Summary of external evaluation

ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS (AP-HP) - HÔPITAL EUROPÉEN GEORGES POMPIDOU

Interventional technical platform, operating theatres, and endoscopy department

Type : Inspection of the radiation protection of workers and patients

Audit date : From 4 February 2019 to 6 February 2019

Organisation: Autorité de Sûreté Nucléaire (ASN) = French Nuclear Safety Authority

1. Summary of the inspection

The aim of the inspection was to assess, by sampling, the radiation protection measures for workers and patients implemented in the context of the use of ionising radiation in the interventional technical platform (ITP), operating theatres and endoscopy.

During the inspection, and during the visits, the inspectors appreciated the quality and transparency of the exchanges they were able to have with the people they met. They did, however, note the refusal of the orthopaedic surgeons in OR 1 to meet with them during their visit to the unit.

The following positive points were noted:
- The good consideration given to the radiation protection of patients and workers in the Endoscopy department
- The recruitment of a medical physicist dedicated to interventional imaging at the beginning of 2018, which has led to an improvement in the consideration of patient radiation protection within the fixed interventional radiology installations since the 2016 inspection
- The optimisation work undertaken in the ITP and in the "SIBO" room as well as that carried out in endoscopy
- The equipment uses sheets present on the mobile equipment
- The establishment's investments in the renewal of leaded aprons
- The educational support for training in radiation protection for workers

2- Summary of findings :

- 6 positive points
- 34 requests for corrective action
- 1 request for additional information
- 5 observations

Type	N°	Wording of the finding	Thematic	Site concerned
Request for corrective action	A1	Implement a robust and sustainable radiation protection organisation to meet regulatory requirements	Organisation of radiation protection	HEGP

Request for corrective action	A2	Review and ensure compliance with the conditions defined for the use of the O-Arm device to ensure the radiation protection of your workers	Using the O-Arm	HEGP
Request for corrective action	A3	Ensure that each employee exposed to ionising radiation benefits from reinforced individual monitoring in accordance with the regulatory provisions	Enhanced individual monitoring	HEGP
Request for corrective action	A4	Supervise the presence and interventions of all external companies in accordance with the regulatory provisions in force to ensure that all personnel benefit from adequate prevention and protection measures with regard to the exposure of workers to ionising radiation	Coordination of preventive measures	HEGP
Request for corrective action	A5	Indicate the preventive measures defined for temporary staff, in particular for training in radiation protection of workers	Coordination of preventive measures	HEGP
Request for corrective action	A6	Review and submit risk assessments for operating theatres. These studies should specify the assumptions made, detail the calculations and conclude on the zoning of the premises	Risk assessment and delimitation of restricted areas	HEGP
Request for corrective action	A7	Review individual assessments of exposure to ionising radiation for all personnel likely to be exposed during interventional procedures by formalising the assumptions taken into account. These assessments should result in an estimate of the annual exposure of workers (whole body dose, extremities and crystalline lens) and conclude as to their classification and the medical surveillance, prevention (wearing of personal protective equipment) and dosimetric measures implemented as a result	Individual assessment of exposure to ionising radiation	HEGP
Request for corrective action	A8	Ensure that radiation protection training for workers is renewed at regulatory intervals to remind workers of the principles of radiation protection and good practice in the use of radiation	Training in radiation protection for workers	HEGP
Request for corrective action	A9	Provide workers with enough operational dosimeters and ensure that they are easily accessible	Operational dosimetry	HEGP
Request for corrective action	A10	Ensure compliance with the wearing of passive and operational dosimetry and PPE imposed by articles R4451-33, R4451-56, R4451-64 and R4451-65 of the Labour Code	Wearing passive and operational dosimetry and PPE	HEGP
Request for corrective action	A11	Ensure that passive dosimeters, when not being worn, and the reference dosimeter are stored in a place accessible to all operators, away from all sources of radiation	Storage of passive dosimeters when not in use	HEGP
Request for corrective action	A12	Implement regular monitoring of workers' passive dosimetry results (whole body, extremities and lens)	Monitoring of dosimetry results	HEGP
Request for corrective action	A13	Return all passive and ambient dosimeters at the end of their wearing period	Management of passive and ambient dosimeters	HEGP

