



Accidental and unintended exposure future regulatory framework

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Current regulatory framework

Accidental and unintended exposure

Mandatory notification of FANC (ARBIS/RGPRI 2001)

1. Exposure in case of accident or emergency situation (art 20)
2. Urgent cases of non conformity with criteria for acceptability of medical radiological equipment (art 51.6.5)
3. Loss or theft of radioactive substances (art 66)
4. Every time an event occurs that could jeopardize the safety or the health of an individual (art 67.2)

Voluntary notification of FANC elaborated with all radiotherapy stakeholders

- 6 criteria
- Related to workers, patients, public,...
- See our dedicated webpage radiotherapy



Future regulatory framework


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, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom




Radiation protection legislation

PUBLIC EXPOSURE
OCCUPATIONAL EXPOSURE

 ARBIS/RGPRI 2001 => ARBIS/RGPRI 2019

MEDICAL EXPOSURE

 ARBIS/RGPRI 2001, chapter VI =>
Royal Decree medical exposure and non-medical imaging exposure with medical radiological equipment

Medical radiological installations : public + occupational + medical exposure
⇒ ARBIS/RGPRI 2019 + RD medical exposure are applicable !



Future regulatory framework

Accidental and unintended exposure

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CHAPTER VII

MEDICAL EXPOSURES

Article 63

Accidental and unintended exposures

Member States shall ensure that:

- (a) all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure;
- (b) for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposures;
- (c) for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;
- (d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;
- (e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;
(ii) the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State;
- (f) mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.

RD medical exposure

CHAPTER IX

GENERAL RESPONSIBILITIES OF MEMBER STATES AND COMPETENT AUTHORITIES AND OTHER REQUIREMENTS FOR REGULATORY CONTROL

Article 96

Notification and recording of significant events

Member States shall require the undertaking to:

- (a) implement, as appropriate, a recording and analysis system of significant events involving or potentially involving accidental or unintended exposures;
- (b) promptly notify the competent authority of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to occupational or public exposure or as defined by the competent authority for medical exposure, including the results of the investigation and the corrective measures to avoid such events.

ARBIS/RGPRI 2019

Medical radiological installations : public + occupational + medical exposure
⇒ ARBIS/RGPRI 2019 + RD medical exposure are applicable !

Definitions RD medical exposure

Medical exposure : exposure incurred by

- patients/asymptomatic individuals as part of their own medical diagnosis or treatment and intended to benefit their health or quality of life
- their carers and comforters
- unborn child of a known pregnancy of the above individuals
- volunteers in experiments on the human being



For all medical exposures and hence for all these individuals

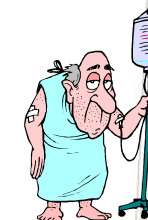
- ✓ justification
- ✓ optimization measures

by the **referrer and/or practitioner** before medical exposure

Definitions RD medical exposure

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In case something “abnormal” happens :

