

**Experience feedback from the report of an
interventional radiology event at the Strasbourg
Academic Hospitals**

March 2010

SUMMARY

On March 20, 2009, the French Nuclear Safety Authority [*L'Autorité de sûreté nucléaire*] (ASN) was informed by the Strasbourg Academic Hospitals (HUS) of reports of patients presenting adverse reactions, of unusual intensity, consisting of hair loss over a large surface area and/or cutaneous erythema. These patients received treatment at the Hautepierre Hospital site by means of the same device using X-rays to guide the practitioners during treatment of cerebrovascular disease.

The ASN carried out a number of inspections on March 23, May 7, and September 29, 2009, so as to analyse the circumstances and causes of the occurrence of these adverse reactions, and to examine the corrective action implemented.

At the same time, the ASN and the French General Directorate for Health [*Direction générale de la santé*] jointly referred to the French Institute of Radioprotection and Nuclear Safety [*Institut de radioprotection et de sûreté nucléaire*] (IRSN) in order to reconstitute the doses received by the patients and to analyse any potential complications in exposed patients. Follow-up of patients carried out by HUS to date does not reveal any neurological, meningeal or subcutaneous abnormalities, and the cases of alopecia observed have fully regressed.

Results of the investigations

The different investigations and expert appraisals carried out revealed that the device in question did not present any technical faults and that insufficient attention had been given to optimising and monitoring the doses received by the patients. The effects observed are due to the use of a new device and the fact that the conditions relating to use and adjustment were not optimised, contributed to by inadequate training and organisational failings.

A number of failings were thus observed, at establishment level, in medical and paramedical personnel training in the knowledge of the devices and in the implementation of a dose-optimisation procedure, and also in the mastery of the maintenance and adjustment process for the device, together with the organisation of medical physics. Furthermore, the investigations evidenced a number of failings in the traceability of the maintenance operations carried out by the manufacturer, in the training provided by the latter for users of the device, and, lastly, in the optimisation of adjustments carried out during commissioning and maintenance operations. A number of contributing factors related to the device were identified, such as the absence of standardisation of measurable dosimetric quantities, the difficulty in monitoring doses based on the DAP¹, the absence of automatic dosimetric data export from the devices to the databases enabling them to be processed.

Moreover, the DAP levels during treatment of cerebrovascular diseases at the HUS as a whole (Hôpital Civil and Hautepierre) generally appear to be higher than those reported in the majority of the French and international literature reviewed. However, although the literature states that a dose-optimisation margin exists, it seems hard to determine whether these levels and the incidence of iatrogenic effects differ considerably from other French sites, in the absence of available reference systems and reliable local data. It appears likely that the findings observed locally during the investigations are not specific to the HUS.

¹ DAP: In order to monitor the doses delivered, the X-ray tubes are fitted with a sensor which is able to measure the dose*area product (DAP). By determining the exposed area and the DAP, it is thus possible to calculate the dose.

Action plan implemented by the establishment, and the results obtained

The lessons drawn from analysis of this event enabled the HUS to define and implement a logical and innovative action plan, the aim of which is to identify and reduce the dose levels for all interventional procedures. Owing to this action plan, the HUS is now among those French establishments which follow the most advanced practices in terms of patient radioprotection in the field of interventional radiology.

The corrective action implemented by the HUS involved:

- implementing an optimisation procedure with regard to adjustments, in connection with the manufacturers,
- modifying the conditions of use of the devices (reduction in the number of images, selection of an image type requiring less radiation),
- modifying the organisation of the interventions (dedicated operators, intervention of an experienced practitioner from the start of complex procedures),
- automatically collecting the DAP for each procedure,
- systematically consolidating and processing the DAP,
- defining in-house dose reference levels,
- implementing self-assessment of practices, through processing dosimetric data,
- identifying and monitoring patients liable to present iatrogenic effects.

Lastly, the HUS initiated an innovative *in vivo* dosimetry process. Furthermore, work has begun with the manufacturer to improve the coordination and traceability of maintenance operations together with the possibility of developing a system able to monitor, in real time, skin dose mapping for doses delivered to patients.

The results obtained are significant and demonstrate the relevance of the action plan. This has led to a considerable reduction in the doses delivered to patients, in the region of 40% related to changes in the settings, and in the region of 30 to 50% related to the changes in practices relating to the use of the devices. Owing to these results, the risk of occurrence of adverse reactions is now very rare.

Action relating to the monitoring of dosimetric data, and, in particular, the implementation of *in vivo* dosimetry, will moreover make it possible to determine more accurately the doses received by patients, which are still poorly evaluated and insufficiently documented.

Experience feedback

In addition to the teaching and corrective action implemented locally by the HUS, this report has given rise to considerable experience feedback for all professionals, and also for manufacturers and personnel responsible for device maintenance.

This event has reiterated the importance of the challenges in terms of dosimetry facing this type of activity, and has shown that the effects it can generate are largely unknown. The current regulatory system is not sufficiently applied or adapted. In particular, the concept of an optimisation procedure, which is a fundamental principle of radioprotection, is not sufficiently known or assimilated in the different departments. Likewise, technical mastery of equipment, radiovigilance and follow-up of iatrogenic complications, which should be at the centre of all procedures aiming for an improvement in

practices, are inadequately defined and organised. This event also demonstrates the existence of considerable margins for progress in terms of dose reduction, without compromising therapeutic efficacy.

Based on this experience feedback, the ASN reiterated the regulatory requirements, in a memorandum dated December 11, 2009, and sent a number of recommendations to the heads of interventional vascular neuroradiology departments, together with the general managers of regional and academic hospitals with a view to improving interventional radiology practices. Furthermore, the ASN informed the French Health Products Safety Agency [AFSSAPS *Agence française de sécurité sanitaire des produits de santé*] of the lessons drawn from this feedback and the improvements which need to be made both in terms of relations between the supplier of the device and the user during commissioning, maintenance, and the training provided, together with the ergonomic aspects and settings for devices used in radiology.

Although failings were evidenced locally, this event made it possible to identify a number of weaknesses and courses of action which need to be taken into account at national level. These were brought to the knowledge of the permanent medical radioprotection expert group (GPMED), convened by the ASN in January 2009, so as to draw up recommendations to improve radioprotection among patients and personnel in interventional radiology. The conclusions of this expert group, expected in the course of 2010, could enable a national action plan to be defined.

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1. Introduction

On March 20, 2009, the French Nuclear Safety Authority [*L'Autorité de sûreté nucléaire*] (ASN) was informed by the Strasbourg Academic Hospitals ² (HUS) of reports of patients presenting adverse reactions, of unusual intensity, consisting of hair loss over a large surface area and/or cutaneous erythema. The patients received treatment, using the same device, for cerebrovascular disease at the Hautepierre Hospital site.

During analysis of this report, the ASN visited the site on March 23, May 7 and September 29, 2009, so as to analyse the circumstances of the occurrence of these adverse reactions, and to examine the corrective action implemented by the HUS.

At the same time as the investigations, the ASN and the French General Directorate for Health [*Direction générale de la santé*] (DGS) jointly referred to the French Institute of Radioprotection and Nuclear Safety [*Institut de radioprotection et de sûreté nucléaire*] (IRSN) in order to reconstitute the doses received by the patients and to analyse any potential complications in exposed patients.

This report aims to present the results of the investigations carried out, the action plan implemented by the HUS, the results obtained, together with the lessons and recommendations drawn from this event in order to improve patient radioprotection.

2. Interventional radiology

2.1. Description

Interventional radiology allows physicians' gestures to be guided by means of a radiology device which emits X-rays. This activity has developed in recent years in numerous fields such as cardiology, neurology, rheumatology and surgery, contributing to a considerable improvement in the quality and performance of care. It nonetheless poses major dosimetric challenges both for patients and medical personnel. Since surgery may take place over a long period of time, patients thus receive high doses, mainly localised on the skin, which may, in certain cases, cause moderate effects (hair loss, cutaneous erythema) or more severe effects requiring specific treatment (dermal necrosis).

It is estimated that approximately 900,000 procedures of this type are carried out in France each year, resulting in a collective effective dose of 7700 Sv/year³ (evaluation based on data from the National Radiological Protection Board, in the absence of French data).

Under these conditions, the use of interventional radiology should be justified by clearly established medical measures, and the practice thereof should be optimised so as to improve the radioprotection of medical personnel and patients.

Numerous and diverse specialist medical fields carry out this type of procedure. For example:

² The HUS is the largest hospital centre in eastern France (2783 beds, 11 000 employees), mainly located at two sites, one in Strasbourg city centre (Hôpital Civil), and the other in the outskirts (Hôpital d'Hautepierre).

³ Source: IRSN-INVS-2006: Overview of medical exposure to ionising radiation among French people.

- in radiology: renal and femoral arteriography, uterine artery embolisation for fibroids, aortic dissection, biopsies, radiofrequency therapy, etc.
- in cardiology and cardiac rhythm analysis: coronary arteriography, angioplasty, dilatation, ablation by radiofrequency, fitting of pacemakers, etc.
- in neuroradiology: thrombolysis, angioplasty, treatment of arteriovenous malformation and aneurisms,
- in urology: Retrograde urethrogram-pyelogram (RUP), nephrostomy, catheter insertion, etc.
- in hepatology-gastroenterology: gastrointestinal endoprosthesis, endoscopic catheterisation of papilla of Vater, biliary endoprostheses, drainage, etc.

These procedures are carried out on dedicated devices located in radiology or cardiology departments. However, an appreciable proportion of these procedures may be carried out in the operating theatre, using portable equipment.

Equipment used

Interventional radiology procedures call for highly advanced technology in terms of implantable materials, catheters and endoprostheses. The main materials used are:

- angioplasty balloon catheters which, when inflated, flattens the atheroma plaque and re-opens the obstructed artery. Current changes in these materials mainly involve reducing their size.
- endoprostheses or stents. Stents are cylinders which remain permanently in the artery after surgery, and keep the vessel open.
- materials which, in contrast, seal off vessels (embolisation) such as "coils" (metallic micro-coils), micro-particles, adhesives, etc.
- different types of catheters able to unblock vessels or the gastrointestinal tract, treat tumours *in situ* or act on the heart's electrical activity (lassos, radiofrequency or cryogenic catheters, pacemakers, cardiac defibrillators, etc.)

These materials are placed within the lesion, guided by X-ray imaging.

Conventional facilities for interventional procedures consist of a cradle which rotates on different axes, fitted with an X-ray tube and a detector (image intensifier or flat detector). In certain cases, mainly in neuroradiology, the same device, then referred to as a "bi-plane" facility, is fitted with two orthogonal tube-detector systems. The detectors allow the procedure to be visualised on a screen in radioscopy mode, or generate images in radiography mode.

The technical characteristics of electrical X-ray generators should ensure sufficient image quality, and be able to withstand occasionally lengthy operating periods and high image acquisition rates. Interventional procedures may be carried out under CT-scan in exceptional circumstances.

