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Text No.17

Order of 29th November 2019 concerning the protection of ionising radiation sources and batches of radioactive sources of categories A, B, C and D against malicious acts¹

NOR: TREK1928142A

ELI:<https://www.legifrance.gouv.fr/eli/arrete/2019/11/29/TREK1928142A/jo/texte>

Public concerned: nuclear activity managers possessing, using, manufacturing, distributing, importing, exporting or transporting ionising radiation sources and batches of radioactive sources of categories A, B, C and D.

Subject: This order sets the procedures for the protection of ionising radiation sources against malicious acts, notably potential theft.

Keywords: ionising radiation source, malicious, nuclear security, nuclear activity.

Entry into effect: the present order enters into effect on 1st January 2020. However, for the nuclear activities authorised, registered or notified as at the date of publication, periods of up to an additional twenty-four months are provided for so that the necessary work can be performed.

Notice: this order specifies the procedures for the application of Article R. 1333-147 of the Public Health Code, for the protection of ionising radiation sources against malicious acts. These sources are more specifically used in radiology and radiotherapy units, or in industry. This Order reinforces the measures for the protection of ionising radiation sources against malicious acts. It is part of the Government's national security strategy, in particular to counter radiological threats. This Order is based on internationally recognised guidelines from the International Atomic Energy Agency, which are also implemented in numerous countries, notably in Europe. It applies a graded approach, with greater resources for sources representing the greater hazard, in other words, sources of categories D, C, B and A in ascending order.

References: The version of this Order subsequent to this modification, can be consulted on the Légifrance website (<https://www.legifrance.gouv.fr/>). However, the annexes are not published in the Official Journal. These appendices are notified on a need-to-know basis, in the conditions set out in the Order.

¹ Translation in English non-official

The Ministry of Ecological and Solidarity-based Transition,

Having regard to the Public Health Code, more specifically chapter III of title III of book III of its first part;

Having regard to the Defence Code, more specifically Articles L. 1333-2, L. 1333-3 and R. 1332-4;

Having regard to the Environment Code, in particular its articles L. 593-1 and L. 595-1;

Having regard to Decree 2018-434 of 4th June 2018 introducing various measures concerning nuclear activities;

Having regard to general interministerial instruction 1300 on the protection of national defence confidentiality, approved by Order of the Prime Minister of 30th November 2011;

Having regard to the interministerial instruction 901-SGDSN/ANSSI relating to the protection of sensitive information systems;

Having regard to the ASN opinion dated 26th September 2019;

Having regard to the opinion of the Interministerial Hazardous Materials Transport Committee dated 1st October 2019,

Orders as follows:

Chapter 1: General provisions

Article 1

I. – This Order defines the technical and organisational provisions for the protection of ionising radiation sources and batches of radioactive sources against malicious acts and to be implemented by the manager of a nuclear activity mentioned in Article L. 1333-1 of the Public Health Code, in the following cases:

- nuclear activities subject to the regimes mentioned in Article L. 1333-8 of the Public Health Code, in accordance with the provisions contained therein;
- nuclear activities carried out in a basic nuclear installation in the conditions defined in II of Article L. 1333-9 of the Public Health Code;
- nuclear activities defined in the nomenclature set out in Article L. 511-2 of the Environment Code, or themselves subject to Article L. 162-1 of the Mining Code, in the conditions defined in III of Article L. 1333-9 of the Public Health Code;
- nuclear activities carried out at points of vital importance meeting the conditions set out in IV of Article R. 1333-104 of the Public Health Code.

The provisions of this Order relating to transport only concern carriage by road.

II. - The provisions of this Order concern ionising radiation sources and batches of radioactive sources of categories A, B, C and D as defined in Appendix 13-7 of the Public Health Code. For category D sources, only the requirements set out in Chapter 1, in Articles 9 and 10 and in Chapter V of this Order are applicable.

