

Opinion on the notification for prior checking from the European Commission's Data Protection Officer regarding the "management of individual medical files - Brussels, Luxembourg" case.

Brussels, 18 November 2008 (Case 2004-225)

1. Proceedings

By letter received on 21 February 2007, notification within the meaning of Article 27 of Regulation (EC) No 45/2001 was given by the Commission's Data Protection Officer (DPO) concerning the "Medical files" case (2004-225). The notification was sent together with a number of documents, including:

- the Decision by the Board of Heads of Administration concerning access of officials and other servants to their medical files (Conclusion 221/04);
- the relevant extracts from the Staff Regulations and European Directives on risks in the workplace;
- the articles from the Staff Regulations concerning the professional and medical confidentiality criteria to be respected by staff of the EU institutions;
- the annual medical check-up form;
- the medical form on recruitment:
- forms for the six-monthly visits by the nuclear inspectors.

In connection with this case, questions were put to the controller via the DPO on 8 March 2007. The controller replied on 1 June 2007. Additional information was requested on 20 June 2007. The controller replied on 13 July 2007. Another request was made on 17 July. An answer was given on 23 July 2007. Further information was requested on 4 September 2007. A reply was received on 27 November 2007 (84 days). In view of the complexity of the case, on 27 November 2007 the EDPS extended the period for issuing an opinion by a month on the basis of 27(4) of Regulation 45/2001.

In order to enable the DPO to provide the additional information and relevant comments, a draft was forwarded on 20 December 2007. The comments were received from the controller on 25 April 2008. In view of the comments received, the period was again extended by a month as from 7 May 2008 on the basis of Article 27(4) of the Regulation. On 9 June 2008 a meeting was agreed between the EDPS and the controller to clarify the scope of the

On 20 July 2004 the European Data Protection Supervisor (EDPS) wrote to the Data Protection Officers (DPOs) asking them to contribute towards making an inventory of data processing operations that might be subject to prior checking by the EDPS as provided for by Article 27 of Regulation (EC) No 45/2001. The EDPS asked to be notified of all processing operations subject to prior checking, including those which had commenced before the EDPS was appointed and the checking of which could under no circumstances be regarded as prior in nature, but which would undergo ex-post checking. The Commission's DPO notified this processing operation, which received the above reference number.

E-mail: edps@edps.europa.eu - Website: www.edps.europa.eu

Tel.: 02-283 19 00 - Fax : 02-283 19 50

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notification. On 10 September 2008 the EDPS again contacted the Commission's DPO by e-mail to clarify the facts. Replies to that e-mail were received on 18 September and 1 October 2008. On 17 November 2008, on the basis of the information received, the EDPS decided to lift the suspension even though the meeting had not taken place.

2. Facts

The management of medical files by the Commission concerns officials, temporary staff, contract staff and detached national experts working at the Commission in Brussels or Luxembourg, at one of the Joint Research Centres (JRC) managed by Luxembourg (Karlsruhe, Geel, Petten), and in agencies and other institutions with which the medical service has signed a relevant agreement. It also concerns auxiliary staff, temporary staff, scholarship holders and private employees holding posts involving risk in Luxembourg or in the Joint Research Centres whose medical files are managed by the Commission in Luxembourg².

The Commission's medical service in Luxembourg is also responsible for the twice-yearly medical fitness examinations carried out as part of the medical monitoring of DG TREN's nuclear inspectors. This service also manages, with the aid of an administrative management programme, the dates of the various medical fitness examinations conducted. The other technical examinations (external and internal dosimetric tests) conducted to monitor the personnel of DG TREN are not carried out by the Commission's medical service in Luxembourg but take the form of separate prior checks³.

The medical files are not scanned and are processed manually.

Purpose and data collected

The processing of the medical information in the individual medical file allows the health of staff to be monitored and enables the Commission to fulfil its statutory obligations to staff. This includes the pre-recruitment medical examination, the annual check-ups, checks on absences, and retirement on grounds of invalidity, as well as all medical documents relevant to monitoring the health of the data subjects. Furthermore, specific information is collected on persons subject to occupational risks with a view to complying with the relevant European Directives.

2.1. Pre-recruitment medical examination

Pursuant to Article 33 of the Staff Regulations, "Before appointment, a successful candidate shall be medically examined by one of the institution's medical officers in order that the institution may be satisfied that he fulfils the requirements of Article 28(e)." Under that article, "An official may be appointed only on condition that: he is physically fit to perform his duties."

All candidates are required to fill in a form in their mother tongue and hand it to the doctor during their pre-recruitment medical examination. Candidates undertake to provide truthful information, otherwise the pre-recruitment medical examination may be declared void. This document is placed in the official's medical file.

According to the notification received, for practical reasons there are two identical copies of each individual medical file in the case of staff at the Joint Research Centres, with the original remaining in Luxembourg and the copy being kept at the Joint Research Centre.

See in particular "Prior checking opinion on Occupational radioprotection data at DG TREN" (2007-0383)

That document contains the following administrative data: surname and first name, date and place of birth, nationality, mother tongue, sex, marital status, children, contact details (postal address, e-mail address, telephone numbers), name of GP, education, language ability, post sought and type of contract. The document also contains a photo of the data subject. Candidates are asked about their professional activity and the nature of the job for which they are applying. They are also asked whether or not they have already worked for a European institution and, if so, whether they have already undergone a medical examination for that institution. Candidates must also state whether they have had to change profession or occupation for medical reasons.

Questions are asked regarding the health of members of the candidate's family, and the cause of any deaths of family members (father, mother, brothers, sisters, children, spouse) and the age at which they took place.

Candidates must stipulate the nature of any occupational illness they have had recognised and mention whether they have first-aid or ambulance driver diplomas.

Questions are then asked regarding the candidate's personal medical history, in particular illnesses or disorders.

Candidates must stipulate whether they have had a permanent or partial incapacity for work following an accident or an illness and, if so, for how long and the nature of the incapacity; whether they have ever undergone surgery and if so, what type and when. They must also state whether they have undergone radiological or nuclear medicine examinations, magnetic resonance imaging or ionizing treatment. They must mention whether they have undergone an electro-encephalogram.

Candidates must provide information on instances of invalidity or disability, any allergies or intolerances, contraception methods used and pregnancy, and vaccinations. The questionnaire also includes some questions on the person's lifestyle, in particular medicines taken on a regular basis, dietary habits (consumption of beer, spirits, wine, and tobacco) and sporting activities.

The Medical Service then carries out an objective examination which leads to a number of additional examinations. A form is completed by the doctor setting out the results of the direct medical examination: medical history, objective examination, results of the laboratory tests, X-rays, results of other medical examinations (eye test, hearing test, ECG, etc.), depending on the individual.

In Brussels, the doctor indicates by hand in the blood test section of the form the data subject's acceptance or refusal of the HIV test.

In Luxembourg, an ad hoc form for accepting the HIV test is signed by the data subject.

The doctor may add comments on abnormal results and summarise the examination. He also gives his conclusions. The document is signed by the doctor conducting the examination and by the institution's medical officer or his deputy.

Following the recruitment medical examination, the human resources officer receives a declaration stating that the person is fit/unfit for work or fit with reservations.

Pursuant to Article 1 of Annex VIII, where the medical examination carried out before an official takes up his duties shows that he is suffering from sickness or invalidity, the appointing

authority, in so far as risks arising from such sickness or invalidity are concerned, may decide to admit that official to guaranteed benefits in respect of invalidity or death only after a period of five years from the date of his entering the service of the Communities (fit with reservations).