Unintended exposure : actual **medical exposure** \neq intended

Accidental exposure : actual **occupational or public exposure** \neq expected

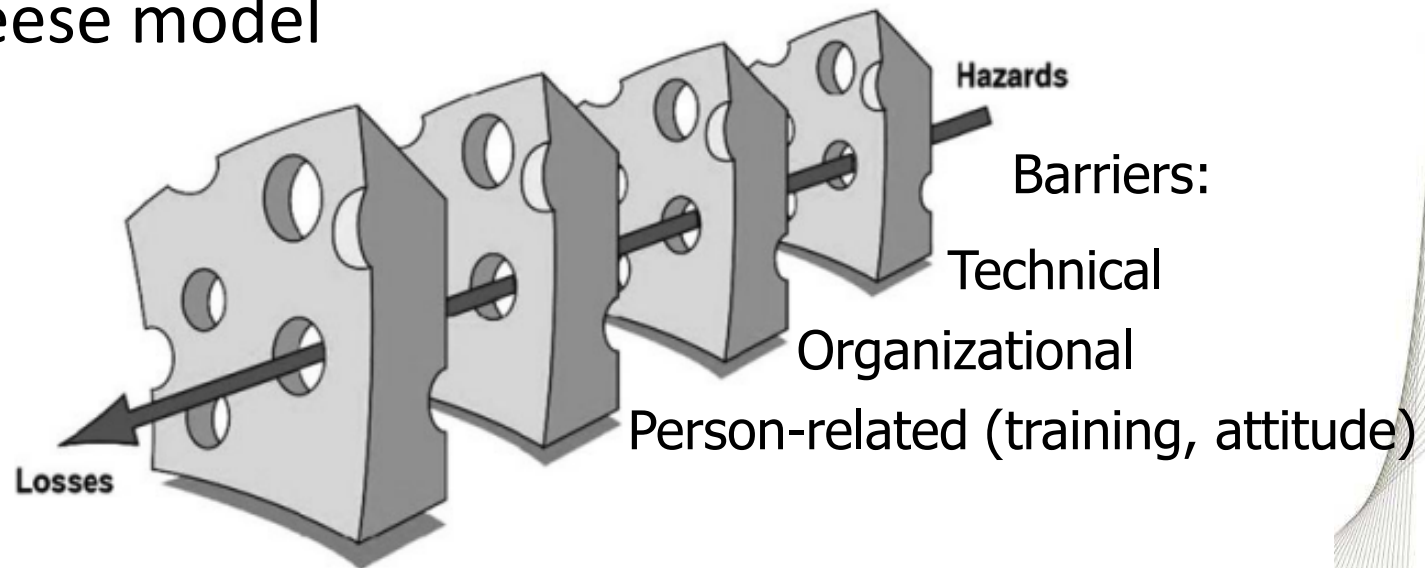
Clinically significant accidental or unintended exposure :

no definition in RD because this classification is medical decision

Accidental or unintended exposure

"All reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures in the framework of medical exposures."

