Pursuant to Article 16(1) and (2), Articles 17 and 18 of the Law on Radiation and Nuclear Safety in Bosnia and Herzegovina (*Official Gazette of BiH*, No 88/07) and Article 61(2) of the Law on Administration (*Official Gazette of BiH*, Nos 32/02 and 102/09), and in connection with the "National action plan for emergency cases of protecting the population against ionizing radiation in case of an emergency event, a nuclear accident or occurrence of nuclear damage", the director of the State Regulatory Agency for Radiation and Nuclear Safety issues the

REGULATION

ON RADIOLOGICAL EMERGENCY EVENTS IN PRACTICES INVOLVING RADIOACTIVE SOURCES

PART ONE – GENERAL PROVISIONS

Chapter 1. Introduction

Article 1
(Subject)

This regulation provides for the cases of radiological emergency events (hereinafter: emergency event) about which the holder of authorization for a practice involving radioactive sources (hereinafter: authorization holder) shall notify the State Regulatory Agency for Radiation and Nuclear Safety (hereinafter: Agency), the categorization of emergency events, the contents of the initial notification in case of the actual and detected emergency event, the form for the final written report on the emergency event, the contents of the international INES scale, and other important matters in this field.

Article 2
(Application)

(1) This regulation shall apply to all radiological facilities and the areas outside the radiological facility where X-ray generators, radioactive sources and nuclear material are possessed, used or stored and where an actual emergency event and a near-miss could occur, and also to the facilities where an orphan radioactive source could be discovered.

(2) The provisions of this regulation shall apply to the emergency events relating to radiation safety, security of radiation sources, transport of radioactive material and medical exposure of the patient.

(3) The report on actual emergency events or near misses sent by the authorization holder to the Agency serve to identify causes of the events with a view to eliminating them and preventing their recurrence in the future.

(4) The main objectives of sending the information about emergency events to the Agency by the authorization holder are:

a) exchange of learned lessons between the authorization holders about reported emergency events;
b) improving the possibility for the personnel of authorization holders to gain and exchange experiences learned from the previous errors resulting in an emergency event in the practice involving radioactive sources.

Article 3
(Prevention and mitigation)

The authorization holder shall take all practicable measures to prevent the occurrence of emergency events and mitigate consequences of the events if they occur.

Article 4
(Definitions)

The definitions used for the purpose of this regulation are:

a) ‘Accident’: Any unintended event, including operating errors, equipment failures or other mishaps, the actual consequences or potential consequences of which are not negligible from the point of view of radiation protection or safety.

b) ‘Patient's error’: A patient's act, either intended or unintended, that affects the application of radiation (e.g., failing to disclose pregnancy or breastfeeding, the patient moves, the patient takes only part of the prescribed dosage etc.).

c) ‘Incident’: Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the actual or potential consequences are not negligible from the point of view of radiation protection or safety.

a) ‘INES scale (eng. International Nuclear and Radiological Event Scale)’: The international scale for classification of nuclear and radiological events.

b) ‘Near miss’: The potential incident that was detected before it occurred. There are no harmful consequences, and a potential risk is identified and prevented. An unintended mistake that is detected before beginning to use a radioactive source.

c) ‘Class 1 emergency events’: Includes the emergency events in a radiological facility that could require an external intervention (fire department, police) and for which the deadline for initial notification to the Agency is one hour from the time of detecting the event.

d) ‘Class 2 emergency events’: Includes the emergency events in a radiological facility that do not require an emergency intervention by external services, that could have radiological consequences for the people, premises, equipment and the environment, and for which the deadline for initial notification to the Agency is 24 hours from the time of detecting the event.

e) ‘Class 3 emergency events’: Includes the emergency events that could have radiological consequences and for which the deadline for initial notification to the Agency is seven days from the date of detecting the event.

f) ‘Medical practitioner’: A doctor of medicine or dental medicine who is authorized to assume clinical responsibility for medical exposure of an individual.

g) ‘Referring doctor’: A doctor of medicine or dental medicine who is authorized to refer individuals to a medical practitioner for medical exposure.

h) ‘Emergency event in medical exposure of the patient’: The emergency event in which radiation from a source is not administered to the patient as prescribed by the competent practitioner of medicine or dental medicine, and also in cases of unintended and accidental medical exposure of the patient.

i) ‘Radiological emergency event’: An event affecting the structures, systems or components of a radiological facility that can actually or potentially give rise to a risk from an increased exposure of exposed workers and the public. This could be an equipment failure, a human error or their combination, either systematic or accidental, that caused (actual event) or could have caused (near miss) a danger to patients, exposed workers, external individuals and the environment.

PART TWO – PREPARATION AND RESPONSE TO EMERGENCY EVENTS

Chapter 1. Preparation for response to emergency events

Article 5
(Anticipation)

The authorization holder shall anticipate the likelihood of occurrence of the emergency event.

Article 6
(Preparation)

(1) The authorization holder shall plan the preparation for response to the emergency event, in which he shall take into account the likelihood of occurrence of the emergency event, its consequences and the prevention of similar occurrences in the future.

(2) Workplaces, radioactive sources in use, structures of protective barriers, warning and alarm systems, work procedures and equipment shall have such characteristics to prevent the emergency event as successful as possible.

Article 7
(Instructions)

(1) In the practices in which an emergency event could occur, exposed workers shall receive written instructions on the actions to be taken in case that an event occurs.