2.2. Annual medical check-up

Article 59(6) of the Staff Regulations requires officials to undergo a medical check-up every year. Officials may choose to be examined by either the institution's medical officer or a medical practitioner of their choice.

2.2.1. Annual medical check-up carried out by the Commission's medical service

During this medical check-up, the doctor responsible for the examination fills in a specific form. In addition to general administrative data, the form contains information on the professional activity of the data subject (post, whether he/she works with a computer screen); family situation; consumption of medicines, alcohol, tobacco; sick leave; health since previous check-up and current state of health. The form sets out the results of the medical examination conducted by the doctor. Additional special examinations may be carried out with the written authorisation of the medical service (eye test; gynaecologist, smear test; mammography, ultrasound scan; urologist). The form also mentions the situation as regards vaccinations. Consent to the HIV test is requested by the doctor and noted accordingly.

The examining doctor sets out his conclusions and signs the document.

In the case of posts subject to risk:

Following the periodic or annual examination, in the case of posts subject to risk:

- work involving contact with food
- drivers
- work involving contact with children
- printing
- conference interpreters
- telephone switchboards
- health care personnel
- work on computer screens
- TREN inspectors
- staff working in controlled areas of the joint research centres (Geel, Petten, Karlsruhe)

depending on the outcome of the medical examination, a certificate stating that the person is fit or unfit for work, or fit under certain conditions, is sent to the human resources department.

In the case of posts involving risk, the medical check-up must be carried out by a doctor from the medical service, since this is an area of occupational medicine which is subject to specific rules.

Staff employed in the crèches undergo specific examinations, including an X-ray of the thorax (to be replaced shortly by an Intradermoreaction or equivalent) and additional blood tests (ASLO and throat smear if ASLO > 200, CMV, German measles and urinary toxicology).

Most of the staff of the JRCs are subject to specific risks (physical and/or chemical and/or nuclear). A risk form setting out the working conditions, associated risks and means of protection used is completed and signed by each employee. This risk form is also signed by the data subject's hierarchical superior. This appropriately updated technical form is presented to the doctor at the regular check-ups and provides guidance regarding the extra technical examinations (dosimetric tests, specific markers of exposure to metals, solvents, etc.)

necessary for medical monitoring of the worker. This technical form setting out the constraints of a post is kept in the medical file. The worker receives a copy, as does the department responsible for risk management at JRC level, which is either the Health and Safety Department or the Radiation Protection Department, depending on the site⁴.

In the case of persons working in controlled areas, a fitness-for-work form is sent to the Radiation Protection department (see point 2.2.3).

2.2.2. Annual medical check-up carried out by a medical practitioner chosen by the official

If the annual medical check-up is carried out by a doctor chosen by the official pursuant to Article 59(6), the specific annual check-up form is forwarded to the medical service. Following the annual medical check-up, the patient sends the following to the medical service:

- the bill from the doctor together with his/her report, along with proof that the fee has been paid by the patient;
- the results of the tests carried out as part of the annual check-up (the list of standard analyses which can be carried out is printed on the back of the annual medical check-up form) and the receipted laboratory invoice (in Brussels there is no laboratory invoice as the tests are carried out in the medical service's laboratory).

The medical service financial controller encodes the fees in ABAC (DG Budget computer application) and the payment authorisation (reimbursement to patient) in ABAC is given after approval from the persons on the financial check-list for the payment procedure - all the persons on the check-list are members of the medical service. The report from the examining doctor is seen by the medical service's medical officer and then filed in the patient's medical dossier. At no time during the procedure does medical information leave the medical service. In SERMED (the computer application used to manage the medical service's activities), the date of the annual check-up is encoded with the reference "examining doctor" - this information is necessary to be able to distinguish - for statistical purposes in particular - external annual check-ups from those carried out by the Commission's medical service.

As regards payment of the laboratory invoice, the content of the invoices (types of test performed and prices charged) is first verified and validated by the medical service, and the invoice is then encoded in ABAC for reimbursement of the fees to the patient.

All invoices to be paid must be encoded in ABAC. As regards bills from doctors, whose fees are reimbursed up to a maximum amount, only the number and date of the bill are encoded as payment information; no document is attached to the payment. In the case of bills for laboratory tests - the cost of which is reimbursed to patients - only the name of the laboratory, the number of the bill and the date of the invoice are encoded in ABAC.

2.2.3. Medical check-up for DG TREN inspectors and JRC staff working in controlled areas

A/ <u>DG TREN inspectors</u> - in particular those classified as "active", i.e. those exposed by virtue of their activity to nuclear risks - are subject to an assessment every six months of fitness for work carried out by the Commission's medical service (Luxembourg).

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The processing of personal data in connection with dosimetric tests in the JCRs is subject to separate prior checking by the EDPS, i.e. files 2008-020 (Petten), 2007-0325 (Geel) and 2007-0378 (Karlsruhe).

This check-up includes technical examinations and a clinical medical examination.

- The technical examinations comprise:
 - (i) standard biological analyses of blood and urine (results sent directly and exclusively to the medical service)
 - (ii) radio-toxicological analyses
 - (a) urine and stool analysis tests performed by a laboratory chosen by DG TREN with the results being sent directly to the medical service, which then forwards a copy to DG TREN, the HPC (Health Protection Cell - Radiation protection), in order to jointly calculate the dose if necessary;
 - (b) whole body counter/lung counter measurements carried out by a laboratory chosen by DG TREN and the results of which are sent to the medical service and to DG TREN.
 - (iii) dosimetric records external personal dosimetry. The reading of the dosimeters is carried out by an external firm chosen by DG TREN and the results are sent to DG TREN, which then forwards them to the medical service as important input information in determining medical fitness for work.
- The clinical medical examination is conducted by a medical officer from the medical service qualified in radiation protection.

The medical officer who receives the results of the additional technical analyses and who carries out the clinical examination then issues an opinion on whether or not the data subject is fit to work in a controlled area. The opinion is added to the data subject's medical file, included in his/her radiation passbook and is sent using the relevant form to the person in charge of the HPC (Health Protection Cell) in DG TREN. That form shows the surname, forename, the dates of technical examinations and clinical examination and the conclusion (fit/unfit).

The list of "active" inspectors (surname, first name and staff number) is sent to the medical service by DG TREN. The nurse enters in an Access database the surname, first name, date of birth, staff number, workplace and telephone number of the data subject, as well as the dates of the above examinations as and when they are performed.

The computer programme for managing medical and technical examinations comprises an MS ACCESS database installed on the local disk of a nurse's PC at the medical service in Luxembourg. Access to the PC is subject to a login and password procedure.

A function in the database enables the list of active inspectors to be printed, as well as the dates of their examinations. Using that list, the nurse notifies those inspectors who are required to re-take one or more examinations according to a pre-determined frequency.

DG TREN also informs the medical service when an inspector (a) changes from active to "non-active" status (i.e. is no longer exposed to ionising radiation) or (b) leaves DG TREN. During periods of non-exposure, inspectors are subject to normal annual check-ups in the same way as other members of staff.

B/ As regards the monitoring of <u>JRC personnel</u> (Geel, Petten, Karlsruhe) working in controlled areas (i.e. subject to nuclear risk), the medical monitoring procedure is very similar to that used for TREN inspectors:

- the radiation protection service of each JRC and the medical service receive the results of the same technical examinations (radio-toxicological and dosimetric tests), while the results of the biological analyses (blood/urine) and of the clinical examination are strictly reserved for the medical service and are entered in the medical file;
- a medical opinion as to fitness/unfitness for work is addressed to the JRC's radiation protection service, using a form setting out the worker's identification details (surname, first name, date of birth), the dates of the technical examinations and the clinical examination and the conclusion as regards fitness/unfitness for work. A copy is kept in the medical dossier and the worker also receives a copy.