Request for corrective action	A14	Pending compliance of the rooms with Nuclear Safety Agency (ASN) decision n°2017-DC-0591, review the organisation for signalling the use of X-ray equipment in the rooms	Zone access instructions	HEGP
Request for corrective action	A15	Check that premises adjoining supervised and controlled areas are unrestricted areas	Compliance with ASN decision n°2017-DC-0591	HEGP
Request for corrective action	A16	Transmit a timetable for compliance of operating theatre facilities using a mobile C-arm for radioguided interventional procedures with the requirements of ASN decision n°2017-DC-0591 of 13 June 2017	Compliance with ASN decision n°2017-DC-0591	HEGP
Request for corrective action	A17	Following the verification of adjoining areas for fixed rooms and the compliance of rooms for operating theatres, draw up and transmit technical reports on compliance with ASN Decision No. 2017-DC-0591 for the facilities, including all the elements provided for in Article 13 thereof	Compliance with ASN decision n°2017-DC-0591	HEGP
Request for corrective action	A18	Use X-ray equipment only in premises designed for this purpose and meeting the requirements of ASN Decision n°2017-DC-0591	Use of equipment in designated areas	HEGP
Request for corrective action	A19	Draw up a programme for all radiation protection checks applicable to the installations	Radiation protection monitoring programme	HEGP
Request for corrective action	A20	Ensure that the applicable internal radiation protection controls are carried out on the installations, according to the periodicity and modalities indicated in the ASN decision n°2010-DC-0175	Internal technical radiation protection inspections	HEGP
Request for corrective action	A21	Ensure that the environmental monitoring required by ASN decision no. 2010-DC-0175 is carried out according to the regulatory periodicity	Ambient dosimetry	HEGP
Request for corrective action	A22	Ensure that periodic checks on the calibration of operational dosimeters are carried out in accordance with the regulatory periodicity	Calibration of operational dosimeters	HEGP
Request for corrective action	A23	Complete the POPM in order to include the mandatory elements specified in ASN guide n°20, by including an action plan for medical physics which will specify the pilots, the associated deadlines and the prioritisation of actions	Medical physics organisation document	HEGP
Request for corrective action	A24	Continue to implement the principle of optimisation for radioguided interventional activities performed in fixed rooms	Optimisation of doses delivered to patients	HEGP
Request for corrective action	A25	Implement the principle of optimisation for all operating theatre equipment by defining standard protocols to be used by default and on the basis of which a new optimisation can be implemented, examination by examination, depending on the patient	Optimisation of doses delivered to patients	HEGP
Request for corrective action	A26	Train operating room practitioners in the use of the equipment	Training of practitioners in the use of the equipment	HEGP
Request for corrective action	A27	Ensure that all relevant staff are trained in radiation protection of patients	Training of practitioners in the use of the equipment	HEGP

Request for corrective action	A28	Draw up written protocols corresponding to the procedures performed on each piece of equipment and for each category of patient concerned	Written protocols	HEGP
Request for corrective action	A29	Ensure that written protocols for procedures are available near the equipment	Written protocols	HEGP
Request for corrective action	A30	Carry out the necessary counter-audits to remove non-conformities identified during external quality controls	External quality control	HEGP
Request for corrective action	A31	Check, in conjunction with the application engineer and the medical physicist, that the parameters of the equipment used for radioguided interventional practices are not modified after a maintenance operation	Maintenance and quality control of medical devices	HEGP
Request for corrective action	A32	Ensure that medical physicists and departments in charge of equipment maintenance are informed when maintenance work is carried out on equipment in the ITP, the endoscopy department and the operating rooms	Maintenance and quality control of medical devices	HEGP
Request for corrective action	A33	Complete the reports of surgical procedures by systematically mentioning all the information necessary for a dosimetric reconstruction, as listed in the order mentioned	Information in the records of proceedings	HEGP
Request for corrective action	A34	Making the process of transcribing doses in procedure reports more reliable	Information in the records of proceedings	HEGP
Additional information	B1	Transmit the passive (whole body and extremity) and operational dosimetry results of classified workers for the period January to December 2018	Recording of dosimetric results	HEGP
Observation	C1	A new declaration must be made prior to the implementation of any change in the declarant, the elements of a declaration or the characteristics of the sources	Administrative regime - Declaration	HEGP
Observation	C2	Revisit the follow-up process for workers who do not attend their medical check-up to make it more effective	Enhanced individual monitoring	HEGP
Observation	C3	Putting up a display reminding the alert levels in the ITP rooms and the "SIBO" room	Alert levels in the room	HEGP
Observation	C4	Reflect on the alert levels defined for the interventional scanner so that they are the most adapted to the activities	Interventional scanner alert levels	HEGP
Observation	C5	Continue to check PPE at intervals appropriate to the activity	Control of PPE	HEGP