In order to monitor the doses delivered, the X-ray tubes are fitted with an ionisation chamber which is able to measure the dose*area product (DAP) expressed in $\mu\text{Gy}\cdot\text{m}^2$ or equivalent units. By determining the exposed area and the DAP, the dose may thus be calculated.

A number of parameters need to be determined in order to evaluate the doses actually received by the patients, together with the exposed areas (namely: beam orientation, DAP value for the sequence concerned, field of exposure, patient position).

2.2. Applicable regulatory reference system

Article L.1333-4 of the French Public Health Code subjects the activities mentioned in Article L.1333-1 of the French Public Health Code to an authorisation or report regime according to the characteristics of the source. X-ray generators used in interventional radiology (excluding CT-scan) are subject to notification to the ASN.

In addition, in pursuance of articles L.6122-1 and R.6122-25 of the French Public Health Code, interventional activities via the endovascular route in neuroradiology are subject to authorisation by the Regional healthcare agency [*Agence régionale de l'hospitalisation*]. Moreover, as regards these activities, Article R.6123-2 of the French Public Health Code stipulates that authorisation to carry out these activities may only be granted a healthcare establishment or healthcare cooperative if hospitalisation facilities, a digital interventional angiography room specifically for these activities, a neurosurgery unit, intensive care unit, and a technical imaging platform able to carry out neuroradiology examinations are available on the same site.

Fixed facilities destined for interventional neuroradiology should meet the requirements of standards NFC15-160 and NFC15-161. The use of the facilities must comply with the three principles of radioprotection which correspond to justification, optimisation and limitation.

Radioprotection of workers

The organisation of workers radioprotection involves the appointment of a radioprotection officer having received specific training, risk assessment enabling the demarcation of radiological zones (supervised zone, controlled zone), and post analysis defining the category of exposed workers. Furthermore, workers should receive regulatory training in radioprotection (valid for 3 years), medical and dosimetric monitoring (passive dosimetry and, depending on the cases, active dosimetry and dosimetry of the extremities) suited to the worker category and activity. The regulatory principle of dose limitation calls for the use of collective and individual protective equipment. In-house and external radioprotection controls of the facilities supplement the regulatory requirements for the protection of workers.

Radioprotection of patients

Patient radioprotection is based on the justification of the procedures and the optimisation of doses delivered to patients. Hence, for each patient, there is cause to ensure that the radiological examinations are justified and that exposure to ionising radiation is kept at the lowest level that may be reached within reason given the current technology and the desired medical objective (Article L.1333-1 of the French Public Health Code). The justification must be stated in the procedure report.

Optimisation namely requires technical knowledge of the equipment, appropriate maintenance thereof, implementation of quality control, the use of optimised radiological procedures, training of operatives, surveillance, together with the recording and processing of dosimetric parameters (dose-area product-DAP- for instance).

Article R.1333-60 of the French Public Health Code and the decree of November 19, 2004, require that a medical physics plan be drawn up in all establishments in which interventional radiology is carried out, describing the procedures for intervention of the person specialising in medical radiophysics (PSMRP)the medical physicist .

The other main regulatory requirements relative to patient radioprotection are described below:

- training in patient radioprotection, for healthcare personnel carrying out the procedures together with professionals carrying out maintenance of radiology devices (Article L.1333-11 of the French Public Health Code and decree of May 18, 2004);
- implementation of in-house and external quality control on equipment (decision by the director general of the Afssaps of September 24, 2007, laying down the procedures for quality control of certain radiodiagnostic facilities);
- the obligation, in compliance with the provisions of Article R.1333-66 of the French Public Health Code and decree of September 22, 2006, for physicians carrying out radiological procedures, to state all information that may be useful in estimating the dose received by the patient in the report on the procedure;
- the obligation to report significant radioprotection events to the ASN (articles L. 1333-3 and R.1333-109 of the French Public Health Code). The criteria for the report of significant events in the field of radioprotection are defined in the guide ASN/DEU/03 which may be downloaded from the ASN website.

A collection of the regulatory provisions for radioprotection applicable in radiology can be downloaded from the ASN website (www.asn.fr).

Furthermore, in addition to radioprotection events, if an event having an impact on patient health should occur, Article L.1142-4 of the French Public Health Code stipulates that "*All persons suffering or believed to have suffered injury attributed to a preventive, diagnostic or therapeutic activity, or their beneficiaries, if the person has died, or, where appropriate, their legal representative, must be informed by the professional, healthcare establishment, health services or organisation concerned on the circumstances and causes of the injury.*

They must receive this information within fifteen days at the latest following discovery of the injury or their formal request, during a meeting in which the person may be accompanied by a physician or another person of their choosing."

3. Report at the Hautepierre site and context

3.1. The report and the initial action taken by the HUS

On March 20, 2009, the ASN was informed by the Strasbourg Academic Hospitals of reports of patients, having received treatment for intracerebral arteriovenous malformations, presenting adverse reactions, of unusual intensity which could be attributed to an excessive dose of X-rays during treatment using a Siemens AXION Artis device at the Hautepierre site.

The head of the radiology department reports 3 patients who came forward spontaneously between March 9 and 13, 2009, owing to alopecia more widespread than that observed during previous therapy. Patients receiving treatment for these disorders generally undergo several procedures in succession requiring the extensive use of X-ray imaging which can give rise to this type of effect. The practitioner describes an area affected by alopecia which is usually clearly demarcated, and measuring approximately 8 cm x8 cm. In the present cases, this area is larger in size, in the region of 15 cm x15 cm.

Further to these findings, the head of department alerted the medical physicist at the HUS. A number of investigations were thus initiated so as to determine the cause of these adverse reactions and to identify the patients potentially concerned.

The HUS suspended the use of the device, apart from in emergency life-threatening situations, for which a specific dose control and monitoring procedure was set in place.

3.2. Procedures carried out using the device

Since the device was commissioned, at the beginning of 2008, approximately 800 patients have been treated, including 28 specifically for cerebrovascular disease.

Interventional radiology procedures are only scheduled on Mondays. Other types of procedures are carried out using the device the rest of the week, by other medical teams present at the site (gastrointestinal, traumatic, and gynaecological procedures, etc.).

No complications have been reported for the non-neuroradiological procedures which, however, cover several shorter procedures using less radiation.

Patients receiving treatment for cerebrovascular disease require lengthy intervention periods, of up to 4 hours. Some of these patients, suffering from intracerebral arteriovenous malformations, undergo several procedures in succession, at intervals of two or three months.

3.3. This report falls into the context of a gradual transfer of activity between two sites for a new-generation device

The head of the radiology department and the team carrying out neuroradiology procedures usually work in the radiology department at the Hôpital Civil site.

Activities via the endovascular route in neuroradiology were transferred to the Hautepierre site, which is also the site of the neurosurgery unit, in order to meet regulatory requirements (cf. § 2.2).

The head of department and his team therefore started their activity at Hautepierre at the beginning of 2008, with diagnostic procedures, gradually followed by therapeutic procedures. Since mid-2008, they have thus been carrying out a collection of "conventional" interventional neurology procedures in this department.

The device at the Hautepierre site is a Siemens angiography system, AXIOM Artis dBA model. It was commissioned at the end of December 2007.

The biplane device comprises two X-ray tubes. Plane B provides profile patient visualisation and plane A, frontal visualisation. The images are generated by means of two flat panel detectors.

This device differs from that normally used at the Hôpital Civil site since it is a different brand (Philips) and uses different technology. Hence, the software interface of the Siemens device is much more advanced and offers numerous functions and settings. Furthermore, the collector generating the images is also different (image intensifier for the Philips device, and flat detector for the Siemens device, delivering different quality images).

Moreover, the dosimetric data (DAP) provided by the two devices are not expressed using the same units.

The transfer of activity between the two sites, described above, has given rise to a number of changes and new constraints for practitioners carrying out neuroradiology procedures, related to the organisation of the department in which they are working, together with the use of the devices and the quality of the images produced. Hence, while they were completely satisfied with the device used at the Hôpital Civil site, this is not the case for the new device located at the Hautepierre site, which, further to repeated reports of user dissatisfaction, required intervention by the manufacturer on several occasions in 2008, in order to improve image quality.

4. Findings

4.1. The investigations carried out on the device do not evidence any technical faults

After carrying out the report, the HUS medical physicist and the manufacturer conducted several control tests to confirm that the device was functioning properly. Furthermore, an expert appraisal was carried out at the request of the *Agence française de sécurité sanitaire des produits de santé* (AFSSAPS) by an appointed expert. The different investigations did not evidence any specific technical problems or faults in connection with the report of the events. Furthermore, the telephone survey carried out by the AFSSAPS targeting departments with the same equipment did not evidence any deviation in doses, and, more notably, the departments did not observe the occurrence of any significant events.

The dosimetric expert appraisal carried out by the IRSN demonstrated that the effects observed, for the limited cases assessed by the expert, are consistent with the dosimetric evaluations performed. These effects stem from the conditions of use and the device settings.

All of the investigations thus show that the device does not present any technical faults and that the adverse reactions observed stem from the use of the machine having led to the delivery of high dose levels.

4.2. Radiovigilance and the follow-up of radiation-induced iatrogenic complications are inadequately organised

4.2.1. Absence of accurate quantification of the observed effects

The report by Strasbourg Academic Hospitals (HUS) concerns the occurrence, in patients having received treatment for intracerebral arteriovenous malformations, of adverse reactions of unusual intensity, consisting of localised hair loss and/or cutaneous erythema. More specifically, it is the highly unusual extent of the alopecia, reported by three patients, rather than the change in the incidence thereof which led the team to question the medical device installed at the Hautepierre site.

The occurrence of alopecia during neuroradiological procedures is a known side effect regularly encountered in the department. However, although patient follow-up related to management of the disorder undergoing treatment is established, no follow-up criteria taking the risks of occurrence of radiation-induced effects into account have been defined.

Hence, in the absence of written information on the side effects observed, an accurate and unquestionable report cannot be drawn up for patients managed in the neuroradiology department whether at the Hautepierre or Hôpital Civil site.

More generally, at establishment level, there is no general policy for the routine detection and follow-up of patients liable to present radiation-induced deterministic effects even though a few practitioners have been able to undertake occasional follow-up processes for these patients in certain departments.

Lastly, the presence of a significant number of cases of alopecia among patients treated in the neuroradiology department at the Hautepierre site has been observed (at least 40% of patients); however, due to the absence of traceability and specific follow-up of radiation-induced lesions, a factual and substantiated assessment of the reports described cannot be provided (increase in the area of alopecia) and the differences relative to the cases of alopecia usually encountered at the Hôpital Civil site cannot be documented from a quantitative and qualitative perspective.

Still, the report and presentation of 3 patients clearly reveals a genuine change in the area of the lesions and does not appear to need to be called into question.