Swiss cheese model

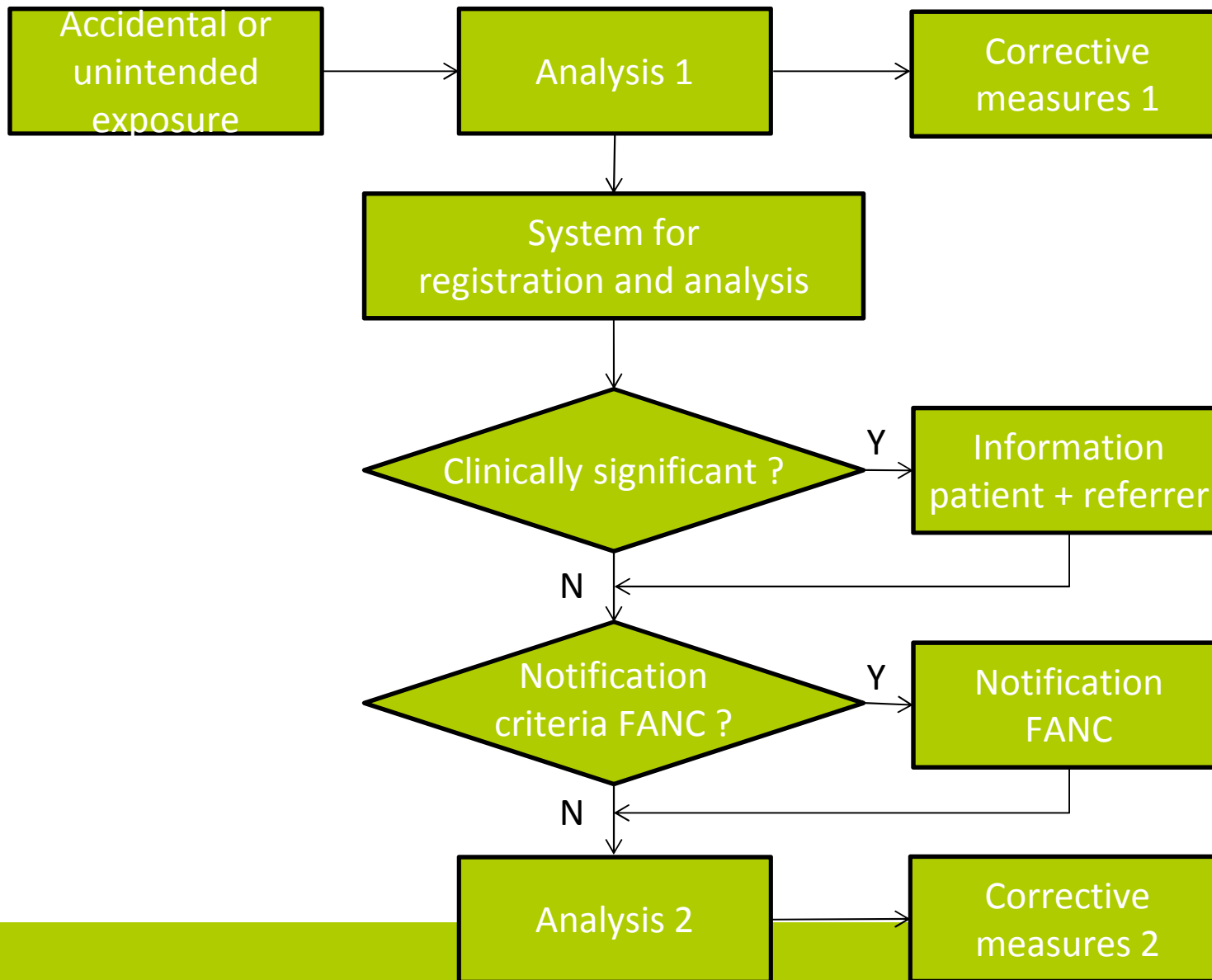


Accidental or unintended exposure

"All reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures in the framework of medical exposures."

- Proactively:
 - Where could it go wrong ?
 - Legal obligation:
to perform a study of risk for all radiotherapeutic practices in collaboration with the recognized expert in medical radiation physics
- Reactively:
 - Where did it almost go wrong ?
 - Where did it actually go wrong?
 - Legal obligations in case of an actual accidental or unintended exposure :
see summary and following slides