However, these provisions do not apply to radioactive sources which are nuclear materials as defined in Article L. 1333-1 of the Defence Code.

III. - The category of an ionising radiation source or a batch of radioactive sources is determined in accordance with Article R. 1333-14 of the Public Health Code. If there is any doubt as to the sealed or unsealed nature of the radioactive source, the provisions to be implemented are those which would apply on the assumption that this source is sealed.

Article 2

The meanings of the terms: “malicious act”, “ionising radiation source category”, “transfer of an ionising radiation source”, “possession of ionising radiation sources”, “batch of radioactive sources”, “sealed radioactive source”, “high level sealed source” and “utilisation” are as defined in Appendix 13-7 to the first part of the Public Health Code.

For the purposes of this Order, the following definitions are adopted:

- “access to a source”, the fact of a person crossing the barrier or one of the physical barriers required for protection of an ionising radiation source or a batch of radioactive sources, for whatever reason;
- “physical barrier”, any physical device preventing or slowing down unauthorised access to an ionising radiation source or batch of radioactive sources;
- “sender”, the authorised, registered or notified entity which provides an ionising radiation source or a batch of radioactive sources so that they can be transported, or which transports them itself;
- “malicious event”:
- any deviation detected on the occasion of the verification set out in Article 10;
- any abnormal situation leading to suspicion of a malicious act against an ionising radiation source or batch of radioactive sources, including if detected by the malicious acts protection system;
- any intrusion, suspected or attempted intrusion, actual or attempted malicious act targeting an ionising radiation source or batch of radioactive sources;
- any compromising of sensitive information, any unauthorised access or attempted access to sensitive information;
- any other situation which led to partial or total failure of the malicious acts protection system;

- “sensitive information”, information concerning the means or measures adopted to protect ionising radiation sources or batches of radioactive sources against malicious acts which, although not classified or protected as defined by general interministerial instruction 1300, approved by Order of the Prime Minister of 30th November 2011, require the adoption of particular protective measures. More specifically, the annexes to this Order constitute sensitive information;
- “malicious acts protection policy”, the general guidelines relating to the protection of ionising radiation sources and batches of radioactive sources against malicious acts, validated by the management, a member of the management committee, or the head of the health facility, as applicable, who directs and oversees the performance of the nuclear activity;
- “receiver”, the authorised, registered or notified entity which takes charge of an ionising radiation source or batch of radioactive sources following transport;
- “malicious acts protection system”, set of technical, organisational and human measures taken by the nuclear activity manager, or which are available to them in order to protect ionising radiation sources or batches of radioactive sources against malicious acts, in the facilities, during transportation and on worksites. These measures notably include measures for deterrence, prevention, detection - including all provisions of use for ensuring that a detected event is real - delay, alerting and preparation for intervention by the law enforcement authorities. They also concern the protection of sensitive information;
- “transport”, the nuclear activity consisting in all carriage of an ionising radiation source or batch of radioactive sources on the public highway, including scheduled and unscheduled short and long term stops in transit between sender and receiver.

Chapter II: Malicious acts protection system

Article 3

I. – The manager of the nuclear system implements a system to protect against malicious acts compliant with the requirements of this Order, including its annexes. This system is designed taking account of the ionising radiation sources category, the usual processes involved in the performance of the nuclear activity as well as any reasonably foreseeable contingencies.

II. - Subject to III below:

- at least one physical barrier is placed between the ionising radiation source or the batch of radioactive sources and the persons not authorised to access them;
- the physical barriers crossing points are permanently locked.

III. - When the installation or locking of a physical barrier is incompatible with the utilisation or transport of the ionising radiation sources or batches of radioactive sources, the sources or batches are placed under the permanent surveillance of a person authorised in accordance with the provisions of Articles R. 1333-148 to R. 1333-151 of the Public Health

Code.

IV. - The management of controlled access by persons to places where ionising radiation sources or batches of sources are kept or used and, in the case of transport, to the cargo of the vehicle, is described in the malicious acts protection plan specified in Article 19. The methods for installing, removing or deactivating means of access are more particularly specified.