4.2.2. National reference systems defining patient follow-up are limited

It should be pointed out that no reference system exists at national level concerning the specific procedures for identifying and monitoring patients at risk of radiation-induced complications. Furthermore, the recommendation issued by the International Commission on Radiological Protection for monitoring patients exceeding a dose to skin of 2 Gy does not provide any information on the specific monitoring procedures.

4.2.3. Lack of knowledge of radiation-induced effects leads to underestimation of risks

In addition to the considerations related to the temporary and aesthetic aspect of alopecia, failure to define a policy for monitoring patients at risk of radiation-induced lesions leads to a lack of knowledge and underestimation of radiation-induced effects, giving rise to poor risk assessment.

Hence, all of the consequences related to exposure to ionising radiation, during procedures involving high levels of radiation, do not appear to have been sufficiently taken into account, namely, not only the deterministic effects (skin dose, deep dose, particularly to the brain), but also the risks of cancer, and skin cancer in particular.

The expert appraisal carried out by the IRSN for 8 patients at the Hautepierre site having received treatment for cerebral disorders, and for whom detailed dosimetric data were able to be extracted from the electronic files still stored on the device, shows that:

- the skin dose can reach 14 Gy, or indeed 17 Gy in case of intersecting beams ;
- permanent alopecia over small areas should not be ruled out for 2 patients; alopecia was temporary for the others;
- the doses to brain for each procedure lie between 5.5 and 15 Gy;
- it is likely that the value of 12 Gy (dose perceived as presenting a risk for the central nervous system) was slightly exceeded for a low cerebral volume in one patient. This patient therefore, *a priori*, is at higher risk of developing neurological complications; however, this risk should be compared with the serious disease treated and the associated life-threatening risk.

The IRSN expert appraisal does not, however, provide any information on the risks related to the other possible complications (risk of increased skin cancer in highly irradiated zones) or on the risk related to the repetitive nature of the procedures liable to produce a high cumulative dose, particularly in the brain.

Follow-up of the patients concerned, carried out by HUS to date, does not reveal any neurological, meningeal or subcutaneous abnormalities, and the cases of alopecia observed have fully regressed.

The dosimetric reconstructions carried out by the IRSN show that these procedures contribute to the delivery of very high dose levels to the skin and brain, largely unrecognised and underestimated both on a local and national scale. This lack of knowledge leads to underestimation of the risks facing patients.

4.2.4. Unsatisfactory retranscription of dosimetric data

At the request of the ASN, the HUS submitted the available files presenting the DAP for each procedure carried out using the Siemens machine at the Hautepierre site.

A number of inconsistencies were thus observed between various data sources (e.g. 158,880 instead of 15,880) related to errors⁴ in the manual retranscription of data from the device to patient records and dosimetric databases.

Moreover, no dosimetric data are shown in the databases or records for certain patients.

In view of these inconsistencies and the variation in DAP according to type of procedure, it is hard to identify any changes in DAP over time, which would be liable to evidence an increase in the doses received by the patients.

4.2.5. However, "regulatory" dosimetric data do not enable patient risks to be assessed

The regulations stipulate that post-2004 devices have to display the DAP and that this is stated in the reports on the medical procedures. This information, the unit of which varies from one manufacturer

⁴ Manual retranscription is necessary due to the unfortunate absence of a function that would automatically transfer the doses from the machines to the computer systems.

to another, is not sufficient in itself, whether in real time or *a posteriori*, to assess the doses received by the patients and the associated postoperative risks.

The DAP value and the size of the cutaneous irradiation field for the patients for each incidence need to be determined in order to evaluate the doses to skin received by the patients. Hence, reconstitution of doses to the skin received by certain patients at the Hautepierre site could only be carried out since these data were still available in the device's files.

It was thus noted that the relevant data enabling estimation of the doses to skin received are available on certain machines and able to be printed. These machines sometimes directly provide a dosimetric indicator representative of the dose to skin received by the patients, possibly displayed as a percentage with reference to a defined limit (this is the case for the device at the Hautepierre site for which the option was available but not activated).

However, the regulations do not currently require manufacturers to provide dosimetric data evaluating the dose to skin and thus enabling evaluation of the risk of occurrence of radiation-induced effects, or to store or provide relevant and consolidated dosimetric data to optimise practices and evaluate risks.

Due to the unreliability of available dosimetric data (DAP) and difficulty in evaluating the doses to skin actually received by patients, the risks of complications and the doses actually received by the patients cannot be determined with absolute certainty.

4.3. A practically non-existent optimisation and evaluation procedure for dosimetric practices

4.3.1. The principle of optimisation is not sufficiently known and assimilated

The principle of optimisation defined in Article R. 1333-60 requires patient exposure to be kept at the lowest possible level that may be reached within reason given the desired medical objective, i.e. without compromising therapeutic efficacy.

Concrete implementation of this principle requires dosimetry to be perceived as a parameter of the procedure which should be monitored and controlled.

The findings drawn up during the investigations showed that this principle was applied inadequately both during the device adjustment phase and during use, and that insufficient attention was given to the dose delivered.

This observation shows a lack of training and awareness as to the implementation of an optimisation procedure; these findings appear to be widespread in the majority of French departments.

4.3.2. Dosimetric data not sufficiently taken into consideration

Dosimetric data during interventional procedures are not subject to a routine general or individual analysis by practitioners in collaboration with the medical physicist.

This analysis is a vital aspect which should be part of the evaluation of professional practices, the objective of which is continually to improve the quality and safety of health care.

The lack of dosimetric data processing enabling the following was thus observed:

- identification of patients requiring medical follow-up;
- evaluation and optimisation of professional practices;
- detection of any deviations relating to the device, practices or settings;
- operational monitoring of delivered doses.

The absence of analysis or sufficient interest in the delivered dose notably did not enable all users of the Siemens device to detect non-optimised settings, which resulted in a dose more than 40% higher than the optimised dose being delivered.

The findings also showed that the dosimetric component did not receive sufficient attention during neuroradiological procedures admittedly owing to the complex nature of the procedure in a potentially life-threatening context, but also owing to underestimation of the risk related to the delivered dose and a lack of knowledge regarding this aspect.

Furthermore, it was noted that, due to the absence of a national reference system and inadequate operator training, they did not have a sufficient understanding of the dosimetric aspects and the challenges thereof.

4.3.3. Training failing to provide technical knowledge of the device and control of doses

The medical radiologist practitioners and radiographers received training in the use of the device from the manufacturer during installation of the system. However, this training is not considered satisfactory.

The investigations carried out showed that users were unfamiliar with some of the device's functions. Moreover, the use of the machine and its different operating modes did not make optimum use of the device's functions which would have made it possible to optimise and control the doses delivered.

Hence:

- the "Carevision" system which enables dose reduction, with which the device is equipped, was not included in the user presentation or training, which would have enabled it to be used effectively;
- failure to change the filters when modifying field size and the lack of filtration at certain times⁵ were presented during the first investigations as machine malfunction whereas this corresponds to a normal operating mode for the machine;
- the configuration of the "Carewatch" system, providing a display mode indicating the percentage of the skin dose with reference to a defined limit value, was not activated.

Furthermore, it should be noted that the additional training, carried out when the room was re-opened, was not performed in a satisfactory manner. This training, carried out by the manufacturer, was provided by an English-speaking German contributor, using training slides written in English and with a French translation provided by a technician from the manufacturer. Since no written documents were given to the participants, the relevance and quality of the training provided could not be assessed.

⁵ Absence of filtration related to optimisation of the absorption spectrum for the contrast product.

Lastly, the level of support from the manufacturer in appropriation of the machine and management of the delivered doses by users does not appear to match the dosimetric challenges.

4.4. Inadequately monitored and managed maintenance and adjustments performed by the manufacturer behind the delivery of non-optimised doses

4.4.1. Inadequate management of settings and insufficient appropriation of manufacturer interventions

The settings for the radiological procedures were adjusted by the manufacturer during installation of the device. Since the device is covered by the contractual guarantee period, only the manufacturer carries out maintenance and adjustment operations on the device.

There are no written documents which define the adjustments or trace the changes made. Only the manufacturer's back-up files, when created, make it possible to reconstitute the changes made. As regards the traceability and monitoring of maintenance operations, the description of the intervention by the manufacturer is sometimes brief and does not accurately state the changes made, both in terms of equipment and software, particularly those affecting the dose.

The overview of the manufacturer's maintenance operations was checked using documents submitted by the HUS (data extracts and manufacturer's intervention reports). It was noted that one of the 27 interventions mentioned by the manufacturer was not listed in the HUS intervention records. Furthermore, the intervention report dated September 2, 2008, by the Siemens firm mentioned a possible table brake problem which needed to be monitored. The subsequent intervention reports by the manufacturer do not mention whether this problem was corrected or followed up. During the inspections, it was not possible to determine whether follow-up with a view to correcting this fault had been undertaken by the HUS.

Furthermore, the weaknesses observed in the traceability of the maintenance and adjustment operations did not make it possible to determine *a posteriori* the changes made which had an impact on the doses received by the patients, particularly the changes made further to requests by the team carrying out the neuroradiology procedures, with a view to obtaining better quality images.

Hence, the various maintenance and adjustment operations carried out on the device by the manufacturer were not sufficiently appropriated by the HUS. The dosimetric impact of the initial or successive adjustments and the changes made were not analysed.

4.4.2. Non-optimised settings

Examination of the device settings showed that these were not subject to an optimisation process resulting in a compromise between the desired image quality and the dose delivered to the patient.

Hence, the dose per image was set to the maximum setting range (5.4 $\mu\text{Gy}/\text{image}$) for the main part of the radiological procedures since November 2008 at least⁶ without any real justification being provided. The impact of this parameter on the dose received by the patient is proportional to the setting. Hence, a setting of 3.6 instead of 5.4 reduces the dose to patient by 33%. Other parameters were also not subject to a sufficiently exhaustive optimisation process (image frequency in pulsed fluoroscopy and radiography, focus size, etc.).

It was observed that the manufacturer's initial settings do not generally correspond to optimised settings from a dosimetric perspective, but rather aim to produce a better quality image. The main approach by users and manufacturers consists in assessing the performance of a device in terms of the quality of the images produced, without taking into consideration the optimisation principle which should yield adequate image quality for the procedure without compromising therapeutic efficacy.

This event also shows that quality control, carried out in compliance with current regulations (AFSSAPS decision), is unable to evidence non-optimised settings.

4.5. A lack of written protocols describing the procedures, governing the use of the device or formally defining the settings

The provisions of Article R.1333-69 of the French Public Health Code stipulate that physicians set in place written protocols for each type of radiology procedure carried out as standard practice. These written protocols, based on the national procedure guides drawn up by professionals, should be constantly available in the proximity of the equipment concerned.

As regards the use of the Siemens device, the absence of procedures and written documents defining the settings was noted and, more generally, procedures or documents governing the use thereof.