Summary of legal obligations in case of Accidental or unintended exposure

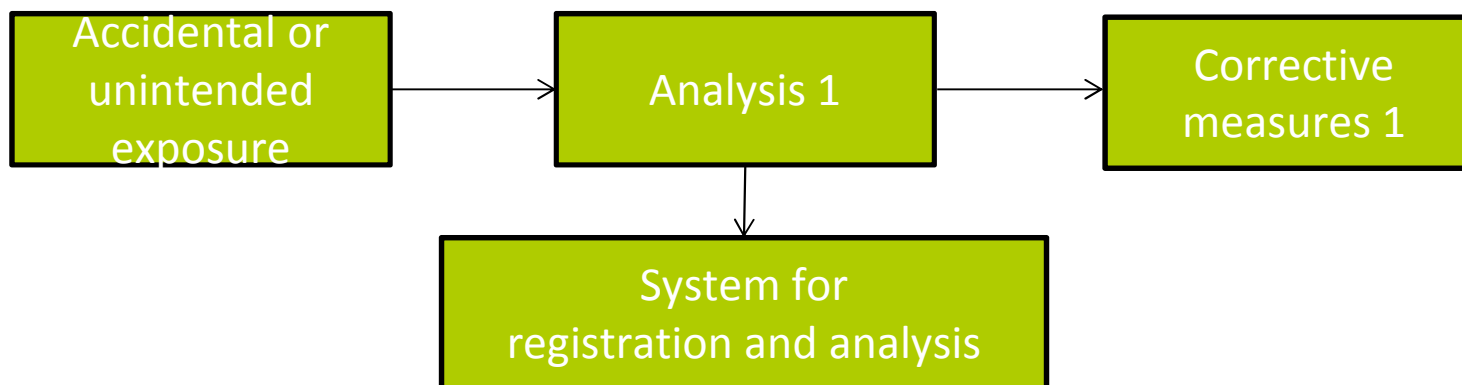


Analysis and corrective measures



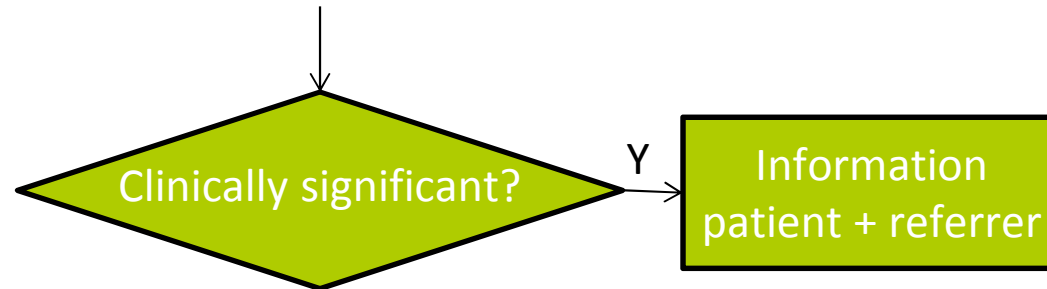
- To prevent the occurring of new/same ones
- Analysis in collaboration with recognized medical radiation physicist
- Dose estimation by a recognized medical radiation physicist for:
 - Clinically significant accidental or unintended exposure
 - Accidental or unintended exposure of a minor or an unborn child when expected dose > 1mSv

System for registration and analysis



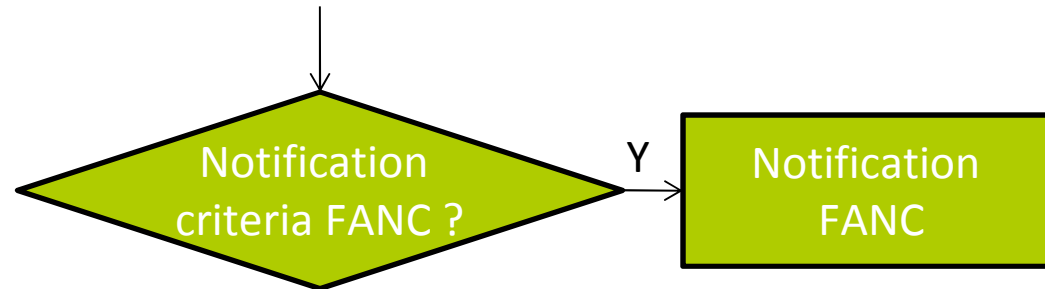
- Introduction into appropriate system for registration and analysis
- Internal to the medical radiological installation
- Hospitals:
 - “Quality and Patient Safety” contracts with FPS Health
 - *e.g.* iProva, Datix,...
 - WIP : extension to make feasible for radiation incidents workers, public, patient
- All others:
 - No contract with FPS Health
 - FANC is willing to draw up a unique notification form for radiation incidents workers, public, patient

Clinically significant?



- Clinically significant accidental or unintended exposure :
no definition in RD because this classification is a medical decision (CTCAE or other scale?)
- Practitioner informs without delay:
 - Person who underwent clinically significant accidental or unintended exposure (or his legal representative)
 - Referring physician
- Information:
 - What happened ?
 - Results of the analysis
 - Further clinical follow-up (if applicable)

Notification criteria FANC ?