Article 4

Subject to any provisions mentioned in Article 26, the nuclear activity manager implements a system for protection against malicious acts which at all times complies with the provisions of:

- Annex 1;
- Annex 2 for the possession or utilisation of an ionising radiation source or batch of radioactive sources of category C;
- Annex 3 for the possession or utilisation of an ionising radiation source or batch of radioactive sources of category B;
- Annex 4 for the possession or utilisation of an ionising radiation source or batch of radioactive sources of category A;
- Annex 5 for the transport of an ionising radiation source or batch of radioactive sources of category C;
- Annex 6 for the transport of an ionising radiation source or batch of radioactive sources of category B;
- Annex 7 for the transport of an ionising radiation source or batch of radioactive sources of category A.

These Appendices set out the requirements which more specifically concern:

- the number of physical barriers to be installed and the delay that they provide;
- the conditions to be satisfied by the barriers;
- recording of accesses;
- the detection and alert means and procedures;
- the verifications of the means of protection;
- the equipment of the conveyances;
- any particular measures applicable to worksites during which ionising radiation sources are used.

Article 5

I. – The material means of the system for protection against malicious acts are chosen and installed such as to comply with the characteristics specified for the malicious acts protection system.

They are covered by a preventive maintenance programme established by the nuclear activity manager. This programme more specifically takes account of the recommendations from the manufacturers or suppliers and installers of the systems concerned.

For as long as these means take part in the malicious acts protection system, the nuclear activity manager keeps in their possession all elements which enabled them to establish this programme.

II. - The information systems intended for the processing, storage, or transmission of sensitive information are subject to protection measures as stipulated in interministerial instruction 901 relative to the protection of sensitive information systems.

Article 6

The nuclear activity manager takes all appropriate measures, as rapidly as possible and for as long as they persist, to compensate for any failures, deterioration or unavailability, whether or not scheduled, of the material or human resources provided for in the malicious acts protection system. For scheduled unavailabilities and reasonably foreseeable failures or deterioration, these compensatory measures are defined in the malicious acts protection plan provided for in Article 19.

The actions needed for return of the malicious acts protection system to nominal mode are decided on and performed with the aim of minimising the time for which the failure, deterioration, or unavailability exists. The implementation of compensatory measures may not constitute the sole reason for postponing the return to nominal mode.

Chapter III: Monitoring of ionising radiation sources

Article 7

I. – Subject to II below, pursuant to the provisions of 1° of I of Article R. 1333-153 of the Public Health Code, the nuclear activity manager shall only release an ionising radiation source or batch of radioactive sources to a third party, even temporarily, after verifying that said party:

- holds a receipt of notification, registration or license allowing it to possess or transport the ionising radiation source or the batch of radioactive sources issued pursuant to Articles L. 1333-8 or L. 1333-9 of the Public Health Code; or

- is exempted pursuant to Articles R. 1333-106 or R. 1333-146 of the Public Health Code.

This verification by the sender nuclear activity manager is made independently of the prior registration by the French Institute for Radiation Protection and Nuclear Safety (IRSN) pursuant to Articles R. 1333-154, R. 1333-156 or R. 1333-157 of the Public Health Code.

The sender nuclear activity manager retains a trace of the corresponding verification.

The sender nuclear activity manager informs the carrier of this verification in writing.

II. - The verification specified in I is not required:

- when the source or batch is returned to its original supplier or to the French National Radioactive Waste Management Agency (ANDRA);

- for the carrier handing over an ionising radiation source or batch of radioactive sources to a receiver when the sender has informed it in writing of the verification mentioned in I.

III. - Except for the exclusions and exemptions mentioned in I of Article R. 1333-152 of the Public Health Code, the nuclear activity manager to whom an ionising radiation source or batch of radioactive sources has been entrusted, for any purpose other than transport, incorporates said sources into the inventory stipulated in Article R. 1333-158 of this Code.