(2) Depending on the practice, the instructions shall contain the following:

a) Identifying a possible emergency event;
b) Urgent actions that shall be taken to limit exposure to radiation:

1. Exposure to radiation must be reduced to the minimum.
2. The area with a radiation hazard shall be identified and cordoned off.
3. Access of unauthorized persons to the area shall be prevented.

4. Protective respirators shall be used if there is a suspicion of radioactive material having entered the air and it is not possible to exit the area.
5. Contamination spread must be prevented (preventing access to contaminated area, no handling of contaminated items, using protective gloves and protective clothing).
6. The radiation protection officer shall be informed about the event.

c) record as soon as possible:

1. the flow of the event, the actions taken and the time they were taken,
2. the names and contact information of possibly exposed individuals and others involved in the event,
3. detailed information about the exposure (duration of stay at different distances from the source, use of respirators, etc.

d) the way of notifying the Agency, police, fire department, health authorities;
e) the procedures to determine the magnitude of exposure to radiation;
f) in the event of high exposures, an emergency assessment of the worker's health status;
g) in the emergency event in medical exposure, instructions on the way of informing the patient and the referring doctor.

Article 8
(Plan)

(1) The legal person/authorization holder shall develop a plan for emergency events that could occur in the practice involving radioactive sources.

(2) The plan for emergency events shall be operational before beginning a practice involving radioactive sources.

(3) The plan for emergency events shall:

a) take into account any emergency event that can be reasonably envisaged;
b) contain specific instructions on how to act during the emergency events, particularly paying attention to the ways of re-establishing the control and keeping human exposure to the minimum.

(4) The authorization holder shall provide equipment and premises, including any instrument, detector or alarm needed to effectively implement the emergency plan.

(5) If the authorization holder determines that an instrument, a detector or on alarm in his possession is malfunctioning, he must replace it with the functional one.

(6) The plan for emergency events shall contain the contact telephone number for emergency events.

(7) The plan for emergency events shall be submitted to the Agency in the process of issuing authorization.

(8) The security plan for radioactive sources containing a response to the security emergency events shall be submitted to the Agency in the process of issuing authorization, in accordance with applicable regulations.

(9) The instructions referred to in the preceding Article shall be an integral part of the plan for emergency event.

Article 9
(Maintenance)

The authorization holder shall maintain operational preparedness for emergency events, which serves to predict the occurrence of an event by:

a) identifying possible emergency events, assessing risk and updating instructions at certain intervals (at least once in three years);
b) consulting relevant experts (qualified experts, medical physics specialist) in order to assess the significance of the emergency event;
c) maintaining at all times the necessary equipment for determining exposure to radiation and ensuring that the equipment is always operational;
d) relevant training of exposed workers, who shall be instructed how to act in the emergency event;
e) knowing the procedures for action in the event of an unintended release of radioactivity to the adjacent premises of the radiological facility or outside the facility; and
f) adopting a procedure for learning lessons from emergency events and avoiding their recurrence in the future.

Article 10
(Prevention)

(1) The authorization holder shall take all necessary measures to prevent the occurrence of an emergency event in the practices involving radioactive sources listed in the authorization.

(2) The authorization holder shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software or as a human error.

Chapter 2. Response to emergency events

Article 11
(Measures)

If an emergency event is detected, the authorization holder shall:

a) notify the natural and legal persons specified in this regulation of detecting the emergency event;
b) take all practicable measures to establish control over the emergency event;
c) take all practicable measures to minimize the consequences of the emergency event;

d) after the investigation, send the final written report on the emergency event to the Agency.

Article 12
(Actions)

(1) If an emergency event is detected, the authorization holder shall act in accordance with the instructions for emergency events.

(2) In case of fire, the radiation protection officer or any other representative of the authorization holder shall provide fire department with necessary information regarding radioactive material and everything else necessary for radiation protection.

(3) The authorization holder shall not take corrective actions at his own initiative without consulting an individual appropriately trained in radiation protection in emergencies.

(4) The spread of radioactive material must be prevented by cordoning off and cleaning the area in accordance with the radiation protection officer's instructions.

(5) If an individual exposed to radiation used a personal dosimeter, the dosimeter shall be immediately sent for reading to a technical service for individual monitoring, with all necessary information about the emergency event.

(6) The authorization holder shall immediately send the received personal dosimeter readings to the Agency.

(7) After the results of individual monitoring are received, they shall be sent to the concerned exposed worker and the competent medical practitioner in the technical service for health surveillance of exposed workers.

(8) The doses due to the emergency event and their distribution in the bodies of the persons taking part in the event shall be assessed.

Article 13
(Investigation)

(1) The authorization holder shall conduct investigation about the emergency event along with the radiation protection officer and professional staff.

(2) The main goals of investigation about the emergency event are:

a) establishing the flow of occurrences that led to the emergency event;
b) identifying the cause of the emergency event;
c) identify and implement measures to remedy the emergency event in order to prevent its recurrence in the future; and
d) estimating the doses received by all persons involved in the emergency event.

Article 14
(Commission)

(1) The authorization holder shall establish a commission to investigate the circumstances surrounding the occurrence of emergency event.

(2) Members of the commission for investigation of the emergency event shall be:

a) the general manager/head of department/personnel where the emergency event took place;
b) a representative of the persons exposed to ionising radiation;
c) the operators during the exposure;
d) the radiation protection officer;
e) the radiation protection expert.