2 sets of notification criteria FANC

- Person undergoing medical exposure
- Exposure unborn child of unknown pregnancy of person undergoing medical exposure
- Workers
- Public
- Environment

Notification criteria FANC (1)

1. Exceeding dose limit of an unborn child (1 mSv) of an **unknown pregnancy** of a person undergoing a medical exposure :
→ **patient/asymptomatic person/carer/comforter/volunteer!**
2. The use of a **sealed source or radiation equipment** that caused or could cause the occurrence of unforeseen deterministic effects and/or the exposure of one or more patients to doses that significantly differ from the prescribed dose :
 1. Deviation of $\geq 10\%$ of prescribed total dose of the complete treatment
 2. Deviation of $\geq 20\%$ of prescribed dose/fraction
 3. Systematic deviations for ≥ 10 patients of limits determined by the College RT
3. Administration of **unsealed radioactive product for radiotherapeutic** purposes that caused or could cause the occurrence of unforeseen deterministic effects and/or where the administered activity differs $\geq 10\%$ from the prescribed activity

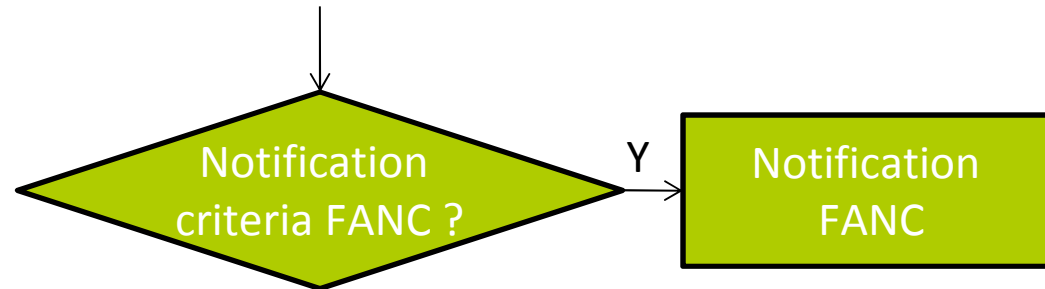
Notification criteria FANC (2)

Significant event :

every event that has consequences or could have consequences if not managed correctly, on radiation protection, health, quality of life and/or safety of **workers, public and environment**

1. Related to safety and/or radiation protection of workers + public
 1. Exceeding of a legal dose limit or FANC dose constraint
 7. Accidental contamination outside predetermined areas
 11. Loss or (attempt of) theft of source of ionising radiation
2. Related to import, export or transit
3. Related to transport of dangerous goods class 7
4. Other interesting events
5. Events that could lead to wrong or malicious interpretations by press
6. Other events that could influence safety, security and/or radiation protection and evaluated as significant by FANC