The management of the dates of medical and technical examinations is computerised at Petten and Karlsruhe, but not at Geel.

At Petten, there is a simple Excel file on a memory stick kept in the medical service and accessible only by the medical secretary; there is no nurse at Petten.

At Karlsruhe, an MS ACCESS database is installed on the local disk of the stand-alone PC of the medical service nurse. Access to the PC is subject to a login/password procedure.

The data encoded are: surname, first name, date of birth, staff number, workplace, telephone number, administrative status and type of work, as well as the dates of the examinations as and when they are conducted and the reference fit/unfit for work. Lists can be printed out by the nurse/medical secretary who, using those lists, notifies workers who are required to re-take one or more examinations on the basis of a pre-determined frequency.

At Geel, however, the nurse does not use a computer programme to manage the dates of the medical examinations. He requests an updated staff list from the human resources department containing the standard information: surname, first name, staff number, sex, nationality, unit, status, date of birth, starting date and (presumed) finishing date. For each type of examination (e.g. medical test, blood/urine test), he ticks off/highlights the names of colleagues on a copy of that list as and when they take the examinations. He keeps the lists under lock and key in a cabinet in his office and destroys the lists each year.

2.2.4. Medical check-ups for auxiliary staff, temporary staff, private employees and scholarship holders working in Luxembourg and in the research centres

In Luxembourg, the auxiliary staff, temporary staff and private employees have contracts under Luxembourg law and come under Luxembourg's occupational medicine and social security services, which manage problems relating to medical check-ups, invalidity, etc.

However, in the case of posts subject to risk (catering and teaching staff, etc.), and in order to avoid discrimination between such staff and Community officials, the medical service requires all staff (in posts involving risk) to undergo appropriate medical check-ups once a year, or even twice a year in the case of personnel who are in direct contact with food. The medical information relating to these periodic check-ups (medical reports, test results) is added to the medical files of the data subjects.

The medical service in Luxembourg uses the same system to manage the medical files of auxiliary staff, temporary staff, private employees and scholarship holders working in posts involving risk at the JRCs, who require evidence of medical fitness to be able to work. This certificate of fitness for work is subject to a clinical examination and various technical examinations depending on the type of occupational exposure. All the results are placed in the

medical file and only the opinion on fitness/unfitness for work is sent to the relevant department (HR, Radiation Protection, Health and Safety).

2.3. Checks on absences

An official who provides evidence of being unable to carry out his duties by reason of illness or accident is entitled to sick leave. He must produce a medical certificate if he is absent for more than three days and it is filed chronologically in files kept in the examining doctor's office/department. The official may at any time be required to undergo a medical examination arranged by the institution (Article 59(1) of the Staff Regulations). A copy of the result of the medical examination is added to the official's medical file.

The appointing authority may refer to the Invalidity Committee the case of any official whose sick leave totals more than 12 months in any period of three years (Article 59(4), of the Staff Regulations). Information on the duration of the official's absence and relevant extracts from his/her medical file are sent directly by the medical service to the doctors on the Invalidity Committee⁵.

2.4. Retirement on grounds of invalidity

An official is entitled, in the manner provided for in Articles 13 to 16 of Annex VIII, to an invalidity allowance in the case of total permanent invalidity preventing him from performing the duties corresponding to a post in his function group (Article 78 of the Staff Regulations).

The decision to retire someone on health grounds is a matter for the appointing authority after it has had the opinion of the Invalidity Committee. The concluding medical report from the IC (copied only to the doctors who signed it, if they so request) and all the medical reports and other IC documents are placed in the person's medical file.

Invalidity medical files are stored in the data subject's medical file⁶

Information to be given to the data subject

A confidentiality statement has been published on the Commission's Intranet site. Every individual going to the medical service for the pre-recruitment medical examination receives a copy of that statement. The statement includes information on the purpose of the medical file; the identity of the data controller; the type of data collected; the authorities and individuals to whom the data are disclosed; the security measures adopted; ways of checking, amending and deleting administrative data; information on how long the data are to be stored and contact details should there be a general problem or a personal data protection problem, and information on the possibility of having recourse to the EDPS.

On their first visit to the medical service, TREN inspectors receive a confidentiality statement on the processing of their personal data under the specific system for medical surveillance of nuclear safety inspectors. That form contains information on the type of examinations carried out, their purpose or purposes, the entry of medical follow-up data on MS ACCESS, the

Checks on absences due to illness are subject to separate prior checking by the EDPS (see opinion 2004-226 of 11 October 2007).

The invalidity procedure is subject to separate prior checking by the EDPS (see opinion 2007-0125 of 29 November 2007).

identity of the controller of the processing, the type of data, the data recipients, the storage period, the existence of a right of access to and rectification of administrative data and the right to have recourse to the EDPS at any time. The same information is also published on Intranet.

Likewise, JRC staff receive and have access to a confidentiality statement explaining the health surveillance procedures used to provide medical follow-up for them, particularly for posts involving risk. That confidentiality statement contains information on the purpose or purposes of processing, the categories of data processed, a description of data management processes, the recipients, the storage period, how to access and modify data, the identity of the controller and the right to have recourse to the EDPS at any time.

Rights of the data subjects

All data subjects may have access to their medical files following a request in writing to the head of the medical service. Pursuant to a decision of the Board of Heads of Administration of 19 February 2004 (Conclusion 221/04), officials and temporary staff have the widest possible access to their medical files, under the following conditions:

- "the file must be consulted on the premises of the medical service of the institution, in the presence of a person designated by the medical service;
- the official or other servant will be able to have access to psychiatric/psychological reports concerning him or her, through the intermediary of a doctor appointed by him or her;
- the official or other servant does not have access to the personal notes of doctors where, under Article 20(1)(c) of Regulation No 45/2001 and on the basis of a case-by-case examination, such restriction is necessary to safeguard the protection of the data subject or of the rights and freedoms of others."

A copy of laboratory tests and medical reports may be sent to the data subject on request. Where the result shows a significant discrepancy, the data subject is immediately informed and receives a copy of the results (with the relevant explanations and advice).

A copy of the laboratory tests and medical reports may be sent to the data subject's doctor at the data subject's request.

The results of medical tests and the diagnosis cannot be modified, but the data subject may add comments.

Administrative data may be blocked or erased within 15 working days of a substantiated request.

Data storage

The general rule laid down by the Commission is that each file should be stored for 30 years after the data subject ceases work. For persons not recruited on grounds of a negative medical opinion the file is stored for 30 years.

In practice, no medical file has so far been destroyed by the Commission.

Special rules exist for certain types of data:

- In the case of workers exposed to ionising radiation at any time in their careers, the medical file is retained until the individual has or would have reached the

- age of 75 years, but in any case not less than 30 years from the termination of the work involving exposure to ionising radiation (Directive 96/29);
- In the case of persons exposed to carcinogens or mutagens, files are kept for 40 years after the last exposure (General Regulation for the Protection of Workers, Belgium, Article 16, occupational medical services);
- In the case of persons exposed to biological agents likely to result in infections, files are kept for 30 years after the last exposure (General Regulation for the Protection of Workers, Belgium, Article 42, biological agents).

The computer management programme for medical monitoring of nuclear inspectors in the MS ACCESS database stores data until the inspector leaves DG TREN, at which time a print-out of the record in the Access base is filed in the inspector's medical file and the electronic data are erased from the database.