(3) If an emergency event resulted from an equipment failure, the following persons shall also take part in the investigation:

a) the service engineer who serviced the equipment following the emergency event;
b) the person responsible for quality assurance of the equipment.

(4) If an emergency event occurred in medical/dental medicine practices, the following persons shall also take part in the investigation:

a) the referring doctor;
b) the medical physics specialist.

(5) In all the cases above, the authorization holder shall inform exposed persons about the implications of the emergency event. This information pertains to the potential risks of harmful health effects and to the dose limits specified in the applicable regulation.

Article 15
(Notification and report)

(1) The authorization holder shall send to the Agency an initial notification about detection of the emergency event in the way and within the deadlines specified in this regulation.

(2) The results obtained after the conducted investigation shall be documented in a written report that shall be sent to the Agency within 30 days, and in case of the emergency event in medical exposure of the patient within 15 days from the date of sending the initial notification.

(3) The report shall be signed by the general manager and the person who made the report and sent it to the Agency within the deadlines laid down in this regulation.

Article 16
(Records and register)

(1) The authorization holder shall keep records of all unusual events that deviate from normal operation in the practice involving radioactive sources.

(2) The authorization holder shall keep the register of emergency events, actual and near misses, that occurred in his facility.

(3) The authorization holder shall send the Agency the information about emergency events from the register referred to in paragraph (1) of this Article.

(4) The authorization holder shall retain the register emergency events for five years.

(5) The records and the register shall be available to the Agency inspectors upon their request.

PART THREE – EMERGENCY EVENTS AND NEAR MISSES

Article 17
(Emergency events)

(1) The emergency events and near misses defined in this regulation are grouped in four areas:

a) radiation safety;
b) transport radioactive material;
c) security of radioactive sources;
d) medical exposure of the patient – except the events resulted from the patient's intervention:

1. in diagnostic and intervention radiology,
2. in diagnostic and therapeutic nuclear medicine, and
3. in radiotherapy with external and internal radioactive sources.

(2) Every area has its categories that are shown in Annex 1, which is an integral part of this regulation.

(3) The emergency event may be classified into only one category defined in this regulation except other events that may be classified into any category.

(4) If an emergency event can be classified into more than category, then it shall be classified into the highest category with the shortest time of initial notification.

Article 18
(Categories)

(1) Categories of emergency events and notification deadlines relating to radiation safety are shown in Table 1 Annex 1, which is an integral part of this regulation.

(2) Categories of emergency events and notification deadlines relating to transport of radioactive material are shown in Table 2 of Annex 1, which is an integral part of this regulation.

(3) Categories of emergency events and notification deadlines relating to security of radioactive sources are shown in Table 3 of Annex 1, which is an integral part of this regulation.

(4) Categories of emergency events relating to medical exposure of the patient are shown in Tables 4, 5 and 6 of Annex 1, which is an integral part of this regulation.

Article 19
(Doses significantly greater than intended)

Doses significantly greater than intended in radiotherapy, nuclear medicine and diagnostic radiology are shown in Tables 4(a), 5(a) and 6(a) of Annex 1, which is an integral part of this regulation.

Article 20
(Other)

(1) The authorization holder shall notify:

a) the Agency about finding out about a project, construction, assembly, operation, maintenance or other situations that could prevent implementation of the safety functions of safety structures, systems or components;

b) the Agency about finding a flaw in the implementation of personnel work procedures that could prevent implementation of the safety functions of safety structures, systems or components;

c) the Agency about any other occurrence that, in the opinion of the authorization holder, could be significant for radiation safety, transport of radioactive material, security of radioactive sources and medical exposure of the patient.

(2) The events referred to in the preceding paragraph of this Article shall be entered in the field "Other – OS“ in the Table shown in Annex 1, which is an integral part of this regulation.

PART FOUR – CRITERIA FOR REPORTING THE EMERGENCY EVENT TO THE AGENCY

Chapter 1. Initial notification and written report

Article 21
(Reporting)

(1) The authorization holder shall notify the Agency about the emergency events listed in the Tables 1-6 of Annex 1, which is an integral part of this regulation, on the basis of the reporting criteria specified in this regulation.

(2) The authorization holder shall establish reporting procedures for emergency events.

(3) The radiation protection officer working for the authorization holder in the radiological facility shall be responsible to prepare all necessary information for reporting to the Agency about emergency events.

(4) The criteria for reporting to the Agency are listed in Annex 1, which is an integral part of this regulation.

(5) The same criteria for the initial notification and the final reporting shall apply to both actual emergency events and near misses.

Article 22
(Initial notification)

(1) After detecting the emergency event, the authorization holder shall send an initial notification to the Agency Inspectorate at the latest within the following deadlines:

a) one hour after detecting the class 1 event;
b) 24 hours after detecting the class 2 event; and
c) seven days after detecting the class 3 event.

(2) The authorization holder shall initially notify the Agency by phone, as follows:

a) During the business hours, to the Agency Inspectorate at the Agency number;
b) Out of business hours at the duty telephone number that can be found on the Agency's official website.

(3) The initial notification shall consist of the following:

a) The name of the person who provided the information;
b) The name of the holder of authorization for a practice involving radioactive sources;
c) The authorization number given by the Agency, if available at the time;
d) The date of the emergency event;
e) The date of emergency event detection;
f) A brief description of the emergency event, containing the types of isotopes, the amounts, chemical and physical form of the given radioactive material, and the radiation generators;
g) A preliminary classification of the emergency event based on Annex 1 of this regulation.

