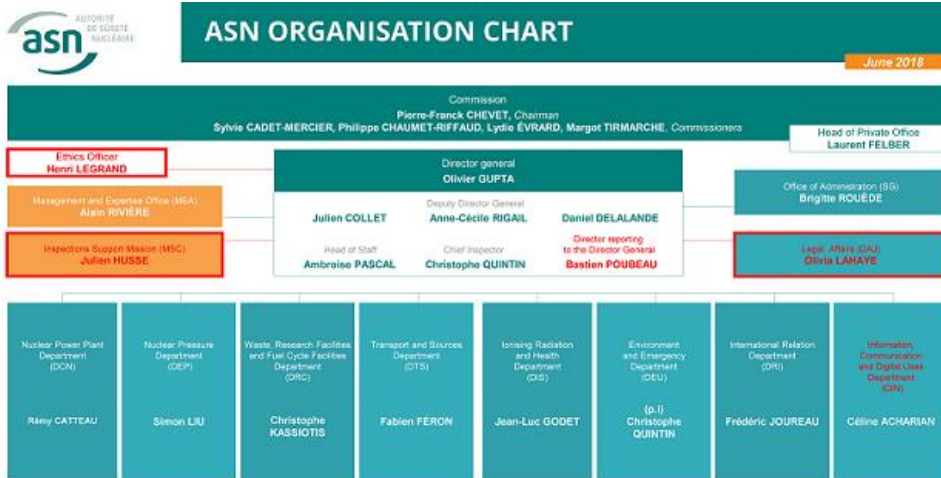


Regulatory Updates

Nuclear safety...

ASN has a new organization chart

June 2018



Since the 1st June 2018, ASN has established a new organization (in red) with the definition of four new entities attached to the Director-General Office: the Director reporting to the Director General, the Ethics Officer, the Inspections Support Mission (MSC) and, the Legal Affairs (DAJ). In addition, the former Communication and Public Information Department (DCI) is now the Information, Communication and Digital Uses Department (DIN).

Publication of three decrees reinforcing protection of the public, patients and workers in the field of nuclear activities

June 2018

On 5th June 2018, two decrees concerning the protection of workers against the risks arising from ionising radiation and one decree containing various nuclear provisions were published in the French Official Gazette. These decrees allows correct transposition into the French law of the Council Directive 2013/59/Euratom of 5 December 2013 *laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation*. They more specifically modify the regulatory parts of the Labour, Public Health, Environment and Defence Codes, and thus supplement the regulatory oversight of certain nuclear activities. These decrees:

- Update the system of radiation protection for all workers liable to be exposed to ionising radiation during the course of their professional activities, with a more consistent and comprehensive regulatory framework. Also monitoring of exposure to radon is extended to all workplaces: in basements and on ground floors, whereas previously, only underground environments were subject to mandatory monitoring.
- Reinforce the general protection of the population and of persons

exposed for medical purposes, with the creation of additional tools as regards to the effectiveness of the oversight of nuclear activities: the possibility of implementing land use restrictions on sites contaminated by radioactive substances and monitoring the protection of certain sources of ionising radiation (in particular those used in industry) against malicious acts.

Most of the provisions will come into force on 1st July 2018. In the coming months, ASN will continue with detailed, substantive work with the Government and the professionals, for the production of Ministerial orders or of its own resolutions.

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ASN reviewed the steps taken to deal with counterfeit, suspect and fraudulent items (CSFI)

June 2018

Irregularities which could be considered to be falsifications were detected in early 2016 on nuclear components manufactured in the Creusot Forge plant following a quality review requested by ASN. Irregularities of the same type had also been brought to light in other countries or were detected by facilities licensees or the manufacturers themselves.

This situation, which only concerns an extremely small part of the nuclear activities, but could nonetheless have significant safety implications, shows

that neither the robustness of the monitoring and inspection chain, at the top of which are the manufacturers and the licensees, nor the high level of quality demanded in the nuclear industry, were able to completely rule out the risk of CSFI.

So, in order to improve prevention and detection on this matter, ASN has issued measures which concern:

- Reinforcing the provisions made by the professionals, who retain the responsibility for the quality of manufacturing and of operations, for example by requiring improved data security;
- Using external inspection organisations, to support the oversight of manufacturing activities, take samples and run cross-checks;
- Improving ASN's oversight practices, more particularly its inspection methods;
- Requiring that any fraud detected by the licensee be systematically reported to ASN;
- Implementing of a system for collecting alerts from whistle-blowers.

In a letter of 15th May 2018, ASN explained to professionals the applicable regulatory requirements on this subject. They shall notify ASN of the implementation of the measures before 1st September 2018. Also, arrangements enabling a whistle-blower to send ASN a report of potential CSFI are being prepared for the second half of 2018 and ASN intends to hire two anti-fraud specialists in 2018 and to supplement the training of its inspectors on this topic.

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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**
www.french-nuclear-safety.fr

ASN has formalised its radiation protection recommendations for the transport of radioactive substances: ASN Guide No. 29

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 radio-pharmaceuticals 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.
- It endeavours to show the relationships between the applicable texts, such as the order of 29th May 2009 amended relative to overland transportation of 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 in relation to the decrees which transpose the Council Directive 2013/59/Euratom of 5 December 2013 *laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation* into the French law. The update will also take into account the feedback from the first period of use of the guide.

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

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

April 2018

On 26th March 2018, ASN conducted an inspection as regard to two significant SRPE occurred in 2017 at the Pitié-Salpêtrière Hospital, in Paris, affecting two practitioners while performing fluoroscopy-guided lumbar puncture procedures, during which their hands were exposed to the primary X-ray beam emitted by the machine. Both received ionising radiation doses on the hands exceeding 500 mSv which is the annual regulatory limit for this category of worker.


The ASN's 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.

Also, in view of the shortcomings observed in many hospitals with regard to the wearing of extremity dosimeters in accordance with the regulatory provisions, ASN firmly underlined 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.

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On 27th March 2018, ASN conducted an inspection to analyse the malfunctions associated with a SRPE, occurred at the Le Mans Hospital, concerning a pregnant woman who underwent a computed tomography (CT) scan. 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.


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 13th June 2016 relative to training in the use of medical devices emitting ionizing radiation.

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

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

April 2018

In 2017, the safety of the operation of the large nuclear facilities and radiation protection in the industrial and medical fields remained on the whole satisfactory. However, with regard to the EDF NPP fleet, vigilance is required in the light of the difficulties encountered in the management of equipment conformity. In the medical sector, the persistence of level 2 incidents, more specifically in radiotherapy and during fluoroscopy-guided interventions, also warrants reinforced oversight.

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

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