The practice is the same for the MS ACCESS database in the JRC in Karlsruhe and the Excel file in the JRC in Petten when JRC colleagues leave. The electronic information is erased and a paper record is kept in the medical file only in Karlsruhe, since that is not possible in Petten. In Geel the management of medical examinations is done only via paper lists and these are destroyed each year.

Recipients

The medical services of the other Institutions or of other Commission sites receive the data when a person is transferred.

Following the recruitment medical examination, the recruitment service of DG ADMIN, of the JRC or of the agency requesting the medical examination receives a declaration stating that the person is fit/unfit for work. Following annual or periodic check-ups, a declaration stating that the person is unfit to work or fit under certain conditions may also be sent to the human resources officer, depending on the result of the medical examination, if the post is a post involving risk.

The Radiation Protection Department in DG TREN, and the equivalent departments in the JRCs, receive a declaration that the person is fit to work in the controlled area.

In the case of JRC staff, the original medical files are kept at the medical service in Luxembourg with an absolutely identical copy in the JRC medical service.

Medical file data may also be disclosed to the Legal Service in the event of an appeal before the Civil Service Tribunal with a view to preparing a statement of defence; to the judges of the Civil Service Tribunal at their request or to the European Ombudsman, at his request.

Security measures

[...]

3. Legal aspects

3.1. Prior checking

The management of the medical file as described in the notification given by the Data Protection Officer on 21 February 2007 relates to processing of personal data ("any information relating to an identified or identifiable natural person" – Article 2(a)). 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)).

The medical file is processed manually. The medical data appear, or are intended to appear, in a personal file, the individual's medical file. Article 3(2) is therefore applicable in this case.

Moreover, the administrative management programme for nuclear inspectors in DG TREN and JRC workers in Petten and Karlsruhe is automated; processing is thus partially automated.

It follows that this processing operation falls within the scope of Regulation (EC) No 45/2001.

Article 27(1) of Regulation (EC) No 45/2001 makes "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" subject to prior checking by the European Data Protection Supervisor.

Article 27(2)(a) of the Regulation states that "the following processing operations are likely to present such risks: processing of data relating to health ..." and makes them subject to prior checking. Data relating to health includes not only medical data in the strict sense of the term, but also any data providing an indication of a person's state of health. Medical files obviously contain data relating to health and the management of such files by the Commission medical service is thus subject to prior checking.

In principle, checks by the European Data Protection Supervisor should be carried out before the personal data resulting from the procedure are processed. In this case, as checking is taking place after the procedure was set up, the check necessarily has to be carried out ex-post. This does not alter the fact that it would be desirable for the recommendations issued by the European Data Protection Supervisor to be implemented.

The medical file contains only the result of certain procedures (invalidity procedure; checking of sick leave; checks on the dosimetric tests for workers in DG TREN or the JRCs exposed to ionising radiation. These procedures were the subject of separate prior checking by the EDPS⁷.

In the case of DG TREN inspectors, this prior check relates only to the medical examination carried out by the medical service on the basis of the results of examinations carried out by DG TREN⁸ and the procedure for monitoring those specific medical examinations. The same applies to JRC staff in Geel, Petten and Karlsruhe.

The notification from the Commission's Data Protection Officer was received on 21 February 2007. Pursuant to Article 27(4) of the Regulation, the European Data Protection Supervisor should have delivered his opinion within two months, i.e. by 22 April 2007. Taking into account the 455-day suspension pending receipt of information or comments from the data controller, suspension during the two intervening months of August and the two-month extension on grounds of complexity, the European Data Protection Supervisor should deliver his opinion by 20 November 2008 at the latest.

Those examinations were the subject of separate prior checking ("Prior checking opinion on Occupational radioprotection data at DG TREN" (2007-0383).

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See EDPS opinion 2007-125 on the invalidity procedure, opinion 2004-226 on checks on absences, opinion 2007-325 on dosimetry checks at the JRC in Geel, opinion 2007-378 on dosimetry checks at the JRC in Karlsruhe and opinion 2008-020 on dosimetry checks at the JRC in Petten.

3.2. Legal basis and lawfulness of the processing operation

The lawfulness of the processing operation should be scrutinised in the light of Article 5(a) of Regulation (EC) No 45/2001. That Article provides that personal data may be processed only if "processing is necessary for the performance of a task carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments adopted on the basis thereof or in the legitimate exercise of official authority vested in the Community institution".

Therefore, the task lies in determining whether the processing operation has been carried out in the public interest on the basis of the Treaties establishing the European Communities or other legal instruments on the one hand, and whether that operation is necessary in order to perform that task on the other.

Most of the data in the medical file are collected and processed in line with the provisions of the Staff Regulations of officials adopted in the form of a Regulation which, in turn, is based on the Treaties establishing the European Communities. The same applies to the pre-recruitment medical examinations (Article 33 of the Staff Regulations and Article 1 of Annex VIII thereto⁹), the annual medical check-ups (Article 59(6)¹⁰), checks on absences (Article 59(1)¹¹) and the invalidity procedure (Article 78 of the Staff Regulations and Articles 13 to 16 of Annex VIII thereto).

The *pre-recruitment medical examination* for officials and other servants is based on Article 33 of the Staff Regulations. The primary purpose of the examination is to ascertain whether the candidates are fit to perform their duties (Article 28(2)). The medical examination performed by the institution's medical officer is designed precisely to establish that the candidate is fit to work.

Furthermore, Article 1 of Annex VIII to the Staff Regulations stipulates that, where the medical examination made before an official takes up his duties shows that he is suffering from sickness or invalidity, the appointing authority, insofar as risks arising from such sickness or invalidity are concerned, may decide to admit that official to guaranteed benefits in respect of invalidity or death only after a period of five years from the date of his entering the service of the Communities. The official may appeal against such decision to the Invalidity Committee. Thus the pre-recruitment medical examination further serves to determine benefits in respect of invalidity or death.

The Staff Regulations do not stipulate that the pre-recruitment medical examination serve preventive purposes as well. That said, the EDPS acknowledges that data collected during the pre-recruitment examination which might prove useful to candidates in serving to alert them to an issue regarding their health could also be used for preventive purposes. However, Article 59(6), which assigns a preventive function to the medical service, leaves individuals free to consult either the medical service or a medical practitioner of their choice. The medical service's preventive function is thus based solely on the consent of the data subject. Some questions could therefore be put for preventive purposes with the consent of the data subject. This point will be taken up again later (point 3.4 - data quality).

Article 13 of the CEOS.

Article 16 of the CEOS.

II Id

The annual medical check-up is based on Article 59(6) of the Staff Regulations, by virtue of which officials are required to undergo a medical check-up every year either by the institution's medical officer or by a medical practitioner chosen by them. The Staff Regulations do not, however, allude to the purpose of said annual medical check-up. It can automatically be construed from this vagueness as to the desired aim that the annual medical check-up does not seek in the same way as the pre-recruitment medical examination to establish the fitness of officials and other staff to perform their duties. Moreover, contrary to established procedure for the pre-recruitment examination, no review procedure has been put in place for instances in which an annual medical check-up results in a decision that the individual concerned is unfit for service. Moreover, the data required for annual medical check-ups are more restrictive, thereby pointing to a different purpose.

Therefore, although the purpose of an annual medical check-up is not to check the fitness of the data subject, the processing operation may nonetheless be considered necessary – and, therefore, lawful – for other purposes, including establishing a joint sickness insurance scheme (Articles 72 and 73 of the Staff Regulations). A medical service at the workplace may be considered beneficial to the employer insofar as it makes for staff in a better state of health. At the same time, employees enjoy the benefits of a health-care service offered to them.