For all that, the national procedure guides currently available need to be expanded so as to take into account the changes in technology and equipment, and the essential implementation of an optimisation process.

4.6. An organisation system preventing routine intervention by the medical physicist

The HUS have a full-time medical physicist, in charge of the medical physics and radioprotection unit in the establishment's nuclear medicine department. He very recently held the post of radioprotection officer.

⁶ information provided by the manufacturer.

The medical physicist, who is experienced in this type of activity, has, in the past, implemented optimisation measures for certain facilities or activities in partnership with several practitioners. These selective optimisation measures seem to stem more from the personal initiative of the physicist or determined practitioners rather than a structured, routine procedure in the establishment which, nonetheless, adopted an medical physics organisational plan in 2006⁷.

Implementation of this plan did not, however, give the physicist a sufficiently strong position within the establishment which would have enabled his intention to be heard and sufficiently rallied all of the teams around him (practitioners, technicians, technical departments).

The organisational system in place did not therefore enable the latter to be involved in choosing the device at the Hautepierre site, its initial and successive adjustments and their dosimetric impact, or even to participate in the initial training carried out by the manufacturer (unlike biomedical engineers at the HUS whose training is clearly stated in the response to the call for tenders by Siemens). Furthermore, he was not informed of the image quality problems reported by the head of department carrying out the neuroradiology procedures.

Lastly, the organisation of medical physics within the establishment did not allow the medical physicist fully to exercise his duties and responsibilities as defined in the decree of November 19, 2004, in the whole establishment and with all practitioners.

These findings show that the presence and mobilisation of a physicist is not sufficient in order to implement a structured optimisation process at establishment level, even if a medical physics organisational plan exists.

4.7. Uncertainty as to the source of the report

All of the investigations conducted have not given rise to any certainty, to date, as to the origin of the development of the cases of alopecia.

This lack of certainty is related to the following difficulties:

- the absence of qualitative and quantitative assessment of radiation-induced lesions and changes between the Hôpital Civil site and the Hautepierre site enabling lesion development to be documented;
- dosimetric data which are either missing or marred by mistakes related to manual retranscription and unit conversions;
- the difficulty in carrying out relevant statistical processing of DAP given the intrinsic variability of the procedures;
- the impossibility of reconstituting the skin doses received by patients from the DAP, apart from a limited number of patients, whose detailed dosimetric data were still available in the devices;
- the difficulties in assessing all of the modifications related to the change in device between the two sites;
- the weaknesses in the traceability of the changes made to the device settings and evaluation of the impact thereof on the delivered dose.

However, a number of aspects provide an idea of the probable causes likely to explain the development in the cases of alopecia reported at the beginning of 2009, i.e. a year after the device was commissioned:

⁷ Plan drawn up in pursuance of the decree of November 19, 2004

- the change in device gave rise to modifications in the distance between the radiation source and the patient, together with the position of the sensors and size of the fields used. These aspects notably give rise to major differences in the intersections of the anterior and lateral beams, and in the surface area of the patients' skin exposed;
- the commissioning of the new machine took place gradually as increasingly complex procedures were carried out, leading to increasingly high doses;
- a larger number of patients treated for complex cerebral disorders was observed at the end of 2008 - beginning of 2009, liable to generate a cluster effect in the first quarter of 2009;
- on the basis of the dosimetric reconstructions carried out for a few patients, the doses for the lateral fields, in contrast to the posterior fields which constantly "sufficiently" exceed the threshold for occurrence of alopecia, are generally at the lower limit of this threshold. Hence, the alopecia related to these lateral fields will be affected to a greater extent by the change in device, by the beam intersections and the changes in practices and settings.

Lastly, even though the exact cause of the development in lesions has not been determined, it should be borne in mind that it appears to be related to the change in device.

4.8. Identical DAP levels at the second HUS site

4.8.1. The high DAP levels are not restricted to the use of the machine at the Hautepierre site and its non-optimised settings

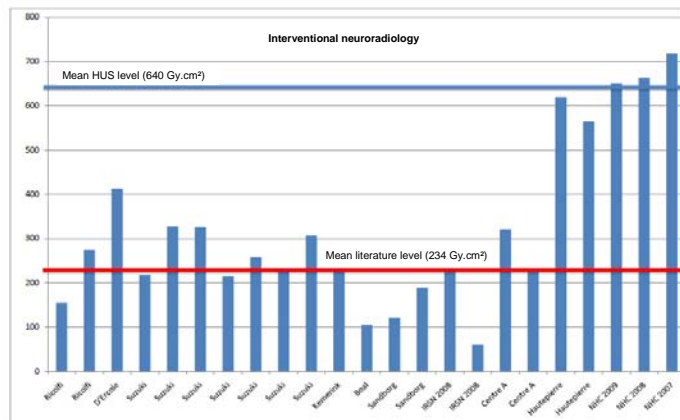
The investigations carried out showed that the DAP levels at the second HUS site (Hôpital Civil), during neuroradiology procedures, are the same size as those observed at the Hautepierre site.

In addition to the previous observations relative to dose optimisation, the DAP levels usually encountered for interventional neurology activities and the presence of iatrogenic effects should also be examined more widely.

4.8.2. Difficult comparisons owing to the absence of available joint reference systems

No "national reference system" exists which would make it possible to compare, on the one hand, the incidence of alopecia and, on the other hand, the DAP level or delivered doses.

However, as regards neuroradiology procedures specifically, the DAP levels observed are higher overall than those reported in the literature examined, and are liable to give rise to radiation-induced effects in an appreciable number of patients.



Although the data from the literature show that there is room for improvement in terms of dosimetry and characterise a lack of optimisation in addition to the findings observed, they cannot serve to compare the dose levels between departments or establishments, or determine whether local dosimetric practice is isolated and eludes those which may be observed in other departments. It has not been ruled out that only those teams concerned with patient dosimetry (and who therefore control and optimise the doses) publish their results. Moreover, a considerable variation exists in the delivered doses depending on the products used (acrylic glue/Onyx) and the techniques which are rapidly developing and thus make comparison difficult.

Although the occurrence of alopecia further to embolisation for a complex intracranial disorder is a known complication, it is rarely reported in the international literature (occasionally using the terms "Uncommon", or "Case report").

At the HUS sites, the occurrence of alopecia is not classified as rare. However, in the absence of accurate, written, local or national data, it is hard to claim that this frequency differs to findings which may be observed in other departments carrying out the same type of procedure.

Hence, in the absence of an available joint national reference system and reliable local data, it would appear difficult to determine whether the DAP levels and incidence of iatrogenic effects particularly differ from findings observed at other French sites. However, the data in the literature suggest that it is possible to reduce the dose levels observed.

5. A large-scale action plan has been implemented

Further to the findings described above, and awareness of the challenges and need for improvement, an action plan mobilising the establishment as a whole was set up by the HUS.

This action plan aims to:

- make available and process reliable dosimetric data,
- evaluate, modify and optimise professional imaging practices,
- determine the delivered doses via *in vivo* dosimetry,
- detect and monitor adverse reactions,
- ensure better personnel training,
- appropriate and manage interventions by the manufacturers,
- optimise the device settings,
- consolidate the organisation of medical physics.

5.1. Action is being taken for better training

In order to ensure that the training provided for all users enables them to master the use of newly installed equipment, the HUS have set up two working groups on the subject of training, one within the establishment and the other with the supplier, SIEMENS.

The working groups deal with the following issues:

- formally defining, in the specifications for equipment purchases, the most important requirements in terms of user training, which will represent a supplier selection criterion (French-language training aids, specific training for medical physicists, training in the functions contributing to dose optimisation, system for evaluating training quality on which receipt of the equipment is dependent);
- the definition of continuing training requirements after the initial training stage, to be carried out in-house or in connection with the supplier.

In addition to training related to the commissioning of the equipment, training in patient radioprotection has also been set in place for operators, enabling the principle of optimisation to be applied: initial practical training over a two-day period based on concrete cases for optimisation, and 4 hours of continuing training every 3 years.

Furthermore, periodic team meetings have been set up in order to discuss optimisation practices and the difficulties encountered during the procedures performed.

5.2. Consideration of the possibilities for substituting procedures has been initiated

In compliance with the principle for justification defined in articles L.1333-1 and R.1333-56 of the French Public Health Code, consideration is being given to investigating non-irradiating or less irradiating techniques which may be able to replace procedures entailing patient exposure. However, this consideration should take into account the available capabilities of the technical platform within the establishment.

5.3. The device settings are optimised and managed

The medical physicist has embarked upon a procedure to optimise the settings for all of the devices in connection with the practitioners and equipment suppliers.

Hence, the physicist is required to take part in the initial adjustment operations for all new equipment installed. These initial settings will be recorded in documents, and the initial in-house quality control will serve as a future reference.

If the settings are modified, the physicist is required to validate formally the new settings, whenever these have an impact on the delivered dose.

It was noted that this procedure for optimising settings requires the physicist to have accurate knowledge of the devices and to work closely with the practitioners, enabling good image quality to be defined according to the procedure performed. As far as the practitioners are concerned, this procedure involves agreeing not to have the best image quality but an image quality which is sufficient to enable the procedure to be performed without compromising therapeutic efficacy.

Experience feedback in optimising the settings shows that it is possible to achieve major dosimetric reductions without markedly decreasing image quality. Hence, as regards the Siemens device at the Hautepierre site, analysis of the dosimetric data evidenced a significant reduction in the DAP, in the region of 40%, solely related to optimisation of the settings defined and set in place by the HUS medical physicist.

5.4. Increased management of the manufacturer's maintenance and adjustment process

In order to improve the management and traceability of the device maintenance and adjustment process, particularly if there is likely to be an impact on the delivered dose, the establishment has made the conditions for monitoring interventions by the manufacturer more stringent:

- improved formalisation of interventions so as to guarantee:
 - the traceability of all maintenance interventions, whether preventive or curative, including remote interventions,
 - notification of the medical physicist during key interventions,
 - the validation of intervention reports by a qualified person.
- the requirement, in the maintenance specifications, for sufficiently detailed intervention reports to assess the services provided by the manufacturer and the consequences thereof.
- implementation of quality control in the event of a significant intervention.

5.5. A structured procedure for the optimisation of practices has been implemented

5.5.1. Automatic retranscription of dosimetric data is carried out

The IT department at the HUS has developed a parser enabling the data available in part of the devices to be decoded then transferred to a dosimetry database, so as to ensure that reliable consolidated data are available, an essential part of establishing an optimisation process. This automated process makes it possible to avoid manual data entry and unit conversion related to the different data formats of the devices, and enables the dosimetric indicators of the devices to be monitored practically in real time (DAP, DLP).

This important and essential function was developed in-house by the HUS further to the refusal by the supplier of the RIS (radiological information system) software program to develop this function, which could, nonetheless, have been effectively distributed to all users of this software program in France.

