

**ANNEX 1****Radiation safety deviations subject to notification of summarized information****Table 1.** Summarized information on radiation safety deviations concerning occupational exposure.

Type of radiation safety deviation	Cause and factor contributing to the radiation safety deviation	Number of radiation safety deviations per year	Remedial measures
Worker exposed to external radiation in a radiation safety deviation that need not be notified without delay	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Hardware or system failure		
Worker exposed to contamination in a radiation safety deviation that need not be notified without delay	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Hardware or system failure		
	Other reason		

**Table 2.** Summarized information on radiation safety deviations concerning public exposure.

Type of radiation safety deviation	Cause and factor contributing to the radiation safety deviation	Number of radiation safety deviations per year	Remedial measures
Representative of the public exposed to external radiation in a radiation safety deviation that need not be notified without delay	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Hardware or system failure		
Representative of the public exposed to contamination in a radiation safety deviation that need not be notified without delay	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Hardware or system failure		
	Other reason		

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**Table 3a.** Summarized information on radiation safety deviations concerning unplanned medical exposure: examinations and procedures using X-radiation and radiopharmaceuticals.

Type of radiation safety deviation	Cause and factor contributing to the radiation safety deviation	Number of radiation safety deviations per year	Remedial measures
Referral made to the wrong person, resulting in the wrong person's exposure to radiation	Human error		
	Other reason		
Wrong examination, procedure, or anatomical object in the referral, which has resulted in an incorrect examination or procedure	Human error		
	Other reason		
Examination or procedure performed on the wrong person	The patient's identity was not verified by means of a reliable method before the examination or procedure		
	Other reason		
Wrong examination or procedure performed, or wrong anatomical object scanned, or wrong radiopharmaceutical used	Human error		
	Other reason		
Failed examination or procedure (other than injection of a contrast medium) or related additional exposure	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Failure or incorrect use of a medical device		
	Other reason		
Additional exposure associated with failed injection of contrast medium or radiopharmaceutical	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Failure or incorrect use of a medical device		
	Extravasation		
	Other reason		
Unnecessarily repeated examination	No information on a previous similar examination, or results of a previous examination unavailable		
	Other reason		

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Type of radiation safety deviation	Cause and factor contributing to the radiation safety deviation	Number of radiation safety deviations per year	Remedial measures
Unintended foetal exposure in the range 1 to 10 mGy	Pregnancy at such an early stage that it could not be confirmed		
	The possibility of pregnancy was not determined using a reliable method before the procedure or examination		
	Other reason		
Examination-related contamination in which the patient received an effective dose in excess of 1 mSv or an equivalent dose in excess of 2 mSv to an organ or tissue	Human error		
	Failure or incorrect use of a medical device		
	Extravasation		
	Other reason		
Unplanned exposure of a carer and comforter, effective dose due to additional exposure of less than 1 mSv, or equivalent dose to an organ or tissue of less than 10 mSv	Human error		
	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Other reason		
A near-miss situation occurring more than once for the same reason	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Operational error		
	Failure or incorrect use of a medical device		
	Other reason		
Other radiation safety deviations related to medical exposure	Other reason		

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**Table 3b.** Summarized information on radiation safety deviations concerning unplanned medical exposure: treatments with devices which produces radiation electrically, sealed sources, radiopharmaceuticals and medical devices using unsealed sources.

Type of radiation safety deviation	Cause and factor contributing to the radiation safety deviation	Number of radiation safety deviations per year	Remedial measures
The dose produced by devices which produces radiation electrically and by sealed sources to the treatment target or reference point deviates by more than 5% from the planned total dose.	Error in dose planning		
	Human error		
	Failure or incorrect use of a medical device		
	Other reason		
The dose produced by devices which produces radiation electrically and by sealed sources to the treatment target or reference point deviates by more than 20% from the planned total dose during a single treatment.	Error in dose planning		
	Human error		
	Failure or incorrect use of a medical device		
	Other reason		
Deviation in dose or targeting during a single treatment which it has been possible to compensate for on subsequent treatments	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Failure or incorrect use of a medical device		
	Other reason		
In treatment with radiopharmaceuticals, the level of activity received by the patient deviates by more than 15% from the planned activity (non-systematic error)	Error in treatment planning		
	Human error		
	Failure or incorrect use of a medical device		
	Other reason		
Incorrect information in the referral, such as incorrect dose or fractionation (or near misses).	Incorrect or incomplete operating instructions or non-compliance with instructions		
	Human error		
	Other reason		
Contamination related to treatment with radiopharmaceuticals or medical devices using an unsealed source in which the effective dose received by the patient is 1–10 mSv	Human error		
	Failure or incorrect use of a medical device		
	Extravasation		
	Other reason		