In order to maintain a suitable balance between these two interests, it is important that interference in each individual's personal choices regarding his or her own health be kept to a minimum. Broadly speaking, therefore, once data subjects have received their medical results, it is for them as individuals to decide on the course of action they wish to take. No information regarding these choices should be forwarded to human resources staff or to any third party.

Furthermore, in the interests of suitable medical follow-up, anyone who receives the results of medical tests requiring follow-up is requested to contact his/her own doctor for treatment.

In this regard, and where the purpose is purely preventive, the EDPS deems the annual medical check-up to be lawful, provided that officials and other staff are able to have the check-up performed by a doctor of their choice and are able to request a thorough explanation of their medical results, rather than merely receiving a copy of the tests.

Where the Communities have no specific rules of their own in a particular area of health and safety at work, the Commission applies the rules offering its staff the highest level of protection, particularly the directives on the protection of workers which, it should be noted, are intended to harmonise national legislation. Some of the processing carried out by the medical service is thus based on those directives. The application of those directives is justified by the fact that the European institutions have a duty to respect the obligations they impose on the Member States.

The medical files for auxiliary staff, temporary staff, private employees and scholarship holders working in the Commission in Luxembourg are processed only for posts involving a risk (cooking and catering). Only medical data relating to annual medical check-ups (medical reports and test results) are involved. Such processing can be based on Directive (EC) 89/391 on the introduction of measures to encourage improvements in the safety and health of workers at work which obliges employers to take measures to prevent occupational risks.

The medical examinations carried out by the Commission medical service for nuclear inspectors in DG TREN and those JRC workers working in controlled areas during periodic visits are based on 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 dangers arising from ionising radiation.

The procedure for checking on absences is provided for in Article 59(1) of the Staff Regulations.

The invalidity procedure is provided for in Articles 72 and 73 of the Staff Regulations.

The legal basis thus supports the lawfulness of the processing.

3.3. Processing of special categories of data

Under Article 10 of the Regulation, the processing of personal data concerning health is prohibited unless grounds can be found in Article 10(2) and (3) of Regulation (EC) No 45/2001. As stated above, the present case very clearly relates to the processing of personal data on health.

Article 10(2)(b) applies in this instance since the Commission is acting as employer, in accordance with obligations laid down in the Staff Regulations. Article 10(2)(b) provides as follows: "Paragraph 1 [prohibiting the processing of data relating to health] shall not apply where: 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 European Communities or other legal instruments adopted on the basis thereof...".

As an exception to the principle of the prohibition of data processing, Article 10(2)(b) must be interpreted narrowly. Firstly, the rights and obligations of the controller must be "specific". Consequently, the processing of sensitive data is not allowed unless of relevance in relation to the purposes set out above (see section 3.2). Secondly, the requirement that processing be "necessary" for this purpose introduces additional constraints with regard to data quality (see section 3.4 below).

Moreover, the processing of sensitive data in the context of the annual medical check-up may also be based on explicit consent to such processing as evidenced by the desire to have the check-up carried out by one of the institution's doctors.

The medical service also operates as a provider of care in medical emergencies and monitors the medical situation. Article 10(3) of Regulation (EC) No 45/2001 on the processing of special categories of data applies in the case in point. It stipulates that: "Paragraph 1 (prohibiting the processing of data relating to health) shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy". On account of their position, the doctors are subject to the obligation of professional secrecy. The other members of the medical service are subject to an equivalent obligation of professional secrecy. In this instance, Article 10(3) of the Regulation is duly complied with.

3.4. Data Quality

3.4.1. Adequacy, relevance, and proportionality

Data must be "adequate, relevant and not excessive" (Article 4(1)(c) of Regulation (EC) No 45/2001).

A/ Pre-recruitment medical examination

The primary purpose of the pre-recruitment medical examination is to establish whether or not the candidate is fit to perform his or her duties. The main issue, therefore, is what health-related data are likely to have an impact on the performance of the duties of the employee. If the data subject is fit for service only subject to certain accommodations made at the workplace, then the medical examination may also help determine the accommodations required.

The second purpose of the pre-recruitment medical examination is to determine whether, insofar as risks arising from sickness or invalidity are concerned, death or invalidity benefits should be limited until after a period of five years from the date of entering the service of the Communities. Thus any information requested during the examination should serve the two aforementioned objectives only.

The pre-recruitment medical examination can also be used for preventive purposes if the person chooses to have his state of health monitored by the Institutions' services. In such cases, the EDPS recommends that at the pre-recruitment medical examination the Commission medical service collect data for preventive purposes only with the freely given specific informed consent of the data subject¹².

Finally, some specific posts require specific health-related data to be checked. There are therefore some questions which should only be put where the person's post so requires.

The principles of adequacy, relevance and proportionality must be upheld with respect to all categories of data collected at all stages of the procedure for pre-recruitment medical examinations.

The EDPS would question the practice of carrying out a HIV test at the pre-recruitment medical examination. Not only does the necessity for that test need to be demonstrated in relation to the purpose of the pre-recruitment medical examination but, in addition, the value of the data subject's consent may be open to question in an examination prior to recruitment. In this connection, the EDPS would refer to the statement by the Working Party set up under Article 29 to the effect that "where consent is required from a worker, and there is a real or potential relevant prejudice that arises from not consenting, the consent is not valid in terms of satisfying either Article 7 or Article 8 as it is not freely given... An area of difficulty is where the giving of consent is a condition of employment. The worker is in theory able to refuse consent but the consequence may be the loss of a job opportunity. In such circumstances consent is not freely given and is therefore not valid." ¹³ The consent required under Regulation No 45/2001 should be interpreted in the same way.

Pre-recruitment medical questionnaire:

The EDPS also questions the relevance and proportionality of certain information requested during the pre-recruitment medical examination and would refer the European Commission to the pre-recruitment medical examination form as adopted by the Interinstitutional Medical Board.

See the definition in Article 2(h) of Regulation (EC) No 45/2001 which describes the consent of the data subject as "any freely given specific and informed indication of his or her wishes by which the data subject signifies his or her agreement to personal data relating to him or her being processed".

Opinion 8/2001 of the Article 29 Data Protection Working Party on the processing of personal data in the employment context (section 10).

First, a check must be made to ensure that the medical history questionnaire completed by candidates at the pre-recruitment medical examination does not collect irrelevant or excessive data.

The EDPS has reservations about the inclusion of a <u>photo</u> of the person on the pre-recruitment medical form. Since the photograph may reveal information regarded as sensitive, the need for it must be demonstrated all the more rigorously. Moreover, if there are no other grounds in Article 10 to justify attaching a photograph to the form, the EDPS considers that it should only be done on a voluntary basis with the consent of the data subject.

<u>Family history</u>: the medical history of a spouse or adopted children, lacking any genetic link, has no place in the medical history questionnaire. Although the state of health of parents and children as blood relatives may indicate a predisposition to certain genetic disorders or increased probability of developing certain conditions in the future (e.g. cancer, cardiovascular problems or certain mental illnesses), the information thus obtained is not a legitimate tool for determining fitness for service. ¹⁴ Moreover, the answers to such questions may reveal sensitive data without the individual concerned having been able to give his consent. Were these questions as to the state of health of parents and children as blood relatives to be considered useful for preventive purposes, they could be asked only on condition that it is made clear that they are optional and used solely for preventive purposes. ¹⁵

<u>Contraception</u>: Article 1d of the Staff Regulations prohibits discrimination on any ground, including sex. This extends to discrimination against a current or future female employee on grounds of pregnancy. The scope of the ban on discrimination also covers circumstances in which a future female employee is asked during an interview whether she uses a means of contraception (impact on potential pregnancy) and, for the same reasons, presents no bar to her recruitment.