5.5.2. These data make it possible to define dose reference levels and evaluate practices

The implementation of this database enabled the HUS to obtain DAP values for approximately 4,500 interventional procedures, and also for 20,000 CT scan procedures, within the space of a few months. Based on these values, the HUS defined in-house dose reference levels enabling practitioners to have precise knowledge of the DAP levels encountered for the procedure carried out and on the device concerned, before each procedure. Knowledge of a target dose and comparison with the dose delivered enables a procedure for the evaluation of practices to be implemented.

Furthermore, the implementation of this evaluation procedure and individual knowledge of dosimetric practices has given rise to a team dynamic, making it possible to include the dosimetric issue in the procedure carried out, and leading to a continuous improvement in the doses delivered.

In addition to these in-house dose reference levels, a search of the literature has been carried out so as to determine the relevance of the in-house values.

Example of the in-house reference level

Procedures	Mean DAP	Min. DAP	Max. DAP	Number of cases
AORTIC ANGIO.	490,347	1,430	1,435,293	33
BILIARY DRAINAGE ANGIO.	74,338	2,586	287,036	56
ANEURISM EMBOLISATION ANGIO.	514,402	178,000	1,740,000	42
ANGIO. LOWER LIMBS	277,698	1,898	2,263,300	824
ANGIO. UPPER LIMBS	136,759	9,133	546,555	49
BILIARY STENT ANGIO.	93,122	10,948	318,031	43
SMACT ANGIO.	666,076	2,234	3,414,844	35
ANGIO. SAT	190,565	7,339	466,306	58
ANGIO. SAT + L.L.	412,438	100,000	720,421	19
CARDIAC ANGIOGRAPHY	3,541	403	25,840	21
MEDULLARY ARTERIO.	760,432	217,000	3,906,000	31
LIVER BIOPSY UNDER ANGIO.	68,993	3,443	288,000	20
CHANGE IN PYELOSTOMY CATHETER UNDER ANGIO.	18,360	1,222	168,014	59
HEPATIC CHEMOEMBOLISATION UNDER ANGIO.	548,567	37,040	1,400,150	85
AVF DILATION UNDER ANGIO.	16,149	1,009	224,397	76
BILIARY DRAINAGE	93,545	2,551	882,235	27
ANEURISM EMBOLISATION	442,393	179,757	848,000	14
GASTROINTESTINAL EMBOLISATION	1,226,090	45,410	3,432,540	18
AVM (ARTERIOVENOUS MALFORMATION) EMBOLISATION	619,000	196,000	1,042,000	2
MEDULLARY EMBOLISATION	490,033	122,000	847,000	3
PELVIC EMBOLISATION	577,630	117,950	2,917,698	11
TUMOUR EMBOLISATION	873,500	523,000	1,224,000	2
UTERINE EMBOLISATION	475,769	227,358	883,288	7
RENAL EMBOLISATION	853,183	548,481	1,168,336	4
BRONCHIAL EMBOLISATION	198,316	31,695	641,000	6
AVF (ARTERIOVENOUS FISTULA)	460,347	292,694	628,000	2
LOWER LIMBS	290,694	27,186	1,370,000	74
UPPER LIMBS	195,088	36,793	819,539	17
SMACT (SUPERIOR MESENTERIC ARTERY CELIAC TRUNK)	727,990	165,656	2,296,458	24

5.5.3. A number of changes have been made to imaging practices.

The findings observed regarding the delivered dose levels, together with the incidence of alopecia observed led practitioners, at the request of the general manager of the HUS, to review the conditions of use of the devices (reduction in the number of images, selection of a less irradiating image type).

The main changes in imaging practices are as follows:

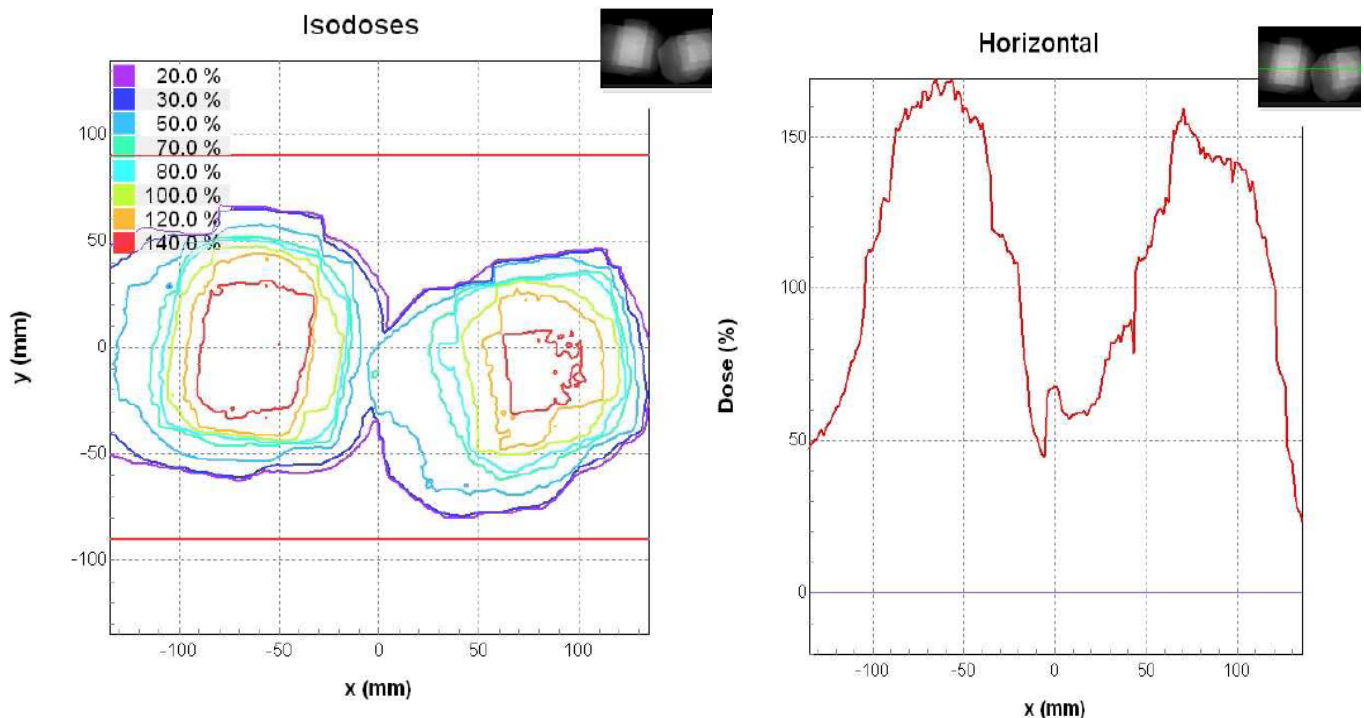
- reduction in the number of serial radiographs;
- use of the road map and rotational 3D;

- complex procedures assigned immediately in terms of seniority (procedures requiring highly technical skills are carried out by a single practitioner with experience enabling the entire interventional procedure to be carried out);

Particular emphasis was placed on changing practices at the beginning of the procedure so as to maintain a margin if necessary.

5.6. *In vivo* dosimetry has been set in place for therapeutic procedures

The establishment has routinely implemented *in vivo* dosimetry using Gafchromics film for all therapeutic vascular procedures so as to determine more effectively the delivered doses. *In vivo* dosimetry is able to generate the actual map of the skin dose delivered to patients.



In addition to the precise information regarding the delivered doses, this map makes it possible to change the position of the beams so as to avoid exposure to the same zones, in the event of later high-dose interventions.

Alongside the implementation of *in vivo* dosimetry, discussions were held with certain suppliers with a view to enabling real-time use by calculating a patient skin-dose map.

Implementation of *in vivo* dosimetry showed that, before the above-mentioned optimisation procedures were carried out, approximately 25 to 30% of patients undergoing therapeutic procedures presented skin dose levels exceeding 2 Gy. Further to optimisation, this dose level is exceeded very rarely.

5.7. Monitoring has been organised for patients liable to present lesions

A general policy for the detection and monitoring of patients liable to present deterministic effects has been set in place within the establishment.

5.7.1. Identification of patients at risk of complications

Patients undergoing diagnostic or therapeutic interventional procedures are subject to routine dosimetric monitoring which makes it possible to identify those at risk of developing radiation-induced lesions based on 3 simultaneous control levels:

- Implementation of a physicist alert system, during the procedures, if one of the following three criteria are exceeded:
 - radioscopy time > 45 minutes;
 - overall DAP value > threshold defined by type of procedure;
 - skin dose (if available) > 2Gy (air kerma at a reference point calculated by the system).The medical physicist is alerted immediately via the telephone on-call system.
- Routine use, for all therapeutic vascular procedures, of *in vivo* dosimetry using Gafchromics film type ISP XR-RV3. Interpretation of the films, carried out after the procedure, provides a second stage for identifying patients liable to present deterministic effects.
- Daily monitoring, by the physicist, of DAP extracted from the dosimetric database established.

Patient identification and the dosimetric database also enable the medical physics unit to manage the cumulative doses for a given patient in the event of repeated procedures.

5.7.2. Implementation of patient follow-up

Patient follow-up is implemented as soon as the skin dose level reaches a value of 3 Gy.

Follow-up is carried out either by the radiologist during an appointment, or by the physician in charge of the patient in the hospital unit, or by the patient him/herself, or a close relative if the patient has returned home. In the event of self-assessment, an information leaflet emphasising the clinical signs to be monitored is given to the patient at discharge.

When a cutaneous lesion is observed, the radiologist refers the patient to a dermatologist for treatment.

Extract from the patient self-monitoring leaflet

" ...

You have just undergone a lengthy and difficult interventional vascular procedure which required the acquisition of numerous series of images. Although unlikely, we cannot rule out the occurrence of adverse reactions.

Please could you inform us immediately of the slightest changes in your clinical condition (redness, itching, hair loss) and arrange an appointment so that we can initiate the monitoring procedure we discussed? ..."

5.8. The dosimetric data are archived in the patients' records

In addition to the dosimetric database, which automatically transfers the DAP into the procedure reports, the establishment routinely prints out the full dosimetric report, for all devices equipped with this function, enabling subsequent evaluation of the skin doses received by the patients.

This dosimetric report is scanned, then included in the patient's electronic file since direct transfer between the devices and computer systems at the establishment is not possible.

The results of *in vivo* dosimetry are added to the patient's dosimetric file when this is implemented.

5.9. Consolidated organisational system for medical physics

The medical physics team has been reinforced so as to enable the physicist to assign quality control to the technicians and concentrate on more technical matters.

Furthermore, consideration has been given to the updating of the organisational plan for medical physics within the establishment, making it possible to officially define the organisation and current position of medical physics within the establishment.