(4) In case of the emergency event in medical exposure of the patient, the authorization holder shall send an initial notification within 24 hours to the:

a) Agency;
b) referring doctor;
c) patient (or the patient's relatives or guardian).

Article 23
(Written report)

(1) In addition to the initial notification, the authorization holder shall also send the final written report on the emergency event to the Agency within the deadlines specified in Article 15(2) of this regulation.

(2) The contents of the written report referred to in paragraph (1) of this Article are shown in the form in Annex 2, which is an integral part of this regulation.

(3) The written report shall be sent to the Agency on a separate form filled in for each individual emergency event.

(4) The written report for the Agency on the emergency event in medical exposure of the patient shall not contain the patient's name or any information that can lead to the patient identification.

(5) The authorization holder shall send a copy of the written report to the referring doctor if the doctor is not employed with the authorization holder, within 15 days after detecting the event and with information about the patient who was the subject of the emergency event in medical exposure.

(6) The authorization holder shall send a copy of the written report on the emergency event to the patient upon the patient's request.

Chapter 2. Responsibilities of the Agency

Article 24
(Inspection)

(1) After receiving the telephone initial notification about an emergency event from the authorization holder, the duty inspector for radiation and nuclear safety shall confirm the receipt of the notification to the authorization holder by fax, email or SMS to the contact telephone number for emergency situations, referred to in Article 8(6) of this regulation.

(2) After confirming the receipt of initial notification referred to in paragraph (1) of this Article, the inspector shall immediately perform inspection monitoring.

Article 25
(Register and dissemination of information)

(1) The Agency shall establish and maintain the national register of emergency events.

(2) Under the law, the Agency shall disseminate the information relevant for radiation protection regarding the lessons learned from the emergency events.

(3) The Agency shall inform the competent fire department about the location of the holder of authorization for categories 1, 2 and 3 sealed sources.

(4) The Agency shall inform the competent fire department about the location of the holder of authorization for unsealed sources.

Article 26
(INES scale)

(1) The INES scale shall apply to any event associated with the transport, storage and use of radioactive sources, whether or not the event occurs at or outside a radiological facility.

(2) The INES scale shall include the loss or theft of radioactive sources or packages and the discovery of sources out of regulatory control.

(3) The INES scale shall be intended only for use in civil applications and shall only relate to the safety aspects of an event.

(4) The INES scale shall not apply to security events or malicious acts to deliberately expose people to radiation or the actual or potential consequences on patients exposed as part of a medical procedure.

(5) The contents of the INES scale are shown in Annex 3, which is an integral part of this regulation.

Article 27
(Classification)

(1) The Agency shall classify emergency events based on the final written report received from the authorization holder.

(2) The Agency shall classify emergency events in accordance with the INES scale and the relevant IAEA's INES scale user's manual.

(3) The Agency shall classify as an accident in medical exposure of the patient any diagnostic or intervention or therapeutic medical procedure resulting in an observable acute radiation effect (deterministic effect).

(4) The Agency shall classify as an incident any other emergency event in medical exposure of the patient listed in Tables 4, 5 and 6 of Annex 1, which is an integral part of this regulation.

Article 28
(Reporting)

(1) The Agency shall report on emergency events rated at level 1 on the INES scale on its official website.

(2) The Agency shall report on emergency events rated at level 2 and higher on the INES scale to the:

a) IAEA;
b) Council of Ministers of Bosnia and Herzegovina;
c) media.

(3) The Agency shall report to the IAEA about emergency events in transport of radioactive material rated at level 1 and higher on the INES scale and emergency events in case of the loss of a radioactive source rated at level 0 and higher on the INES scale.

Article 29
(Additional information)

(1) If it deems necessary, the Agency may request additional information about the emergency event from the authorization holder or an appropriate revision of the written report at any time.

(2) In case of discrepancies in the authorization holder's written report, the Agency Inspectorate's opinion shall prevail, and the report shall be sent in accordance with the Agency criteria.

Article 30
(Annual report)

(1) The Agency shall prepare, keep, update and publish the annual report on emergency events occurred in the authorization holder's facilities.

(2) The annual report referred to in paragraph (1) shall include causes of the emergency events, a description of each individual emergency event, and the received doses.

(3) The Agency shall publish the annual report on emergency events on its official website by 31.03. the following year.

PART FIVE – TRANSITIONAL AND FINAL PROVISIONS

Article 31
(Harmonization)

(1) The authorization holder shall harmonize the radiation protection programme and the security plan with the provisions of this regulation within 90 days after the effective date of this regulation.

(2) The authorization holder shall send to the Agency the plans and programmes referred to in paragraph (1) of this Article as harmonized with the provisions of this regulation within 15 days after the harmonization.

Article 32
(Entering into force)

This regulation shall enter into force within eight days following the date of its publication in the *Official Gazette of BiH*.

