N#7 May 2018

Regulatory Updates

Nuclear safety...

Flamanville EPR project

May 2018

ASN has published the Information Letter No.20 reporting on its actions for monitoring the Flamanville 3 EPR reactor construction site and the various manufactured items intended for it. The significant points for 2017 and early 2018 detailed in this Information Letter are about:

- Deviations detected during welding and weld checks on the main secondary systems;
- Monitoring of the preparation for and performance of the reactor start-up tests;
- Monitoring of the preparedness of the EDF teams responsible for future operation of the reactor;
- Discovery of buried waste on the construction site;
- Preservation of equipment from its installation on the construction site until commissioning of the reactor;
- Continued examination of the commissioning authorisation application file and the partial commissioning authorisation application files.

The ASN monitoring work carried out in 2017 more particularly highlighted several points requiring particular attention and which led ASN to call the EDF and Framatome senior management to a hearing on 7th February 2018 concerning the Flamanville EPR reactor project

During this hearing, the ASN Commission more specifically questioned EDF and Framatome on the anomalies affecting nuclear pressure equipment, the reactor start-up tests and the technical investigations in progress relating to the installation's commissioning authorisation application.



For more information <u>www.french-nuclear-safety.fr</u>

ASN has formalised its radiation protection recommendations for the transport of radioactive substances

May 2018

The inspections carried out by ASN reveal that the risk of exposure to ionisation radiation is not sufficiently integrated in the preventive measures relating to the transport of radioactive substances. Yet some transport activities have significant radiation protection implications, particularly for the workers due to their close proximity to the packages. The annual dose for a driver transporting radiopharmaceuticals can thus reach 14 millisieverts per year (mSv/year), the maximum regulatory value being 20 mSv/year.

The ASN Guide No. 29 is intended for professionals exercising a radioactive substance transport activity:

- It aims at providing advice to help carriers meet their regulatory obligations relative to the radiation protection of workers and the public.
- Tt endeavours to show the relationships between the applicable texts, such as the order of 29th May 2009 amended relative overland transportation of to hazardous goods, and the Labour and Public Health Codes. The guide includes the ASN recommendations regarding the minimum content of the radiation protection programme required by the regulations, along with concrete examples.

The ASN Guide No. 29 underwent a public consultation at the end of 2017. It will be updated once Council Directive 2013/59/Euratom of 5 December 2013 laying down basic protection standards against the dangers arising from exposure to ionising radiation has been transposed into French law. The update will take into account the feedback from the first period of use of the guide.

For more information www.french-nuclear-safety.fr

ASN has reported on the state of nuclear safety and radiation protection in France in 2017

DE SÛRETÉ NUCLÉAIRE

April 2018

ASN considers that in 2017 the operating safety of the large nuclear facilities and radiation protection in the industrial and medical sectors were maintained at a satisfactory level on the whole.

Nevertheless, for the EDF nuclear fleet, continued vigilance is required: the control of equipment conformity and the detection, notification and handling of deviations must be improved.

The general situation appears in other respects to be less worrying:

- The anomaly relative to the carbon-rich segregate zones in steels has been widely dealt with, particular as regards the EPR reactor pressure vessel and the steam generators of the reactor fleet in service.
- The review of all the manufacturing files of the Creusot Forge plant is progressing satisfactorily.
- The industrial reorganisations and recapitalisations of EDF and Areva have been carried out.

The scale of the safety and radiation protection issues, however, is unprecedented which will necessitate the maintaining of a high level of vigilance, regarding in particular:

- The better prevention and detection of irregularities such as those found at the Creusot Forge plant.
- The essential question of the extension of the service life of the oldest nuclear facilities.
- The nuclear facilities under construction (Flamanville EPR; Jules Horowitz reactor; Iter project) which are experiencing significant delays and numerous difficulties due primarily to the loss of experience in design and construction.
- In the area of radiotherapy, the shortcomings in certain departments, particularly in the management of technological and organisational changes.
- For more information www.french-nuclear-safety.fr

...and Radiation Protection

ASN has conducted inspections on significant protection events at the Pitié-Salpêtrière Hospital and at the Le Mans Hospital

April 2018

On 26th March 2018, ASN conducted an inspection concerning two significant radiation protection events occurred in 2017 at the Pitié-Salpêtrière Hospital, in Paris, affecting two practionners respectively while performing interventional procedures in neuroradiology:

- Between April 2017 and September 2017 a head of clinic received a cumulative dose to the hands exceeding 500 mSv.
- In June 2017 an acting resident physician received a dose to the hands exceeding 500 mSv, and a dose close to this value in September 2017.