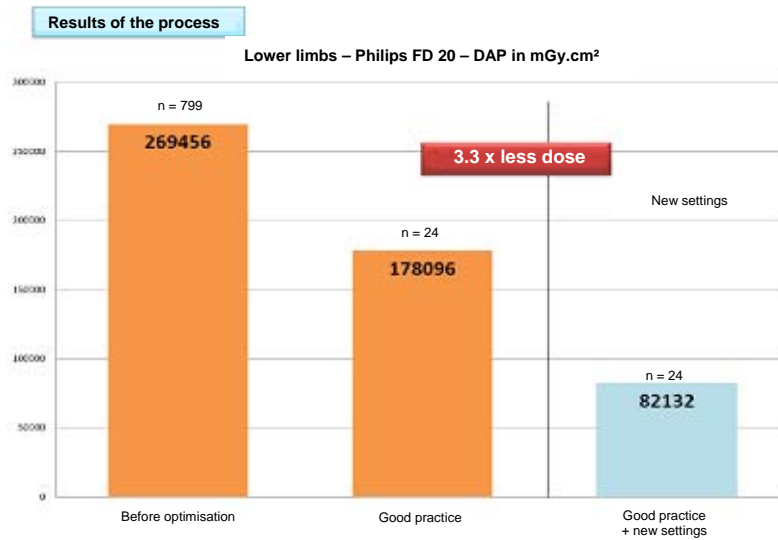
5.10. Sizeable dose reductions have been obtained

The implementation of this sizeable and innovative action plan has enabled the HUS to rank among those French establishments which follow an optimisation procedure for the most advanced practices in terms of patient radioprotection and knowledge of delivered dose in comparison with those observed at other sites. In addition to the optimisation action taken at local level, the knowledge acquired by the HUS will also help to improve the precise knowledge of doses received by patients and optimisation thereof.

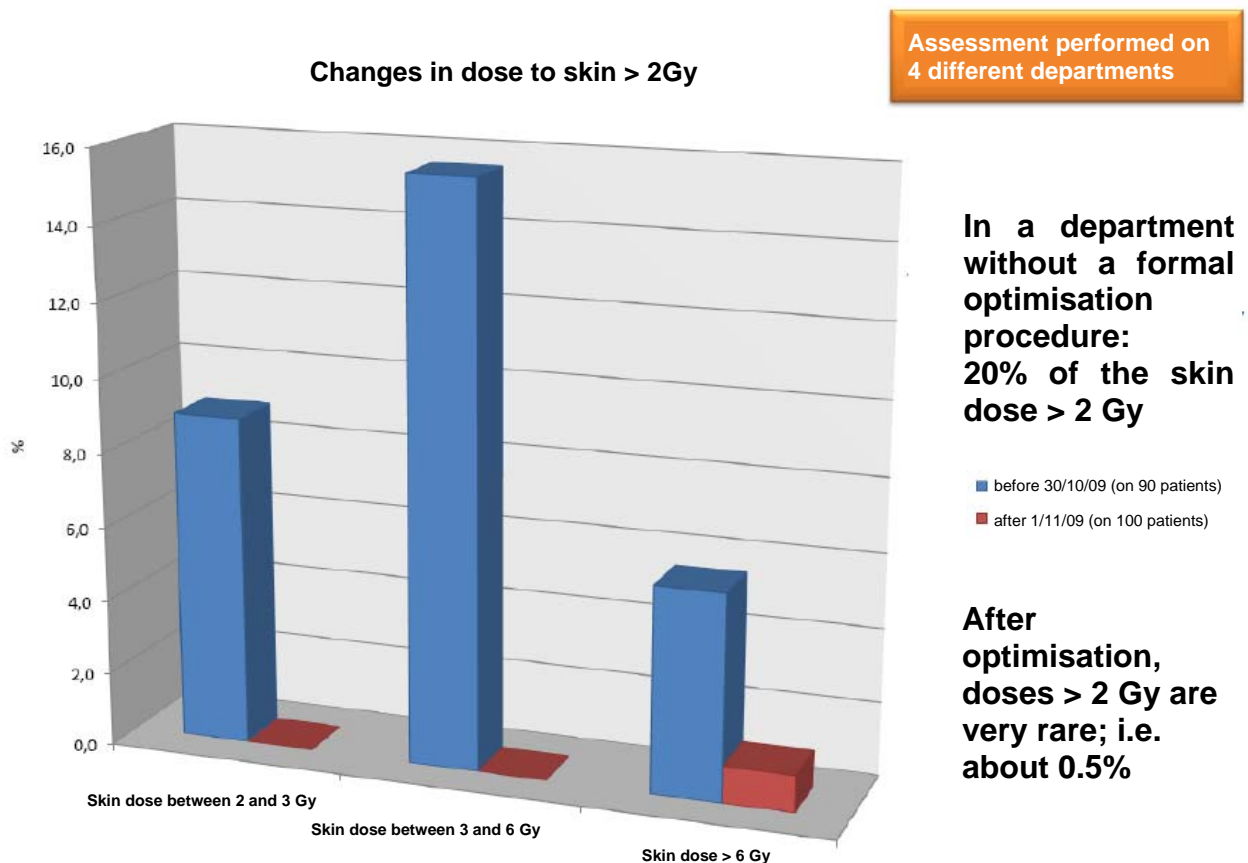
The results obtained are significant and evidence the relevance and efficacy of the action plan implemented. They demonstrate the existence of considerable margins for progress in terms of dose reduction, without compromising therapeutic efficacy.

The changes in practices have, for instance, reduced the exposure level of patients treated for cerebrovascular disease by a factor of two.

Furthermore, optimising the settings on the devices has also made it possible to reduce the doses approximately by a factor of two.



The implementation of *in vivo* dosimetry reveals the improvements made in practical terms. These results also evidence the high dose levels which may be observed in the absence of an optimisation procedure.



6. This event has given rise to significant national experience feedback

The lessons drawn from analysis of this event have enabled not only the HUS to improve the optimisation of interventional radiology procedures in-house, but, more generally, to generate

significant experience feedback for all of the professionals concerned, including manufacturers and personnel responsible for maintenance of the devices used.

It appears likely that the findings observed during the investigations are not specific to the HUS.

Based on this experience feedback, the ASN reiterated the regulatory requirements, and sent a number of recommendations to the heads of interventional vascular neuroradiology departments, together with the general managers of regional and Academic hospitals with a view to improving practices. Furthermore, the ASN informed the AFSSAPS of the lessons drawn from the analysis of this event so that interventional radiology devices and the conditions for maintenance meet the requirements relating to radioprotection more effectively (Appendix 1 and 2).

Since interventional radiology had been identified, before the report of the event by the HUS, as a sector facing major challenges in terms of radioprotection, the ASN convened the permanent medical radioprotection expert group (GPMED), in January 2009, so as to draw up recommendations to improve radioprotection among patients and personnel in this sector. The expert group is expected to issue its conclusions in the course of 2010. The lessons drawn from this report were brought to the knowledge of the working group so as to provide food for thought in its deliberations.

The experience feedback regarding this event which occurred in interventional radiology thus made it possible to identify a number of weaknesses and courses of action to be studied at national level, namely:

1. Consider implementing a procedure such as the "dose reference level" delivered (DRL)⁸ comparable to that used for conventional radiology procedures, enabling self-assessment of practices. This type of approach has already been initiated in other countries. On this subject, the voluntary procedure by the GACI (Atheroma and Interventional Cardiology Group) was noted in France, bringing together professional in interventional cardiology, which set in place reference levels and an innovative approach enabling self-assessment of patient dosimetry by each practitioner.
2. Ensure the systematic availability and processing of consolidated data, and set in place the self-assessment of practices in connection with the dosimetric management system defined above.
3. Invite learned societies to revise the procedural guides, notably to incorporate technical methods for optimisation and the dosimetric impact related to the choice of imaging techniques.
4. Increase operator training (practitioners and radiographers in medical radiology) in the optimisation of practices and processing of dosimetric data. This training should include a section on the choice of imaging techniques selected by the practitioners so as to choose the imaging technique delivering sufficient quality, in view of the medical procedure performed, rather than that providing the best image quality.
5. Take action with the manufacturers and maintenance personnel with a view to the following:
 - in the short-term:
 - the implementation of a dosimetric optimisation procedure for settings, during installation of the devices and after maintenance operations;
 - the implementation of automatic dosimetric data collection;

⁸ DRL diagnostic: reference levels

- the improvement of intervention reports and the traceability of changes,
 - assisting local teams in implementing an optimisation procedure related to the use of the devices;
 - the improvement in the user training provided by the manufacturer, which should include knowledge of device functions, and the parameters affecting the dose of radiation delivered;
 - providing training for personnel with a view to taking radioprotection constraints into account, by reiterating the obligation to provide training in patient radioprotection for professionals involved in the maintenance and quality control of medical devices, in pursuance of Article L.1333-11 of the French Public Health Code;
- in the medium-term:
- the use of a common unit for DAP display;
 - display on new machines, in addition to the DAP, of data which are more operational than the DAP, such as dosimetric data representative of the skin dose received by the patient. These types of data, which are available on certain machines, are essential to enabling practitioners to adapt the procedure in progress, where appropriate, or to modify current standard procedures. Real-time dosimetric data should be combined with an alert system as soon as the skin dose passes a certain threshold.
6. Evaluate the benefit of routinely storing all elements making it possible to determine the doses received by patients *a posteriori*, for procedures involving greater levels of irradiation.
 7. Define a reference system laying down the procedures for the medical follow-up of patients in the event of significant exposure (risks encountered, type of follow-up, duration, frequency).
 8. Consolidate the knowledge of the dose levels observed and the iatrogenic consequences according to specialist area.
 9. Consolidate the role of the radiographer in the optimisation of doses and device settings.
 10. Verify the actual implementation of an optimisation procedure as provided for in Article L.1333-1 of the French Public Health Code.
 11. Evaluate the clinical practices exposing individuals to ionising radiation for medical purposes, notably giving priority to the implementation of clinical audits in this field, as stipulated in Article R.1333-73 of the French Public Health Code.

APPENDICES

Appendix 1: Letter from the ASN dated September 21, 2009 further to the inspections carried out.

Appendix 2: Reply from the HUS dated October 23, 2009

Appendix 1: Letter from the ASN dated September 21, 2009 further to the inspections carried out.

Strasbourg, September 21, 2009

The General Manager
CHRU de STRASBOURG ⁹
1, Place de l'hôpital
BP N° 426
67091 Strasbourg cedex
France

Re.: Your report of a neuroradiology incident.

Ref.: 1: ASN letter dated April 3, 2009, relative to the re-opening conditions.

2: Your letter dated September 17, 2009.

To the General Manager,

On March 20, 2009, the ASN was informed by the Strasbourg Academic Hospitals of reports of patients presenting adverse reactions of unusual intensity which could be attributed to an excessive dose of X-rays during endovascular treatment of arteriovenous malformations and intracerebral aneurisms using a Siemens AXIOM Artis device.