No: Director
Sarajevo, / / (year) Emir Dizdarević

ANNEXES

Annex 1: TABLES WITH CRITERIA FOR INITIAL NOTIFICATION/FINAL NOTIFICATION OF THE AGENCY ABOUT EMERGENCY EVENTS

Table 1: Criteria for notification/reporting – radiation safety

Category	Description	Initial notification deadline
RS-01	Any emergency event preventing urgent protective actions needed to avoid exposure to radiation or radioactive material that could exceed regulatory limits; a release of radioactive material that could exceed regulatory limits (these emergency events include fire, explosion, toxic gases)	1 hour
RS-02	A natural or an external phenomenon that could compromise the safety of a facility, e.g. a strong wind, precipitations or an uncontrolled fire near the facility; any emission of toxic radioactive substances that could cause an unauthorized concentration inside the facility or an explosion near a radiological facility	1 hour
RS-03	Any event in a radiological facility involving the emission of radiation or the release of radioactive or toxic substances, causing or likely to cause death or a serious radiation injury of workers inside or outside the radiological facility	1 hour
RS-04	Any emergency event leading to a release or suspected release or spread of radioactivity inside or outside a radiological facility and warranting operator's special action or a special investigation	1 hour
RS-05	Contamination with radioactive material or its dispersion inside a radiological facility resulting in the surface contamination with spilled radioactive substances the activity of which is 100 times greater than the exemption level specified in the applicable regulation for the given material	1 hour
RS-06	An out-of-control radioactive source, e.g. the sources is not adequately protected with a protective barrier or is outside the protective container	1 hour
RS-07	Any emergency event resulting from unplanned contamination with radioactive substances and warranting: 1. restricted access of workers and the public to the contaminated area for more than 24 hours by imposing additional radiological controls or prohibiting entry to the area; 2. restricted access of workers and the public to the contaminated area except in the case of decay of isotopes with a half-life of less than 24 hours before performing decontamination.	24 hours

RS-08	Any emergency event resulting from the disabled or improperly functioning equipment when: 1. it is the equipment required by applicable regulations or authorization requirements to prevent the release of radioactive material above the regulatory limits, to prevent exposure to radiation and radioactive material above the regulatory limits or to mitigate the accident consequences; 2. the equipment required to be available and operational is either disabled or not functioning; 3. there is no available and operational spare equipment to perform the required safety functions in radiation practices as required in applicable regulations.	24 hours
RS-09	Any emergency event warranting an unplanned clinical treatment of an individual whose clothing or body are contaminated with radioactive substances	24 hours
RS-10	A fire or an explosion damaging radioactive material or any device, container or equipment containing radioactive material, thus affecting the integrity of the radioactive material or its container	24 hours
RS-11	Any emergency event in which, according to a preliminary assessment, an exposed worker or a member of the public could receive a dose by external irradiation or internal contamination during the individual exposure that exceeds the dose limits specified in the applicable regulation	24 hours
RS-12	A release of radioactive material into the environment that exceeds the disposal limits specified in the authorization or a disposal by using a method not specified in the authorization	24 hours
RS-13	Any situation in which the authorization holder believes that in the event of accumulated exposure an exposed worker could have received a dose above the limits specified in the applicable regulation	24 hours
RS-14	A radioactive material spill due to a source leaking through protective systems, which causes the contamination of an unrestricted area and warrants reclassification of the affected area within 24 hours on the basis of the criteria of dose rate or contamination	24 hours
RS-15	Unintended individual exposure due to an equipment defect or incorrect handling of the equipment	24 hours
RS-16	Any uncontrolled release of radioactive material outside the facility	24 hours
RS-17	Exceeding the release limits specified in the authorization of an authorization holder	24 hours
RS-18	Accidental bringing of radioactive material or radioactive waste into a radiological facility	24 hours
RS-19	A stuck or detached radioactive source	24 hours
RS-20	A damage or failure of a radiation generator or device containing sealed source, in which the damage or failure could affect radiation safety of the source, including integrity of the protective barrier or by increasing the radiation level	24 hours
RS-21	Leakage of a sealed radioactive source (>200 Bq)	24 hours

RS-22	External exposure (non-medical)	24 hours
RS-23	Contamination with radioactive substances	24 hours
RS-24	The registered dose exceeds the dose limits	24 hours
RS-25	Discovery of a radioactive source	24 hours
RS-26	Unauthorized possession of a radioactive source	24 hours
RS-27	Unauthorized storage and disposal of a radioactive source	24 hours
RS-28	Intentional exposure of a personal dosimeter	24 hours
RS-29	An accidental or unauthorized release of radioactive material or a likely accidental or unauthorized release of the material into the atmosphere from a controlled area as a gas, aerosol or dust, or is spilled or otherwise gives rise to significant contamination, and the amount of the given radioactive material exceeds 10 times the exemption level specified in the applicable regulation or 100 times the activity concentration specified in the applicable regulation	24 hours
RS-30	The registered dose to a classified exposed worker in a 4-month period equals to or exceeds the following values: Effective dose 2 mSv Dose to eye lens 5 mSv Dose to skin, hands, feet and joints 50 mSv	24 hours
RS-31	Any emergency event potentially affecting a security system, e.g. security interlocks, monitors or alarms	24 hours
RS-32	Contamination of laboratory clothing or work areas with radioactive substances	24 hours
RS-33	Incorrect parameter setting for a safety system	24 hours
RS-34	Any other event not listed in the points above, which in the opinion of the authorization holder could lead to unwanted public exposure, such as a failure of the release system or an out-of-control patient with an implanted radioactive source or material or appearance of radioactive material in an unrestricted area	24 hours
RS-35	Exposure of a worker during the emergency event	24 hours
RS-36	Operational events with a potential risk of receiving an unwanted dose in case of equipment failure, equipment damage, a failure while returning the source to the shielded position, uncontrolled access to workplaces with high levels of radiation such as the irradiation areas; a failure of a safety system in a facility or a human error	24 hours
OS-01	Other events involving near misses that can serve as a warning to other users, e.g., a situation involving alarm of the portal monitor at the entrance of an iron factory or a scrap metal storage facility	24 hours