Article 8

I. – When they are different, the sender, the receiver and the carrier agree on the dates of transport and delivery, the scheduled delivery time-slot for the ionising radiation source or batch of radioactive sources, the person(s) to be contacted if necessary during transport, the conveyance used and its crew members.

The receiver acknowledges receipt of the source or batch of radioactive sources from the sender as rapidly as possible and in any case no later than twenty-four hours from this receipt.

II. - In the case of importation or transfer in France of an ionising radiation source or batch of radioactive sources and prior to entry onto French territory of the ionising radiation source or batch of radioactive sources, the receiver shall check with the sender that the carrier possesses the required receipt of notification, registration or license.

The receiver retains a trace of the corresponding verification.

III. - Each crew member of a vehicle carrying an ionising radiation source or batch of radioactive sources shall, during transport, be able to present an identification document carrying their photograph. At least one of the crew members shall be able to speak French so that they can alert the law enforcement authorities if necessary.

Article 9

I. – Subject to II, pursuant to Article R. 1333-158 of the Public Health Code, when the ionising radiation source is not installed or used in a fixed location, the nuclear activity manager ensures that each movement of the source away from its usual place of storage or utilisation is logged in a registry, mentioning:

- the actual date and time of collection of the source;
- the place in which it is to be held, used or transported;
- the identity of the person taking charge of it;
- the expected duration of transport;
- the actual date and time of return;
- the identity of the person returning it.

II. - The provisions of I above are not however applicable:

- to radioactive sources for which the activity or specific activity is lower than the exemption limits set in the second and third columns respectively of table 2 of Appendix 13-8 to part one of the Public Health Code;
- to electrical devices emitting ionising radiation which do not meet the criteria mentioned in Article R. 1333-106 of the Public Health Code, when transport takes place within the facility.

Article 10

I. – Subject to II below, the nuclear activity manager verifies the presence of the ionising radiation sources at least once a year and compares the results with the information in the inventory specified in Article R. 1333-158 of the Public Health Code.

The verification and the results of the comparison are written up in reports mentioning the date, names and functions of the person(s) who carried them out, along with any deviations detected. Any deviation detected is then:

- reported in the conditions set out in Article R. 1333-22 of the Public Health Code;
- recorded and analysed in the conditions set out in Article 17 of this Order.

II. - These provisions do not apply to radioactive sources for which the activity or specific activity is lower than the exemption limits set in the second and third columns respectively of table 2 of Appendix 13-8 to part one of the Public Health Code;

Chapter IV: Management of the malicious acts protection system

Article 11

The management, a member of the management committee or health facility manager, as applicable, determines a policy for protection against malicious acts and a quality management system incorporating the provisions of this chapter. This policy is implemented by the nuclear activity manager to whom the necessary authority and

resources are delegated.

Article 12

The nuclear activity manager informs the personnel assigned to the facility or to performance of a transport operation, in writing:

- of the need to report without delay any event which could indicate a potential malicious act;
- of the corresponding reporting procedures.

Article 13

The nuclear activity manager checks that the persons to whom they envisage issuing the license mentioned in Article R. 1333-148 of the Public Health code have the skills and information concerning the prevention of and fight against malicious acts appropriate to their function and responsibilities and limited to their need to know, more specifically:

- the means and measures for protection against malicious acts that they must implement and comply with during their activities;
- their responsibilities in the malicious acts protection system, the monitoring of ionising radiation sources or the management of protection against malicious acts;
- the alert chain and the required response to a malicious event;
- the steps taken for information protection;
- the instructions to be followed when accompanying a person in the conditions set out in article 16.

As often as necessary and at least once every three years, the nuclear activity manager ensures that the above-mentioned skills and information of the persons to whom they have issued this license are up-to-date.

Article 14

The nuclear activity manager keeps to the strict minimum the number of persons they authorise pursuant to Article R. 1333-148 of the Public Health Code.