As part of the analysis of the report of the incident, the French Nuclear Safety Authority visited your establishment on March 23, 2009 and May 7, 2009. These inspections served to take stock of the report of the event, together with compliance with the regulations and conditions for radioprotection related to the use of the device.

Furthermore, several expert appraisals were carried out in order to identify any potential device malfunctions, to evaluate the doses delivered to the patients and the possible effects induced, and to examine the conditions of use with regard to existing practices and recommendations drawn up by professionals.

The present letter sets out the different aspects recorded by the ASN, for some of which you have already taken corrective measures, notably further to my letter mentioned in ref. 1.

Summary

The inspections and expert appraisals carried out on the Siemens AXIOM Artis device did not evidence any technical faults in the device liable to have caused the effects observed. It has emerged from these investigations that the effects observed partly stem from the methods of use of the device

⁹ Strasbourg Regional University Hospital

leading to delivery of a very high dose level in relation to the treated disorder, and partly to the non-optimised adjustment conditions owing to organisational and human failings.

A number of failings were thus observed in the training received by medical and paramedical personnel in the dose optimisation procedure, management of the maintenance and adjustment process for the device, together with the organisation of medical physics.

However, the inspectors noted that a number of optimisation actions had been taken on other equipment or for other interventional radiology activities in the establishment. Hence, some of the observations presented below, further to the inspections concerning the use of the Siemens AXIOM Artis device in neurology, do not need to be extended routinely to your establishment as a whole.

Please find below the main requests and comments further to the inspectors' findings.

A. Requests for corrective actions

Dosimetric data

The inspectors noted that the available dosimetric data are copied manually into the patients' files, which has led to retranscription errors. Furthermore, certain patient files did not contain any dosimetric data for the procedures performed.

I would like to remind you that all medical procedures involving the use of ionising radiation must be the subject of a declaration comprising information making it possible to estimate the dose received by the patient during the procedure (Decree of September 22, 2006, relative to the dosimetric data to be included in a report for procedures involving the use of ionising radiation).

Request A.1: Please could you ensure that the dosimetric data, which should be included in the reports for the procedures, are available and reliable, at establishment level?

I have duly noted the action already taken and described in your above-referenced letter relating to the collection and processing of dosimetric data. Your actions regarding this aspect do not call for any comments.

Evaluation and optimisation of dosimetric practices

The inspectors noted that the dosimetric data relative to the procedures carried out at your establishment were not routinely analysed in all departments, in collaboration with the practitioners and the medical physicist. This procedure makes it possible to evaluate and optimise professional practices and, where appropriate, to detect any deviations in the device or in practices. This is a vital aspect which should be part of the evaluation of professional practices, the objective of which is continually to improve the quality and safety of health care.

As regards the methods of use of the devices, it is up to each professional to keep patient exposure to the lowest level that may be reached within reason given the desired medical objective. I have duly noted, in your above-referenced letter that, given the level of the doses delivered in neurology and the values available in the literature, you embarked upon an optimisation procedure which was able to considerably reduce the level of patient exposure.

Request A.2: Please could you routinely implement a process for the evaluation of dosimetric practices concerning therapeutic interventional radiology procedures? Please let me know the action taken and the time-limits.

Detection of adverse reactions

The inspectors noted that your establishment does not have a general routine policy for the detection and follow-up of patients liable to present radiation-induced deterministic effects.

Request A.3: Please could you define and implement a general policy for the detection and follow-up of patients liable to present deterministic effects?

I have duly noted the actions, described in your above-referenced letter, that you have taken within your establishment relative to the medical monitoring of patients having undergone an interventional radiology procedure. Please could you keep me informed if any unexpected deterministic effects are detected?

Training

The inspectors noted that although practitioners and technicians receive training upon commissioning of the machine during installation, training in the optimisation and management of delivered doses is not satisfactory and does not make optimum use of the functions of the device enabling a reduction in doses. For instance, the "Carevision" dose reduction system was not used.

Furthermore, training in the specific features of the device was not carried out in a satisfactory manner either: failure to change the filters when modifying field size and the lack of filtration at certain times were presented to the inspectors from the ASN as being a machine malfunction whereas this corresponds to a specific operating mode for the machine.

The inspectors noted that the training provided by Siemens, requested in the above-referenced letter from the ASN, which was a condition for re-opening of the room, was carried out by a German contributor, in the English language, using English-language training aids with a French translation provided by a technician from Siemens.

I should remind you that the implementation of an optimisation procedure for the doses delivered to patients is a regulatory obligation (Article L 1333-1 of the French Public Health Code). This procedure mainly involves appropriate training of personnel.

Request A.4: Please could you ensure, whenever any new equipment is installed at your establishment, that the training provided for all users (radiographers, physicians, medical physicist, etc.) allows them to master use of the equipment? Please verify the quality of the training services provided, notably as regards the functions used to master and optimise the delivered doses.

Procedures for adjustment and use of the device

The inspectors noted the absence of written procedures and documents defining the settings for the devices and, more generally, procedures and documents governing the use thereof.

The provisions of Article R.1333-59 of the French Public Health Code require the implementation of procedures when carrying out operations involving exposure of patients to ionising radiation so as to keep patient exposure at the lowest level that may be reached within reason given the desired medical objective.

Request A.5: Please could you define, in collaboration with the medical physicist, procedures governing the use and adjustment of the device, enabling an optimisation procedure for the doses delivered to patients to be implemented? Please keep me informed of the action taken along these lines.

Organisation of medical physics

The inspectors noted that the medical physicist at your establishment was not informed of the image quality problems reported by the neuroradiologist. Neither was the latter involved in the initial adjustments and various interventions by the manufacturer which led to changes in the device settings, having an impact on the doses delivered.

Request A.6: Please could you set in place an organisational system for medical physics allowing the medical physicist to carry out the duties defined in the decree of November 19, 2004, in the establishment as a whole, and formally define this organisational system in the context of the medical physics organisational plan?

The medical physicist should notably be informed of any defaults reported for equipment generating ionising radiation and routinely involved in the various maintenance operations so as to evaluate the dosimetric consequences of the operations carried out.

Furthermore, in order to optimise the doses, and in addition to dialogue with practitioners concerning the device settings, please could you ensure that the medical physicist is party to the evaluation and choice of the imaging techniques selected by practitioners in view of the desired medical objective?

Management of the maintenance and adjustment process for the device

The inspectors noted that the maintenance and adjustment process for the device was not sufficiently mastered.

Hence, the intervention report dated September 2, 2009, by the Siemens firm mentioned a possible table brake problem which needed to be monitored. Subsequent intervention reports from Siemens and your in-house traceability records do not mention any corrective or monitoring action related to this fault.

The inspectors noted that the intervention by Siemens on January 14, 2009, is not shown in your record of interventions as requested by Article R.5218-28 (5°) of the French Public Health Code

Moreover, the inspectors noted that the traceability of the various adjustment and maintenance operations on the Siemens AXIOM Artis device was not satisfactory and did not enable the changes made to be identified at a later date.

Lastly, the inspectors noted that the head of radiology department A at the NHC made several requests for improvement of the generated image quality. Further to these requests, they were able to be improved by action taken by the manufacturer, without this action being managed by your establishment.

I should remind you that the provisions of Article R.5212-28 of the French Public Health Code lay down the obligations in terms of the monitoring of medical devices.

Request A.7: Please could you set in place an organisational system allowing you to manage the maintenance process? This organisational system should notably allow you to monitor and evaluate the maintenance operations, particularly those leading to adjustments on the medical devices liable to have an impact on the delivered doses, and also to respond to requests from users experiencing problems when using these devices, notably with the assistance of the medical physicist.

Declaration of the devices

On the day of the inspection, the inspectors noted that the Siemens AXIOM Artis device had not been notified to the ASN. This device was commissioned on December 12, 2007. I have duly noted that the dossier rectifying this notification was sent on March 31, 2009.

I should remind you, in compliance with Article R.1333-39 of the French Public Health Code, that any changes or modification to devices emitting ionising radiation should be the subject of a new notification. The absence of such a notification constitutes an offence stipulated in Article L.1337-5 of the French Public Health Code.

Request A.8: Please could you ensure that Article R.1333-39 of the French Public Health Code is strictly followed? Please could you check that the all devices generating ionising radiation have indeed been the subject of a notification to the ASN, and ensure that your notification is updated further to any new devices being installed? Please inform me of the provisions that you intend to implement for this purpose.

Periodic control report

You were unable to provide the annual external radioprotection control report drawn up by an organisation accredited for the Siemens AXIOM Artis device. I have duly noted declaration explaining that this control was indeed carried out, but that the report had not been sent by the organisation having carried out the control.

Request A.9: **Please could you set in place an organisational system aiming to ensure that you have an annual control report for your facilities?**

B. Further information:

Request B.1: **Please could you send me, immediately then every 3 months, a summary of the patients followed up regarding the report of this event?**

C. Comments:

- **C.1:** The inspections showed that the organisational system in place did not enable the paramedical teams to become familiar with the techniques used. I have duly noted the actions you have set in place, and your considerations relating to specialisation of the teams, or indeed, unification regarding interventional activities.

- **C.2:** The inspectors noted that some of the results obtained for dosimetric monitoring by personnel do not indicate a recorded dose. Please could you remind your personnel of the obligation to observe passive dosimetry and, where appropriate, active dosimetry?

Please could you submit your comments and responses regarding these points within a period of not more than **one month**? Regarding the actions to which you are committed in order to conform to the regulatory requirements, I would be grateful if you would clearly identify and specify the implementation deadlines for each one.

Yours faithfully,

On behalf and on the authority of the Chairman of the ASN,
The Head of the Strasbourg Division

Signed

Pascal LIGNÈRES

Appendix 2: Reply from the HUS dated October 23, 2009

Strasbourg, October 23, 2009

PGIL/DE AD/AS no. 270/09

Autorité de Sûreté Nucléaire¹⁰

1, rue Pierre MONTET
67000 STRASBOURG
FRANCE

Re.: Reply to your follow-up letter further to the interventional neuroradiology incident reported on March 20, 2009

Ref.:

- your letter Strasbourg-Dep. ref. VB.VB.2009.1477 dated September 21, 2009, received on September 23, 2009
- my letter PGIL/DE AD/AS 238/09 dated September 17, 2009
- my letter PGIL/DE AD/AS 243/09 dated September 24, 2009

**Encl.: 1 full dossier
1 CD-ROM**

Dear Sir,

In reply to your above-referenced follow-up letter, please find enclosed the response from Strasbourg Academic Hospitals:

Corrective action A1: Dosimetric data

You asked us to ensure that the dosimetric data to be included in the reports on the procedures are available and reliable at establishment level.

As suggested during your various visits, and during the conference calls held with the competent regional and national bodies, we have experienced a number of technical problems hindering dose collection:

- Each room uses a different dose measurement unit, even for the same manufacturer, and the RIS uses yet another one, which is why the technicians require conversions to be carried out;
- inability of our RIS, despite repeated requests sent to the supplier, to collect data directly from the modalities, and hence manual retranscription of the DAP in the RIS.