Table 2: Criteria for notification/reporting – transport of radioactive material

Category	Description	Initial notification deadline
TS-01	A radiological emergency situation arising during the transport of the class 7 goods that requires urgent action in order to protect exposed workers and the public from exposure to ionizing radiation	1 hour
TS-02	Theft or loss of the class 7 goods in shipment	1 hour
TS-03	Transport of packages without appropriate documents, placards or labels	1 hour
TS-04	Emergency arrangements have been initiated in relation to class 7 goods even if, in the event, no intervention was made pursuant to those arrangements	1 hour
TS-05	Any event during loading, carriage or unloading of class 7 goods involving any release of radioactive material from a package or shipment	1 hour
TS-06	Any event during loading, carriage or unloading of class 7 goods involving exposure leading to exceeding the dose limits specified in the applicable regulation	1 hour
TS-07	Any event during loading, carriage or unloading of class 7 goods where there is reason to believe that there has been a significant degradation in any package safety function (containment, shielding, thermal protection or criticality) that may have rendered the package unsuitable for continued carriage without additional safety measures	1 hour
TS-08	Any event in which class 7 goods have been transported with any non-compliance regarding radiation or contamination levels for the package as specified in the applicable regulation	24 hours
TS-09	Receipt of a shipment contaminated with radioactive substances	24 hours
TS-10	The package damaged in transport	24 hours
TS-11	Discovery of radioactive material in a shipment believed to be non-radioactive	24 hours
TS-12	Class 7 goods is not transported in full compliance with the applicable regulation except the cases listed under TS-07	7 days
OS-01	Other relevant information	7 days

Table 3: Criteria for notification/reporting – security of radioactive sources

Category	Description of the emergency event	Initial notification deadline
B-01	Disappearance (theft or loss) of the Category 1, 2 or 3 radioactive source, or the Category 1 or 2 radiation generator	1 hour
B-02	Discovery of the Category 1, 2 or 3 orphan source	1 hour
B-03	A security threat, such as attempted intrusion or sabotage, intentional degradation of security, preventing access to a source or a bomb threat	1 hour
B-04	Disappearance (theft or loss) of the Category 4 or 5 sealed source	24 hours

B-05	Disappearance (theft or loss) of the Category 3 radiation generator	24 hours
B-06	Any event for which the authorization holder believes it is an error in the control of radioactive sources or a defect of the equipment that ensures security of the radiological facility	24 hours
B-07	Any unauthorised intrusion on the premises or any attempted intrusion into a radiological facility	24 hours
B-08	Any emergency event involving an explosive or incendiary device or a firearm	24 hours
B-09	Any malicious damage to a building or equipment in the business premises that could affect the security of the premises or radioactive material	24 hours
B-10	Any actual or attempted theft, loss or unauthorized removal of the nuclear material in use or storage in the business premises or is in transit to or from the premises	24 hours
B-11	Any theft or attempted theft, or any loss or unauthorised disclosure, of sensitive information kept in the business premises, or any suspected such theft, loss or disclosure	24 hours
B-12	Any actual or attempted unauthorized access to sensitive information kept in the business premises	24 hours
B-13	Any failure to comply with the requirements and procedures described in the approved security plan of the authorization holder	24 hours
B-14	Any event that could affect the security of the premises with nuclear and radioactive material or sensitive information	24 hours
B-15	Loss of nuclear material	24 hours
B-16	Discovery of a nuclear material	24 hours
B-17	Information that nuclear material shipped by or to the authorization holder has been or may have been lost or considerably delayed	24 hours
B-18	Any theft or attempted theft, or any loss or unauthorized disclosure or distribution of sensitive information or any attempted such theft, disclosure or distribution	24 hours
B-19	Any event that could affect the security of sensitive information	24 hours
OS-01	Other relevant information	24 hours

Table 4: Criteria for notification/reporting – medical exposure of the patient (diagnostic and intervention radiology (DI) and dental medicine (ST))

Category	**Description** **Emergency events not resulting from the patient's error**	**Initial notification deadline**
	Diagnostic and intervention radiology	
DI-01	Any unexpected patient's skin injury resulting from a prolonged exposure in an intervention procedure	24 hours
DI-02	Any dose significantly greater than intended (*)	24 hours
DI-03	Unintended exposure of an external person (the wrong patient) in which the wrong patient received a dose above the dose limit for the public – 1 mSv of effective dose	24 hours
DI-04	Any conducted unplanned examination	24 hours

DI-05	Wrong body part irradiated	24 hours
DI-06	Unnecessarily repeated examination	24 hours
DI-07	Any failure of medical radiological equipment	24 hours
	Dental medicine	
ST-01	Any equipment defect	24 hours
ST-02	Unintended exposure of an external person (the wrong patient)	24 hours
ST-03	Unnecessarily repeated examination	24 hours
OS-01	Other relevant information	24 hours
Emergency events resulting from the patient's error		
IP-01	Any event resulting from the patient's error and in which the application of radioactive sources results or will result in an unintended permanent functional damage to an organ or a physiological system, which is determined by the relevant specialist	24 hours
OS-01	Other relevant information	24 hours

(*) Table 4(a): Doses significantly greater than intended in diagnostic and intervention radiology