They keep an up-to-date nominative list of these persons and, for each one, of the ionising radiation sources or information which they are authorised to access.

Article 15

When one of the radioactive sources is contained in a device and the implementation of this device implies the use of a remote-control, the activity manager takes steps so that

only persons they have authorised pursuant to Articles R. 1333-148 to R. 1333-151 of the Public Health Code and who are trained accordingly, may use the remote control.

Article 16

Pursuant to the final paragraph of I of Article R. 1333-148 of the Public Health Code, when, to access an ionising radiation source or batch of radioactive sources, a person authorised accordingly accompanies an unauthorised person, the following shall be recorded:

- the name, first name and employer (as applicable) of the person accompanied;
- the reason for access or for participation in the transport operation;
- the dates and times of the beginning and end of access or the beginning and end of the transport operation;
- the names and first names of the accompanying person, and their signature;
- any comments by the accompanying person.

Article 17

I. – All malicious events are recorded and analysed within a time commensurate with the potential consequences, but which should not exceed two months. The nuclear activity manager ensures that this recording and this analysis are carried out and enable:

- the detailed circumstances of the event to be described;
- the actual and potential consequences of the event for the interests mentioned in Article L. 1333-7 of the Public Health Code to be evaluated;
- the causes of the event, whether technical, organisational or human and the causes and measures which could mitigate the actual consequences of the event to be identified;
- the steps to be taken to prevent the reoccurrence of such an event or a similar event to be determined;
- a calendar to be defined for the implementation of the identified provisions within a time commensurate with the potential consequences and the ease of implementation.

The analysis is documented and the steps taken following a malicious event are recorded, with their effective date of implementation.

II. - For application of Article R. 1333-22 of the Public Health Code, the nuclear activity manager provides all information useful for rapid action on the part of the State's services, notably the law enforcement authorities, more particularly:

- the date and place the act, attempted act or loss was discovered;

- the date and place, if necessary presumed, of the act, attempted act or loss;
- the nature, category and activity of the source or batch of sources concerned;
- any information that could help identify the persons originating the act or attempted act;
- any information that could help identify the source or batch of sources;
- any information that could help recover the source or batch of sources;
- the point of contact for the authorities, their contact details and telephone number;
- any other information considered to be pertinent.

Article 18

The nuclear activity manager draws up a malicious events management plan which describes the steps to be taken in the case of a malicious event and identifies the persons in charge of conducting them, where necessary by name.

When drafting this plan, the nuclear activity manager may take account of the on-site emergency plan defined in II of Article L. 1333-13 of the Public Health Code and the other contingency plans or emergency instructions applicable within the facility or during the transport operation.

Article 19

In a malicious act protection plan for the facility or transport, the nuclear activity manager formally lays out the following:

1° The malicious acts protection policy mentioned in articles 2 and 11;

2° A description, as required:

a. Of the main characteristics of the facility, its general operations, its access conditions, its occupancy, its environment and, more particularly, the location of the nearest law enforcement authorities;

b. A description, as applicable, of the main characteristics of road transports involving ionising radiation sources or batches of radioactive sources;

3° A description of the ionising radiation sources or batches of radioactive sources and, as applicable, their conditions of storage, utilisation, or transport;

4° The list of persons intervening or carrying out a malicious act protection function, specifying their roles and their responsibilities;

5° A precise description of the malicious acts protection system and proof of the technical and organisational measures taken with respect to the regulations, more specifically this Order;

6° The steps taken to ensure monitoring of ionising radiation sources or batches of radioactive sources as stipulated in Articles 9 and 10 of this Order.

This plan constitutes sensitive information protected in accordance with Article 22.

Article 20

A good operating check is performed immediately following any maintenance operation or modification of a component of the protection system or any suspicion of deterioration, failure or unscheduled unavailability. These good operating checks are logged as specified in Article 24.