Furthermore, the information which, according to the regulations, is required to be stated in the reports (DAP/DLP) cannot be used for dose reconstitution.

Now, the available dosimetric information in the RIS should meet the following requirements:

- Comply with regulatory obligations
- Enable the reports to be automatically filled in
- Enable dosimetric comparison with the values published in the good practice guides (evaluation of dosimetric practices)
- Enable dose reconstitution (disputes, undiscovered pregnancy, incident analysis, etc.)

¹⁰ French Nuclear Safety Authority

Considering the extent of the challenges and despite the major difficulties, the HUS have taken several actions aiming to make the dosimetric data available, reliable, but also useful:

- Request for the creation by the supplier of the RIS (EDL) of a new dosimetric table in the XpLore software program (cf. PPT file attached – A1a). Envisaged deadline: beginning of 2010 for submission of a test version;
- Development by the HUS IT department of a parser to "decode" and format the MPPS field as per the attached PPT file (see attached results – A1b). The parser is already operational for the CT scanners and will be extended to the other modalities by the end of 2009. It will make it possible to avoid the need for conversions and retranscription by the technicians.
- The dosimetric data should not be considered from an overall perspective under any circumstances; it should be available for each anatomical level investigated or each examination in the event of multiple examinations so as to enable dosimetric evaluation: now operational in the requested area, and incorporated into the RIS in 2010.
- Paper print-out of the full dosimetric reports which are included in the patients' files (routinely performed on all modalities with the appropriate facilities)
- Use of Gafchromics films enabling a map of the skin dose to be obtained: carried out since September 1, 2009, on all invasive therapeutic procedures (interventional cardiology, neurology or vascular procedures). cf. specimen map generated by the gafchromic films attached. – A1c and A1d

Corrective action A2: Evaluation and optimisation of dosimetric practices

You asked us to adopt a systematic approach to the evaluation of dosimetric practices for therapeutic interventional radiology procedures.

Appendix A2 to the present letter provides a detailed description of the procedure already implemented by M. M., the HUS medical physicist.

As mentioned in my above-referenced letter ref. 243/09 of September 24, the optimisation actions undertaken have already given rise to results as a mean reduction in the delivered doses by a factor of 2 or even 3 has been observed since they were implemented in interventional neuroradiology at the beginning of September 2009. (cf. analysis – A2a)

Corrective action A3: Detection of adverse reactions

You asked us to define and implement a general policy for the detection and follow-up of patients liable to present deterministic effects.

Appendix A3 to the present letter provides a detailed description of the detection and monitoring procedure drawn up by M. M., the HUS medical physicist.

Examples of patient follow-up are also appended – A3a.

Corrective action A4: Training

You asked us to ensure that the training provided for all users during installation of any new equipment at the HUS, enables them to fully master the use thereof.

In return, I should inform you that two working groups have been set up on the theme of training, one within the establishment and the other in connection with the supplier, SIEMENS (cf. minutes from the first meetings attached – A4a and A4b).

The lines of work are as follows:

- inclusion in the specifications of much more extensive requirements in terms of training, before selecting equipment (by the end of 2009):
 - o training in handling the equipment and in dose optimisation suited to medical and paramedical users
 - o specific advanced training for the physicist who will therefore perfectly master the techniques offered by the machine
 - o the candidates should provide French-language training aids: the quality of training will be a criterion in the choice of equipment
- compulsory measurement of user attentiveness and satisfaction by the supplier and the HUS (when the next equipment is installed):
 - o receipt of and payment for equipment will be subject to the satisfactory evaluation of training by users, determined on the basis of satisfaction questionnaires
- consideration on the possibility of repeated training in addition to initial training, in connection with the supplier and the physicist (considerations to be taken further in the course of 2010 in connection with the suppliers).

Corrective action A5: Procedures for adjustment and use of the device

You asked us to define, in collaboration with the medical physicist, procedures governing the use and adjustment of the device, enabling an optimisation procedure for the delivered doses to be implemented.

Until now, the settings have initially been adjusted by the manufacturers' application engineers in connection with the operators. It has now been decided that the medical physicist will be involved in the initial adjustment operations for the equipment on installation. These initial adjustments will be traced in documents formally describing the acceptance test. Moreover, the initial in-house quality control will serve as a subsequent comparative reference.

Any subsequent changes in the settings will be based on the evaluation of dosimetric practices (cf. action A3), routinely searching for dose optimisation. This will be based on:

- the possible change in practices
- optimisation of the dosimetric settings of the facilities
- consideration of the bibliographic information relating to optimisation

The medical physicist is required to be notified of the new settings and will formally validate these when they have an impact on the delivered dose.

Corrective action A6: Organisation of medical physics

You asked us to set in place an organisational system for medical physics allowing the medical physicist to carry out his/her duties throughout the HUS and to formally define this organisational system in the physics organisational plan.

You requested that the medical physicist be informed of any faults found in the equipment and routinely involved in the maintenance operations so as to evaluate the dosimetric impact thereof.

Sizeable duties are assigned to the medical radiophysicist, in terms of quantity and importance, especially in an establishment on the scale of the HUS comprising more than 100 ionising radiation generators and a multisite nuclear medicine department.

Since it is currently practically impossible for public establishments without a radiotherapy unit to recruit a medical physicist to reinforce the current team, it is essential to organise the medical physics unit so as to enable M. M. to focus personally on his most strategies duties.

I would thus like to inform you that the medical physics and radioprotection team has been expanded due to the arrival of 3 quality control technicians and dosimetrist (November 2009 and January 2010 – cf. organisational chart attached – A6a). This reinforcement should make it possible to formally implement on-call duty on three levels in the course of 2010:

- dosimetric duty
 - o level: medical physicist
- technical duty for equipment
 - o Level: medical physicist and quality control technician as soon as the latter has received training
 - o eliminating doubts on intermittent malfunction or after intervention by the maintenance technician
- Radioprotection duty
 - o Level: Radiation protection officer
 - o Monitoring of incidents (nuclear medicine tank alarms, etc.)

This on-call duty system enables the activities described above to be applied to the procedures for routinely involving the radiophysicist in the initial adjustments and the interventions carried out by the manufacturer.

This new organisational system will be described in the update to the HUS medical physics organisational plan, which will be drawn up by the summer of 2010.

Furthermore, you requested that the medical physicist be party to the evaluation and choice of the imaging techniques selected by practitioners in view of the desired medical objective.

As mentioned in section A4, the physicist will henceforth receive advanced routine training on all of the facilities which may be problematic in terms of dose. This training, supplemented by literature searches and the procedure for evaluation of practices described in section A2, will unquestionably allow the physicist to have a dialogue with practitioners, advising them in their choice of imaging techniques. This dialogue between experts will not, however, relieve practitioners of their personal medical responsibility in their ultimate choice of imaging technique.

Corrective action A7: Management of the maintenance and adjustment process for the device

You asked us to set in place an organisational system able to manage the maintenance process so as to monitor and evaluate the operations carried out on the machines, particularly those leading to adjustments liable to have an impact on dose.

You noted that corrective and preventive interventions are traced using the HUS computerised maintenance management software program (CMMS). The intervention reports by the different suppliers have been associated with the equipment in electronic form for several years already. Unfortunately, experience has nonetheless shown that certain reports could be missing or prove too brief to enable relevant assessment of the intervention.

Two working groups on maintenance were set in place by the Equipment Division in order to rectify these problems, one within the establishment and the other with the supplier, SIEMENS (cf. attached reports – A7a and A7b).

The main lines of work are as follows:

- description of a reporting circuit for maintenance requests which guarantees (validated and implemented by the end of 2009):
 - o the traceability of all maintenance interventions, whether preventive or curative, including remote interventions
 - o the presence of the physicist or a member of his/her team during or after key interventions, to give full discharge to the installation
 - o the validation of intervention reports by a qualified person from the HUS

- requirement in the specifications for sufficiently detailed intervention reports so as to assess the service provided and the consequences thereof (incorporation into forthcoming maintenance agreement)

Corrective action A8: Notification of the devices

You asked us to ensure that all devices generating ionising radiation have been the subject of a notification to the ASN.

It is true that, at the time of the incident in March 2009, you had not received the updated *notification* of devices at the HUS emitting ionising radiation since the opening of the Nouvel Hôpital Civil had given rise to numerous changes which called for further in-house and external control, and we were waiting to obtain all of the information before submitting our dossier.

As mentioned in section A9, we encountered a number of major difficulties in obtaining the external control reports from our supplier, documents which are essential in drawing up the *notification*.

I should point out that the full dossier was indeed sent to you as soon as the last of these documents was received, and that it is currently being processed by your departments.

From now on, and in compliance with our meeting on September 18, at your premises, you will be sent the documents in electronic form, in the format which we jointly validated. This should facilitate the time-consuming but essential updating of this notification for both of our institutions, which concerns more than a hundred generators.

Corrective action A9: Periodic control report

You asked us to set in place an organisational system ensuring that an annual control report is obtained for our facilities.

We kept you informed, via various letters and emails, of the problems we were experiencing with our service provider carrying out the external control tests on our devices. Despite numerous reminders and several visits for control tests on the same device, it took practically a year to obtain all of the reports necessary in order to draw up the declaration mentioned in section A8.

For the year 2010, as we were able to explain during our meeting on September 18, we planned to change the way in which the control tests are organised so as to oblige our service provider to provide regular reports of a satisfactory quality.

I believed that the ASN was planning to take steps against this defaulting service provider so as to improve the quality of its services. I hope that our joint efforts will lead to a satisfactory response to this request for corrective action.

Further information B1:

In compliance with your request, please find enclosed, as forwarded by the head of department (B1a), an anonymous overview of the patients monitored regarding the report of events (patients from the initial cohort at the Hautepierre site (B1b), and also patients managed in interventional neuroradiology since March 20, 2009 (B1c) and monitored according to the procedure described in section A3).

Comment C1: specialisation of the paramedical teams

The technicians working in the vascular rooms at the Nouvel Hôpital Civil have been dedicated exclusively to this activity for several years now, and have therefore received training in interventional activities.

As regards the Hautepierre site, I should confirm that re-organisation is underway so as to ensure that the technicians called on to work in the vascular room will all have received specific training in this activity.

A working group is responsible for proposing and implementing an organisational system, by the end of 2009, which meets the needs of the specialist areas at all sites, irrespective of the nature or time of the procedure.

Comment C2: obligation for personnel to carry a dosimeter

The large majority of medical and paramedical personnel ensure that they carry the dosimeters made available to them by the institution.

However, certain individuals may escape this rule. I would therefore like to confirm that everyone will be firmly reminded of the obligation to observe passive or indeed active dosimetry from next week (cf. draft letter – C2a).

Yours faithfully,

The General Manager

Signed

P.Guillot