Diagnostic examinations	Multiplying factor applied to intended dose
Intervention radiology, radiographic and fluoroscopic procedures involving contrast agent, and CT examinations	1.5
Mammography and other radiographic examinations not listed in this table	10
Radiography of extremities, teeth, shoulders, lungs, skull, elbows, knees	20

Table 5: Criteria for reporting – medical exposure of the patient (diagnostic and therapeutic nuclear medicine)

Category	Description	Initial notification deadline
	Emergency events not resulting from the patient's error	
NM-01	Radiation dose significantly greater than intended (*)	24 hours
NM-02	Unintended exposure of an external person (the wrong patient) in which the wrong patient received a dose above the dose limit for the public – 1 mSv of effective dose	24 hours
NM-04	Administration of the wrong radiopharmaceutical	24 hours
NM-04	Administration of an unnecessary radiopharmaceutical	24 hours
NM-05	Any error in the preparation of the radiopharmaceutical	24 hours
NM-06	Any error in the administration of radiopharmaceutical	24 hours
NM-07	Equipment failure	24 hours
NM-08	Incorrectly implemented scanning procedure	24 hours
NM-09	Administration of the radiopharmaceutical but the scan was not performed	24 hours
NM-10	Wrong dose/wrong activity	24 hours

NM-11	Unnecessarily repeated scanning	24 hours
NM-12	Radiopharmaceutical applied to a patient but the result is a poor image	24 hours
NM-13	The patient contaminated with radioactive substances	24 hours
NM-14	The improper supply of the radiopharmaceutical by supplier	24 hours
NM-15	The patient and medical staff contaminated with a radiopharmaceutical, resulting in the incontinent patient	24 hours
NM-16	Therapeutic dose delivered instead of diagnostic dose	24 hours
Emergency events resulting from patient's error		
IP-01	Any event resulting from the patient's error in which the application of radioactive sources results or will result in an unintended permanent functional damage to an organ or physiological system, which is determined by the relevant specialist	24 hours
OS-01	Other relevant information	24 hours

(*) Table 5(a): Doses significantly greater than intended in diagnostic and therapeutic nuclear medicine

Type of diagnostic procedure	**Multiplying factor applied to intended dose**
Nuclear medicine with the intended effective dose of E>5 mSv	1.2
Nuclear medicine with the intended effective dose of 0.5 mSv<E≤5 mSv	2
Nuclear medicine with the intended dose of E≤0.5 mSv	20
Type of treatment	**Multiplying factor applied to intended dose**
Treatment with radiopharmaceuticals – any administration	1.15

Table 6: Reporting criteria – medical exposure of the patient (radiotherapy with external sources – ET and internal sources – BT)

Category	**Description**	**Initial notification deadline**
	Emergency events not resulting from the patient's error	
	External radiotherapy	
ET-01	Exposure of one or more patients to a radiation dose significantly greater than intended (*)	24 hours
ET-02	Unintended exposure of an external person (the wrong patient) in which the wrong patient received a dose above the dose limit for the public – 1 mSv of effective dose	24 hours
ET-03	Treatment of the wrong tissue	24 hours
ET-04	Use of the wrong beam or beam quality	24 hours
ET-05	Wrong dose	24 hours
ET-06	Wrong region	24 hours
ET-07	Unnecessary CT imaging	24 hours
ET-08	Wrong treatment	24 hours
ET-09	Repetition of CT imaging	24 hours

	Brachytherapy	
BT-01	Exposure of one or more patients to a radiation dose significantly greater than intended (*)	24 hours
BT-02	The treated volume differs from the planned target volume sufficiently enough to make it clinically significant	24 hours
BT-03	Unintended exposure of an external person (the wrong patient) in which the wrong patient received a dose above the dose limit for the public – 1 mSv of effective dose	24 hours
Emergency events resulting from the patient's error		
IP-01	Any event resulting from the patient's error in which the application of radioactive sources results or will result in an unintended permanent functional damage to an organ or physiological system, which is determined by the relevant specialist	24 hours
OS-01	Other relevant information	24 hours

(*) Table 6(a): Doses significantly greater than intended in external and internal radiotherapy

Description of treatment	Multiplying factor applied to intended dose
External therapy, brachytherapy (the limit applies to overdoses and underdoses)	1.1 (whole course) or 1.2 (any fraction)

Annex 2: FORM FOR THE FINAL REPORT ON THE RADIOLOGICAL EMERGENCY EVENT

FINAL REPORT ON THE
RADIOLOGICAL EMERGENCY EVENT

1. General information

The authorization holder: Address: Authorization no:	☐ Actual event ☐ Near miss ☐ Emergency event class		
Date of the emergency event:	Date of emergency event detection:		
Date and time of initial telephone notification:	Date and time of sending the final written report:		
Name of the author of the report:	Phone:	Fax:	Email:
Name of the contact person for the report:	Phone:	Fax:	Email:
Practice involving radioactive sources: ☐Medical ☐Non-medical ☐Science and research ☐Technical service for radiation protection			
Specific practice involving radioactive sources:			

2. Details of the emergency event

Emergency event location:	Address:
Emergency event impact on exposed workers: ☐ No ☐ Yes If yes, please specify the details:	
Emergency event impact on the public: ☐ No ☐ Yes If yes, please specify the details:	
Involved external emergency service: ☐ Police ☐ Firefighters ☐ Paramedic services ☐ Technical service for radiation protection ☐ Other	
Description of radioactive source: ☐ X-ray generator ☐ Device containing sealed source ☐ Sealed source ☐ Unsealed source The source category according to the applicable regulations (enter the number) ☐	
Release of radioactive material	☐ No ☐ Ongoing ☐ Finished ☐ Unknown

Possible contamination with radioactive substances	☐ No ☐ Yes ☐ Unknown

3. The nature of the emergency event: area, category and category description
(Enter the category and the description of the categorized emergency event in the relevant fields)

Field	Category	Description
Radiation safety	RS-	
Transport of radioactive material	TS -	
Security of radioactive sources	B-	
Medical exposure of the patient	DI- ST- NM- ET- BT-	

4. Detailed description of the emergency event

Please provide a description of the emergency event (human error, equipment failure etc.), including who discovered the error/failure, how it was found, when it was found, where it was made, who made it, and what caused the event.