Information relating to means of contraception, the date of the last period and whether or not the woman is pregnant is requested on the medical questionnaire.

Given the highly sensitive nature of this information and its discriminatory potential, the EDPS recommends that the Commission reconsider whether or not there is a real need, for medical purposes, for medical files to state whether the data subject uses a means of contraception and to mention the date of her last period and state whether or not she is pregnant, since this could be deemed to be an argument against recruitment. That evaluation should not simply consider whether contraception in general should be mentioned, as some forms of contraception (in particular oral contraception) constitute pharmacological treatment. A genuine need for or

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In cases T-121/89 and T-13/90, the Court of First Instance found that "the medical officer of the institution may base his finding of unfitness not only on the existence of present physical or psychological disorders but also on a medically justified prognosis of potential disorders capable of jeopardising the normal performance of the duties in question in the foreseeable future". Even though the ruling was subsequently annulled by the Court (C-404/92), this interpretation of the concept of "fitness" was not challenged. While terms such as "potential disorders" and "foreseeable future" are somewhat vague for the purposes of data protection, relevance of the data with respect to the normal performance of duties must be proven. The link between a potential disorder and fitness to carry out one's duties has to be demonstrated. The collection of genetic information or examinations regarding family history with a view to identifying potential hereditary diseases that the candidate might develop in the future with a lesser or greater degree of probability, in particular, appears to be problematic.

To protect the privacy of family members, consideration ought also to be given to whether the detailed information obtained orally during the consultation regarding the state of health of each family member could be registered in the medical files in an aggregate form, without directly and personally identifying the individual family members. For instance: "several instances of high blood pressure and obesity in the family history".

benefit derived from collecting this type of information in the context of the pre-recruitment medical examination must be demonstrated ¹⁶.

<u>Lifestyle</u>: questions on lifestyle, such as those relating to the amount of alcohol or tobacco consumed or physical exercise taken, although they may prove useful for prevention, also appear excessive for ascertaining fitness for service except in specific cases where it is justified in view of the nature of specific posts¹⁷. The EDPS therefore recommends that the presence of such questions in the medical questionnaire be examined. If these questions are considered useful for preventive purposes they could be answered, provided that it is made clear that they are optional and that the data obtained from them will be used solely for preventive purposes.

<u>Change of employment on health grounds</u>: Lastly, except in the case of certain specific jobs, on principle the EDPS does not see the benefit of asking candidates if they have changed jobs on health grounds. The EDPS therefore recommends that this question be reconsidered.

The EDPS thus recommends that the data requested in the medical history questionnaire be reconsidered in the light of the principles of adequacy, relevance and proportionality for the purposes of judging fitness for service. The European Commission proposes to use the pre-recruitment medical examination form proposed by the Interinstitutional Medical Board and the EDPS recommends that it do so.

B/ Annual medical check-up

In addition, these principles of adequacy, relevance and proportionality must also apply to data collected during the annual check-up, the aim of which is preventive. This should not, however, impinge upon employee medical self-assessment or include excessive data collection. By way of good practice, the EDPS recommends a full reassessment of the questions in relation to the annual medical check-up, in cases where the proportionality of the collection of certain data remains doubtful, and if there is a real risk of discrimination based on health conditions, or if the data provide only limited preventive benefits.

Should the Commission decide, for medically justified occupational health reasons, to collect some such data during the annual medical check-up, the candidate should be offered the choice as to whether or not to provide the information. Collection of such data is permissible only if the employee gives his or her informed consent with a clear understanding that (i) the provision of the information is entirely optional, and (ii) the data so obtained will be used only for purposes of prevention, that is, for alerting the candidate to a possible health problem or recommending a course of action.

The EDPS is satisfied that specific examinations are carried out for staff employed in the crèches in view of the nature of their jobs and the importance of detecting certain infections to prevent any risk for those they come into contact with.

Should the Commission's assessment conclude that collecting information on contraceptive pills is necessary, the EDPS notes in this respect that there is a question on the medical history form which asks

necessary, the EDPS notes in this respect that there is a question on the medical history form which asks what regular medication the candidates take. It might be appropriate to reformulate the question thus: "Do you take regular medication (including contraceptive pills)?"

The EDPS would point out that this opinion does not deal with whether, and to what extent, data may be collected in instances in which there may be increased risk to public safety if individuals addicted to alcohol or certain forms of medication are employed (the opinion does not, for instance, broach the issue of examining pharmaceutical products taken by armed security guards).

The same applies to specific yearly or half-yearly check-ups for DG TREN inspectors to determine whether they can be admitted to risk areas and to update their "Radiation Passbook", and to the half-yearly check-ups for persons exposed in the JRC.

A person may also agree to have a HIV test carried out during the blood test for the annual medical check-up. The data subject is asked for explicit consent in writing. The EDPS welcomes the explicit consent requirement in view of the particularly sensitive nature of the information. He would nevertheless stress that it should be stated on the questionnaire that there is no obligation to provide that information.

<u>Clinical examinations and results of urine and blood tests</u>: The medical form containing the results of the physical examination and the list of tests required (including a detailed description of the blood and urine tests) must also be evaluated in the light of the principles of adequacy and proportionality.

Medical check-up by a medical practitioner: Article 59(6) of the Staff Regulations stipulates that the annual medical check-up may be carried out by a medical practitioner chosen by the staff member. The medical service receives the bill from the doctor together with his report, proof that the fee has been paid, the results of tests carried out and the laboratory invoice.

This raises the question of passing on the doctor's report and the results of the tests to the Commission's medical service. While the Staff Regulations (Article 59(6)) do indeed stipulate that the annual medical check-up may be carried out by a medical practitioner chosen by the staff member, they make no provision for forwarding the results of the examination to the institution. Nor does refunding the cost of that examination as provided for in the Staff Regulations in itself justify forwarding the results.

The EDPS considers that the preventive purpose of the medical check-up can be achieved by having the doctor confirm that the examinations have been carried out. If need be, the declaration could include specific information if the person requires special accommodations.

The EDPS recommends that, by way of good practice, the results be communicated to the Commission medical service only with the free and informed consent of the employee. Some might decide to give their consent, whereas others might prefer their own doctor to keep their health data.

3.4.2. Accuracy and updating of data

Under Article 4(1)(d) of the Regulation, personal data must be "accurate and, where necessary, kept up to date", and "every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified".

The data in this case comprise the results of medical examinations and doctors' notes and it is not easy to ensure or assess the accuracy of data of this kind. However, the EDPS would emphasise that the institution must take every reasonable step to ensure that data are up to date and relevant. For example, to ensure that medical records are as complete as possible, any other medical opinions submitted by the data subject must also be kept in the file. The EDPS would also stress that in the sections of the questionnaire to be filled in by the data subject no addition or comment should be made later by the doctor or by any other person.

The EDPS notes that for practical reasons of day-to-day management there are two copies of JRC staff medical files, the original in Luxembourg and a copy in the JRC. He would emphasise the importance of both copies being completely identical.

In this instance, Article 4(1)(d) of the Regulation is duly complied with. The data subject is made aware of his or her rights to access and rectify data in order to ensure that the file remains as comprehensive as possible ¹⁸.