Modalities for notification to FANC

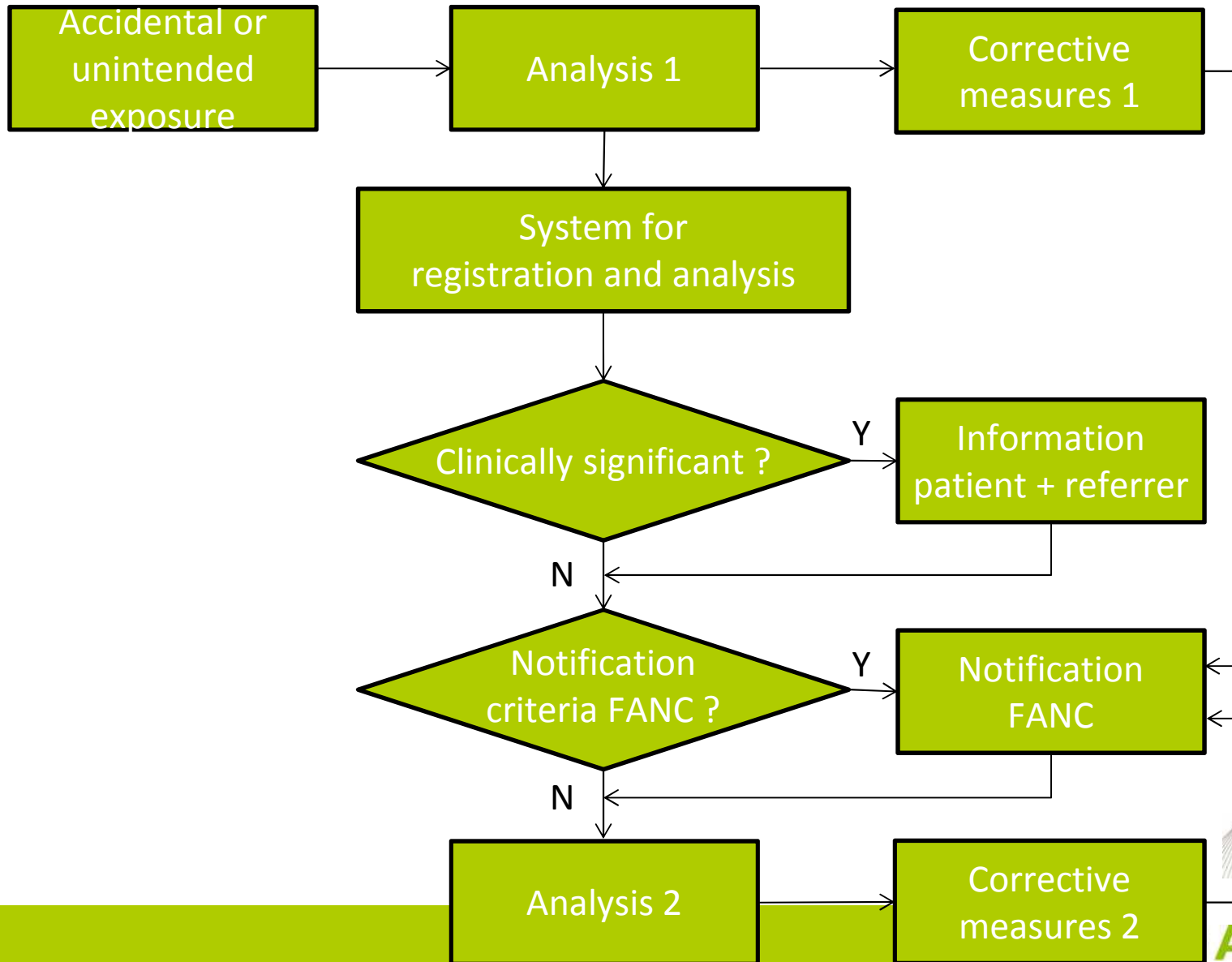


2 sets of notification criteria FANC

- Person undergoing medical exposure
- Exposure unborn child of unknown pregnancy of person undergoing medical exposure
 - By the practitioner
 - Within 7 days after discovery
- Workers
- Public
- Environment
 - By the undertaking
 - Orally immediately after discovery + written within 48h + final report within 2 months

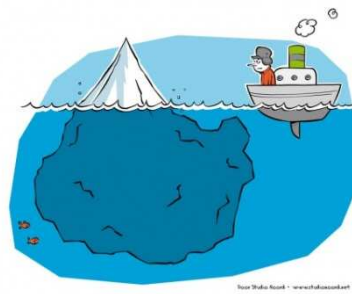
All other modalities will be kept in common as much as possible !

Summary of legal obligations in case of Accidental or unintended exposure



Dissemination of information by FANC

- Dissemination of lessons learned by FANC
- Anonymous
- No name, no blame, no shame
- Main objective = sharing information, knowledge and experience
 - ⇒ Prevention of new (near) accidental or unintended exposures
 - ⇒ Corrective actions
 - ⇒ Continuous improvement of quality of patient care
 - ⇒ Continuous improvement of radiation protection of patients, staff, population and the environment





Thank You ! Questions ?