In case of medical emergency event, please provide the name of the medical practitioner who prescribed administering the radiation to the patient.

What improvements are necessary to prevent recurrence of the emergency event?

5. Received dose of radiation

Please enter an assessment (including methodology or references) of the radiation dose received as a result of the emergency event. Indicate the type of radiation, the number of affected persons and the magnitude of individual exposure to radiation or radioactive material without specifying individual names.

6. Parties notified about the emergency event

Was the Agency notified before this report?

If there was a medical emergency event, was the patient informed?

☐ Yes ☐ No. If not, why?

If the patient has been informed about the incident, which information have been provided? Provide additional information where necessary.

7. Corrective actions taken by the authorization holder

Please elaborate conducted examinations or corrective actions taken in order to minimize the likelihood of similar emergency events in the future.

8. Persons directly involved in the emergency event

Name:		
Job title:		
Company/department:		
Phone:	Fax:	Email:

9. Details about the radiation generator

Please provide the following information for emergency events involving equipment failure or equipment as a factor contributing to the occurrence of the emergency event:

Number of authorization for use:	Source location:
Source description and purpose of use:	
Manufacturer:	Model:
Serial number of the tube:	☐ Fixed ☐ Mobile ☐ Portable
Other relevant information:	

10. Details on radioactive material (including sealed sources)

Please provide the following information about the emergency event involving radioactive material:

Radionuclide(s):	Number of authorization for use:
Source activity:	Calibration date: / /
Identification number (serial number):	Quantity of radioactive material:
Physical form (solid, powder):	Chemical form:
Source storage location:	
Other relevant information:	

I hereby confirm that the information above is true and complete.

_____

Author of the report

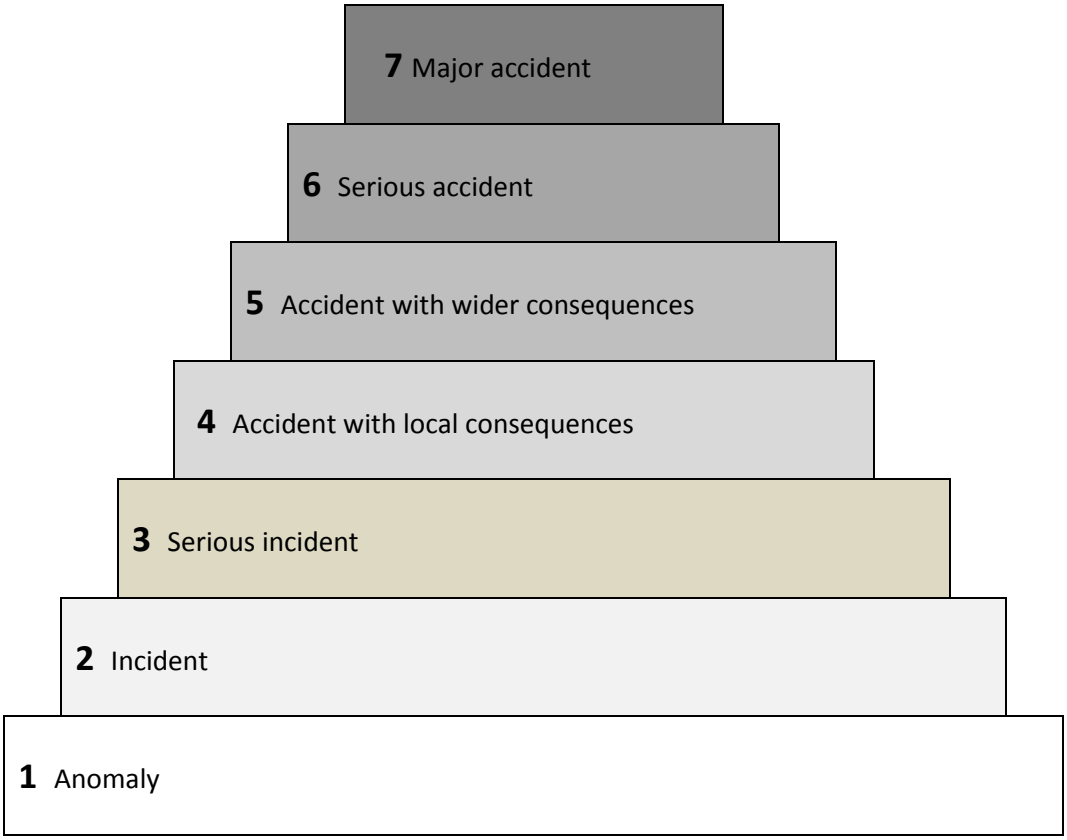
_____

Signature

Place:

Date: / / (year)

Annex 3: INES SCALE



0 Below scale / No safety significance