3.4.3. Fairness and lawfulness

The data must be *processed fairly and lawfully* (Article 4(1)(a) of Regulation (EC) No 45/2001). The matter of lawfulness has been reviewed above. Given the sensitivity of the subject, fairness warrants considerable attention. It is linked to the information to be given to the data subject (see section 3.9 below).

3.5. Data storage

Article 4(1)(e) of Regulation (EC) No 45/2001 lays down the principle that 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 this case, the data are stored by the medical service for 30 years after the data subject ceases work. To date, however, no medical file has been destroyed.

We must therefore consider to what extent and for what purposes it is necessary to keep, throughout an official's career, and even beyond, the contents of a medical file which includes data such as the results of medical examinations.

The EDPS acknowledges the significance of keeping the data, even after the death or retirement of the data subject, for those data can in certain cases contribute to the discovery of information relating to the cause of death or illness (exposure to asbestos, for instance). However, it would appear, in the light of Regulation (EC) No 45/2001, that the institution must set a time-limit for storage.

In this context, the EDPS would draw the Commission's attention to the recommendations he issued on 26 February 2007 in response to the consultation with the Board of Heads of Administration concerning the latter's proposal for a 30-year storage period for medical documents¹⁹. In his recommendations the EDPS calls on the Board of Heads of Administration to examine the various types of medical document in the light of the limited storage principle set out in Article 4 of Regulation (EC) No 45/2001 and to draw up specific rules, depending on document type and storage purpose. Such storage periods may take account of the particular features of certain types of data such as those relating to workers exposed to ionising radiation or those exposed to carcinogenic or mutagenic agents or biological agents likely to result in infections.

There is also the question of the storage of results of medical examinations performed on candidates who, having undergone the medical examination, have not been recruited. Data relating to these candidates which are obtained in the context of the medical examination

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Rights of access and rectification are discussed in section 3.8 below.

Available on the EDPS website.

provided for under Article 33 of the Staff Regulations should not be kept indefinitely. The EDPS considers that the files of those not recruited as a result of an unfavourable medical opinion should be kept for only a certain period of time; this could be the same length of time as that during which the data, or a decision taken on the basis of such data, can be contested. The EDPS approves the Commission proposal as set out in the notification regarding the storage of pre-recruitment medical examination files relating to those not recruited for non-medical reasons for one year. The EDPS thus recommends a limited data storage period for candidates not recruited.

The EDPS is satisfied with the storage period for data in JRC databases.

Under Article 4(1)(e) of the Regulation, data may be stored for a longer period than is required for the purpose for which they have been collected, and especially for statistical use, provided that they are kept either in anonymous form or, if that is not possible, with the identity of the data subject encrypted. The data contained in the medical file are not used for statistical purposes.

3.6. Transfer of data

Article 7(1) of Regulation (EC) No 45/2001. Transfers of personal data within or to other Community institutions or bodies may take place only "if the data are necessary for the legitimate performance of tasks covered by the competence of the recipient." Moreover, Article 7(3) of Regulation (EC) No 45/2001 provides that "the recipient shall process the personal data only for the purposes for which they were transmitted".

Medical files may be transferred to the medical service of other institutions if the data subject is transferred. Such transfers should be scrutinised in the light of Article 7. Since the data are necessary for the legitimate performance of the task of the institution receiving the person, Article 7(1) is fully complied with as regards the transfer of a medical file when a staff member is transferred. Care should be taken to ensure that the data are sent only to recipients authorised to receive medical data (medical service, for example).

The opinion on fitness relating to DG TREN nuclear inspectors is included in the data subject's radiation passbook and is sent on the relevant form to the person in charge of the HPC (Health Protection Cell) in DG TREN. That form shows the surname, forename, the dates of technical examinations and clinical examination and the conclusion (fit/unfit). This transfer also complies with Article 7(1) of Regulation (EC) No 45/2001.

A copy of the medical files for temporary auxiliary staff, temporary staff, private employees and scholarship holders working in the research centres (JRCs in Karlsruhe, Geel and Petten) is sent to the JRC. The notification does not specify who the data recipients are. Care should be taken to ensure that the data are sent only to recipients authorised to receive medical data (medical service, for example).

The EDPS is pleased that no information from the medical file is sent to the human resources officer in the DG concerned following the pre-recruitment medical examination, other than the declaration stating that the person is fit to work (or fit with reservations, or unfit). Following annual or periodic check-ups, the declaration stating that the person is unfit to work or fit under certain conditions may also be sent to the human resources officer, depending on the result of the medical examination. The EDPS is in agreement that only the declaration that the person is fit to work in the controlled area should be sent to DG TREN.

A person who chooses to have the annual check-up carried out by the doctor of his/her choice is required to send the doctor's bill, the report and proof of payment by the patient to the medical service. The person must also provide the medical service with a copy of the results of examinations and the invoice for them in order to have the fees reimbursed. Only the medical service financial controller encodes the fees and the payment authorisation in ABAC (DG Budget computer application). The EDPS is satisfied that no medical information is forwarded to DG Budget.

Furthermore, data may be transferred to external doctors appointed by the data subject. If those doctors are nationals of countries whose national law was adopted pursuant to Directive 95/46/EC, the data transfer will come under Article 8 of Regulation (EC) No 45/2001. The transfer is covered by Article 8(b), which stipulates that data may be transferred if "the recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subject's legitimate interests might be prejudiced". In the case in point, the transfer may take place not if the recipient doctor proves that it is necessary, but at the data subject's request. Such a request from the data subject is proof of the necessity for the transfer. Furthermore, it is self-evident that this does not prejudice the data subject's legitimate interests.

Lastly, transfers to recipients who do not come within the scope of Directive 95/46/EC (if the external doctors are citizens of a country with national legislation not based on Directive 95/46/EC) need to be examined in the light of Article 9 of Regulation No 45/2001. Article 9 states that: "personal data shall only be transferred to recipients, other than Community institutions and bodies, which are not subject to national law adopted pursuant to Directive 95/46/EC, 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".

If the country of the recipient does not ensure an adequate level of protection, the exceptions provided for in Article 9(6) and (7) may apply. In the case under examination, Article 9(6)(a) and (e) would be particularly relevant: "By way of derogation from paragraphs 1 and 2, the Community institution or body may transfer personal data if: (a) the data subject has given his or her consent unambiguously to the proposed transfer; or (...) (e) the transfer is necessary in order to protect the vital interests of the data subject (...)."

If health-related data are transferred to third parties other than the medical service, such as external doctors appointed by the data subject, or other Community institutions or bodies in the event of a change or transfer of post, compliance with Article 10 must also be ensured. As the data are transferred to comply with labour-law obligations arising from the Staff Regulations, Article 10(2) of the Regulation is fully complied with. As regards the last hypothesis (other institutions), however, it would seem necessary to specify that the data should be transmitted only to persons authorised to have access to them – i.e. persons who are subject to professional secrecy.

The European Data Protection Supervisor recommends that, in the context of transfers to other institutions, only persons authorised to have access to data relating to health, and who are subject to professional secrecy, receive medical files.

As regards transfers in exceptional cases to other parties such as the Legal Service in the event of an appeal before the Civil Service Tribunal, to judges of the Civil Service Tribunal or to the Ombudsman, at his request, the EDPS is of the opinion that Article 7 is fully complied with.

The EDPS would point out that he himself may be considered a data recipient under Regulation (EC) No 45/2001. For example, on the basis of Article 33 (complaints by Community staff) or of Article 47(2)(a), he has the right to obtain from a controller or Community institution or body access to all personal data and to all information necessary for his enquiries.