Article 21

By holding periodic exercises, the nuclear activity manager checks the effectiveness of the malicious events management plan drafted pursuant to Article 18. These exercises are the subject of a report which analyses them and presents the lessons learned along with any corrective and improvement measures identified.

These exercises are performed:

- at least once a year for ionising radiation sources or batches of radioactive sources of category A;
- at least once every two years for those of category B;
- at least once every three years for those of category C.

Article 22

I. – The nuclear activity manager is in charge of protecting sensitive information and its distribution solely on a need-to-know basis.

II. - This sensitive information, whether in paper or digital format, is placed in locked cabinets or rooms.

III. - When sensitive information needs to be sent by post, this is done:

- by a means guaranteeing correct reception of the document by the addressee;
- in a double envelope, with the interior envelope specifically identified and the outer envelope containing no clues as to the contents.

Article 23

The registers, programmes, records of compensatory measures, inspection results, drawings, reports, recordings, lists, checks and records of corrective measures, specified

by this Order, are kept and placed at the disposal of the personnel in charge of inspecting application of the provisions of this Order, for a minimum period of five years.

Article 24

I. – The nuclear activity manager organises and holds an annual review of the regulation requirements regarding the protection of sources against malicious acts.

These reviews also concern the updating of the malicious events management plan specified in Article 18 and the malicious acts protection plan specified in Article 19.

II. - These reviews are recorded and mention:

- their date;
- their nature;
- the names and functions of the person(s) who carried them out;
- the results obtained and any non-compliances identified.

III. - Any non-compliance found is formally processed so that it is corrected within a time-frame commensurate with the potential consequences and, in the meantime, so that the ionising radiation sources or batches of radioactive sources are protected. To this end, the interim or compensatory measures to be taken immediately are identified and then implemented, the required corrective measures, the time-frames and associated procedures are defined and their effective implementation is then verified.

Chapter V: Application measures and interim provisions

Article 25

The provisions of this Order enter into effect on 1st January 2020.

However, for a nuclear activity authorised, registered or notified as at the date of publication of this Order, or for which the license or registration dossier was submitted prior to this same date:

- the provisions of Chapter II of this Order, and the management provisions specified in Chapter IV concerning the means detailed in Chapter II, enter into effect on 1st January 2022;
- the provisions of Chapter III of this Order, and the management provisions specified in Chapter IV which do not concern the means detailed in Chapter II, enter into effect on 1st July 2022.

Article 26

The nuclear activity manager authorised, registered or notified as at the date of publication of this Order, who wishes to benefit from an adaptation of the provisions of this Order, shall send a request to the competent authority in the conditions set out by the applicable administrative regime, comprising:

- the requirements concerned;
- proof that it is impossible to comply with these requirements in economically acceptable conditions, given the situation of the facility or transport operation and current knowledge and practices;
- the planned alternative provisions and proof of a level of protection offered at least equivalent with respect to the requirements concerned.

The nuclear activity manager sends this request to the authority no later than:

- 1st January 2021 for the provisions of Chapter II of this Order, and the management provisions specified in Chapter IV concerning the means detailed in Chapter II;
- 1st July 2020 for the provisions of Chapter III of this Order, and the management provisions specified in Chapter IV which do not concern the means detailed in Chapter II.

The authority issues a decision within the time-frame and in the conditions set out in the applicable administrative regime.

Article 27

The Defence and Security High Official at the Ministry for Energy is responsible for implementation of this Order, which – with the exception of the Appendices - will be published in the Official Journal of the French Republic.

These appendices may be obtained:

- from ASN by the nuclear activity manager holding a license, registration or receipt of notification issued by ASN pursuant to Articles L. 1333-8 or L. 1333-9 of the Public Health Code;
- from the Defence and Security High Official at the Ministry for Energy, by any other person who so requests and can justify their need to know.

Done on 29th November 2019.

For the Minister and by delegation:

The Head of the Defence, Security and Economic Intelligence Department,
M. Pain