the Regulation, the EDPS recommends that the Privacy Statement is completed as to information about the purpose of the processing, the categories of data processed, the possible data recipients (by adding a reference to the national supervisory authorities and the employers of the external workers), the way how to rectify medical data processed within the Dosimetry Schedule, DRS and Radiation Passbook, as well as information about the legal basis applicable. In addition, the reference to the EDPS functional mailbox should be updated (edps@edps.europa.eu).

3.10. Security measures

(...)

4. Conclusion

There is no reason to believe that there is a breach of the provisions of Regulation 45/2001 provided that the above considerations are fully taken into account. In particular,

- the need for processing of the data subject's fiscal code should be reconsidered in order to comply with Article 4 (1) (c) of the Regulation,

- the data recipients within the JRC Ispra should be reminded of their obligation not to use the data received for any other purposes that the one for which they were transmitted (Article 7 (3) of the Regulation),
- the possibility of including a reference to external expert opinions submitted by the data subject into the respective dosimetry documents and software should be considered (Articles 4 (1) (d) and 14 of the Regulation),
- the Privacy statement posted at the dosimeters' distribution boards, as well as on the JRC C1 Intranet should be completed as to information about the purpose of the processing, the categories of data processed, the data recipients, the way how to rectify medical data processed within the Dosimetry Schedule, DRS and Radiation Passbook, as well as the legal basis applicable (Articles 11 and 12 of the Regulation),
- the reference to the EDPS functional mailbox provided in the Privacy Statement should be updated.

Done at Brussels, 6 February 2008

Peter HUSTINX European Data Protection Supervisor