3.7. Processing including the personal or identifying number

The Commission uses the personal number in the form to be filled in for medical check-ups for nuclear inspectors in Luxembourg. While the use of an identifier is, in itself, no more than a means (and a legitimate one in this case) of facilitating the task of the personal data controller, such use may have significant consequences. This is why the European legislator decided to regulate the use of identifying numbers under Article 10(6) of the Regulation, which makes provision for action by the European Data Protection Supervisor.

In the case in point, use of the personal number may allow the linkage of data processed in different contexts. Our concern here is not to establish the conditions under which the Commission may process the personal number, but rather to draw attention to this point in the Regulation. In this instance, the Commission's use of the personal number is reasonable because it is a means of facilitating the processing task.

3.8. Right of access and rectification

Article 13 of Regulation (EC) No 45/2001 makes provision, and sets out the rules, for right of access at the request of the data subject. Under Article 13 of the Regulation, the data subject has the right to obtain from the controller, without constraint, communication in an intelligible form of the data undergoing processing and any available information as to their source.

The procedure under which officials and other staff may gain access to their medical file is referred to in Conclusion 221/04 of the Board of Heads of Administration of 19 February 2004. By virtue of that decision, the file must be consulted on the premises of the medical service of the institution, in the presence of a person designated by the medical service. The indirect access provided for in the decision covers psychiatric and psychological reports, where direct access might prove harmful to the data subject. Indirect access via a doctor appointed by the data subject is therefore provided for.

The official or servant may not have access to personal notes by doctors if, under the terms of Article 20(1)(c) of Regulation No 45/2001 and on the basis of a case-by-case examination, this is necessary to guarantee the protection of the data subject or the rights and freedoms of others. The EDPS welcomes the fact that this is subject to examination on a case-by-case basis in accordance with the principle of proportionality. The above limitation must not be allowed to result in a general refusal of access to the personal notes of doctors in the medical file.

The access procedure covers officials and staff ("other servants"). The EDPS would welcome the introduction of a procedure for persons not recruited and other persons (temporary staff, private employees and scholarship holders working in the Commission in Luxembourg and in the research centres) in respect of whom medical information has been recorded and who are also entitled to access under Article 13 of Regulation (EC) No 45/2001. He also emphasises that, as a matter of good practice, data subjects must be able to obtain a copy of their medical file.

Article 14 of Regulation (EC) No 45/2001 allows the data subject the right of rectification. In addition to being given access to their personal data, data subjects may also have the data amended if necessary. The EDPS is satisfied that that right is being complied with as regards administrative data the accuracy of which may be queried.

3.9. Information to be given to the data subject

Regulation (EC) No 45/2001 provides that the data subject must be informed where his or her personal data are processed and lists a series of specific items of information that must be provided. In the present case, some of the data are collected directly from the data subject and others from other persons.

Article 11 (*Information to be supplied where the data have been obtained from the data subject*) on informing the data subject applies in the case in point since the official himself supplies the information at the medical check-up.

The provisions of Article 12 (*Information to be supplied where the data have not been obtained from the data subject*) on information to be given to the data subject also apply in this case because information is obtained from the various parties involved in the process (external doctors, for example).

3.9.1. Time at which information is to be supplied

Article 11 provides that where the data are obtained from the data subject, the information must be given at the time of collection. Where the data have not been obtained from the data subject, Article 12 provides that the information must be given at the time of recording or no later than the time when the data are first disclosed.

The EDPS is satisfied that a confidentiality statement is published on the Commission's Intranet site and is distributed as an information note to all those going to the medical service at the time of the pre-recruitment medical examination. He also considers it highly desirable to enclose that information with the invitation to the pre-recruitment examination. The EDPS is also satisfied that, on the first visit to the medical service, TREN inspectors receive a confidentiality statement on the processing of their personal data under the medical follow-up programme and that that information is also on the Commission's Intranet site.

The EDPS notes that the JRCs intend to post a confidentiality statement on their website. He invites the Commission to provide proof that that confidentiality statement has been posted.

3.9.2. Content of the information

Articles 11 and 12 of the Regulation provide a detailed list of information that needs to be provided to data subjects. In basic terms, the controller must state the identity of the controller, the purposes of the processing operation, the recipients of the data, whether replies are obligatory or voluntary, and the possible consequences of failure to reply. The information must also cover the right of access and rectification. Further information, including the legal basis for the processing, the time limits for storing the data, and the right of recourse to the EDPS at any time must also be provided insofar as the specific circumstances in which the data are collected make it necessary to do so in order to guarantee fair processing.

Both Articles 11 and 12 allow for exceptions from the notification requirement where the data subject is already in possession of the information. Article 12 allows for further exceptions in a

limited number of cases, including where Community legislation expressly provides for data to be registered or communicated, or where the provision of information proves impossible or would involve disproportionate effort.

The EDPS is satisfied that the general confidentiality statement comprises information on the identity of the controller, the purpose or purposes of the processing, the data recipients, the existence of a right of access and rectification, the type of data, the general security measures, the time limits for storing data, the contact addresses in the event of any questions and the right to have recourse to the European Data Protection Supervisor. The information on the purpose of processing is as follows: "The purpose of processing personal and medical data is to monitor the state of health of staff working at the Commission in line with the applicable provisions of the Staff Regulations". The EDPS would emphasise that the information on purposes should be more detailed to enable data subjects to assess the relevance of the data.

The medical questionnaire to be filled in at the annual check-up should state, in the section to be filled in by the data subject, whether the replies to medical questions are optional or compulsory and what the consequences of failure to reply would be. The same applies to the HIV test.

The EDPS is also satisfied that the confidentiality statement relating to medical follow-up of DG TREN inspectors comprises the information required under Regulation (EC) No 45/2001. The same applies to the JRC confidentiality statements.

3.10. Security measures

Under Article 22 of Regulation (EC) No 45/2001 concerning the security of processing, "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 Article 22 has been complied with.

Conclusion:

The processing proposed does not appear to involve any infringement of the provisions of Regulation (EC) No 45/2001 provided that the comments made above are taken into account. This means, in particular, that the Commission should:

- Adopt the pre-recruitment medical examination form as adopted by the Interinstitutional Medical Board;
- State on the annual medical check-up form that there is no obligation to have an HIV test;
- Review the annual medical check-up form showing the results of the physical examination and the list of tests required in the light of the principles of adequacy and proportionality;
- Adopt as a point of good practice the principle that the results of medical examinations carried out by a doctor of the person's choice will be forwarded to the Commission medical service only with the free and informed consent of the employee;
- Ensure that in the sections of the questionnaire to be filled in by the data subject no addition or comment is made later by the doctor or by any other person;

- Ensure that both copies of the medical file for JRC staff are identical;
- Set a limited storage period for data relating to persons not recruited;
- Specify that those in charge of dispensary treatment may not use medical data made available to them for any other purposes;
- Ensure that, where transfers take place, only persons authorised to have access to data relating to health, and who are bound by professional secrecy, receive medical files;
- Introduce a data access procedure for persons not recruited and other persons (temporary staff, private employees and scholarship holders working in the Commission in Luxembourg and in the JRCs) in respect of whom medical information has been recorded and who are also entitled to access under Article 13 of Regulation (EC) No 45/2001;
- Ask the JRCs to provide proof that JRC staff have been given the confidentiality statement on the processing of medical data under the medical surveillance programme;
- In the medical questionnaire to be filled in at the annual check-up, specify in the section to completed by the data subject whether the replies to medical questions are optional or compulsory and what the consequences of failure to reply would be.

Done at Brussels, 18 November 2008

(signed)

Joaquín BAYO DELGADO Assistant European Data Protection Supervisor