Due to late forwarding of the dosimeters to the laboratory responsible for analysing them, it was discovered in September 2017 that these practitioners had received ionising radiation doses on the hands exceeding the annual regulatory limit for this category of worker (dose to the 500 mSv). "extremities" exceeding Consequently, on 14 November 2017 the Pitié-Salpêtrière Hospital Group notified ASN of these events.

The hospital group took measures immediately after discovering these two incidents and, on the advice of the occupational physician, stopped the two physicians concerned from practising any further interventional neuroradiology procedures.

The analysis of the events showed that these persons received the majority of the dose while performing fluoroscopyguided lumbar puncture procedures, during which their hands were exposed to the primary X-ray beam emitted by the machine.

Corrective actions were put in place to enhance the radiation protection training of the personnel involved in interventional neuroradiological procedures, ensure that dosimeters are analysed in good time, and modify current practices to avoid any exposure of the hands to the primary X-ray beam during these procedures. The ASN's inspection confirmed the effectiveness of the corrective actions implemented in consultation with the medical professionals concerned to avoid the recurrence of such an event. The inspection highlighted the need to keep better track of the occupational radiation protection training given to students and new physicians before they perform interventional neuroradiological procedures.

ASN firmly underlines the obligation for all workers who are exposed to ionising radiation to wear all their dosimeters, particularly in situations of potentially heterogeneous exposure of the hands or the lens of the eye with respect to the whole body, in order to detect any abnormal exposure. In view of the shortcomings observed in many hospitals with regard to the wearing of extremity dosimeters in accordance with the regulatory provisions, ASN does not exclude the possibility that other similar cases of exposure might have occurred but gone undetected.

Considering the exceeding of the annual exposure limit for the hands over a short period of time, ASN rates these events level 2 on the INES scale.

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On 27th March 2018, accompanied by members of the IRSN (French Institute for Radiation Protection and Nuclear Safety) and of the Regional Health Agency (ARS) of the Pays de la Loire, ASN conducted an inspection to analyse the malfunctions associated with a significant radiation protection event, occurred at the Le Mans Hospital, concerning a pregnant woman who underwent a computed tomography (CT) scan during the night of 6th March 2018.

Due to the inappropriate and repeated use of a one of the CT scanner control buttons during the examination, the patient and her child were accidentally exposed to a radiation dose very much higher than that usually delivered in this type of examination. This situation had generated no alert signal and the radiographer did not have immediate access to the information concerning the total dose delivered.

On 8th March 2018, the Le Mans Hospital notified ASN of this event and, on 23rd March 2018 the hospital notified the ANSM (French Health Products Safety Agency). The ASN's inspection provided information on the first corrective and preventive measures identified by the hospital to prevent the recurrence of such an event, such as:

- the drafting of a procedure concerning the utilisation of this control button;
- the activation of a delivered dose monitoring function;
- the training of all the radiographers with regard to these changes,

and highlighted the need to:

- organize, for medical emergencies, the possibility of increased use of examinations by MRI (medical resonance imaging);
- fill the radiographer vacancies;
- improve the structure of the training and define the radiographer authorisation conditions;
- improve the ergonomics of the control button on this type of scanner in order to monitor patient exposure levels and inform the medical staff if the alert thresholds are exceeded.

In view of the large number of scanners of this type in service in France, ASN will - after consulting the medical learned societies - publish technical recommendations based in particular on its recommendations of 13^{th} June 2016 relative to training in the use of medical devices emitting ionizing radiation.

For more information www.french-nuclear-safety.fr

Setting up and renewing of the Advisory Committees of experts (GPE) for nuclear safety

March 2018

ASN recalls that the process for recruiting members for the six GPE for nuclear safety covering is still in progress. The GPEs must be duly constituted before 30th September 2018.

For more information www.french-nuclear-safety.fr

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