M. Marengo

IMPLEMENTING SAFETY BARRIERS AND PREVENTING ACCIDENTAL EXPOSURE OF PATIENT AND STAFF

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Accidents and incidents

A major concern of safety is preventing accidents / incidents in human activities.

Numerous definitions exist of accidents and incidents at work. The nature of the definitions often depends on the context and the purpose, such as accident prevention, compensation and statistics.

In the context of accident prevention, the phenomenon of accidents and incidents are often viewed in light of accident investigation and analysis. The main purpose is to gain insight in the (underlying) causes in order to prevent accidents in the future and to improve the safety.

An accident can be defined as an unplanned and uncontrolled event in which the action or reaction of an object, substance, person or radiation results in personal injury or the probability thereof.

Heinrich, H., Industrial Accident Prevention, fourth edition, New York, 1959, first edition, 1931.
European Agency for Safety and Helath at Work. http://oshwiki.eu/wiki/
Mahajan R.P., British Journal of Anaesthesia 105 (1): 69–75 (2010)

Incidents in Health Services in Italy

Accidents at work - Qualified professions in health and social services

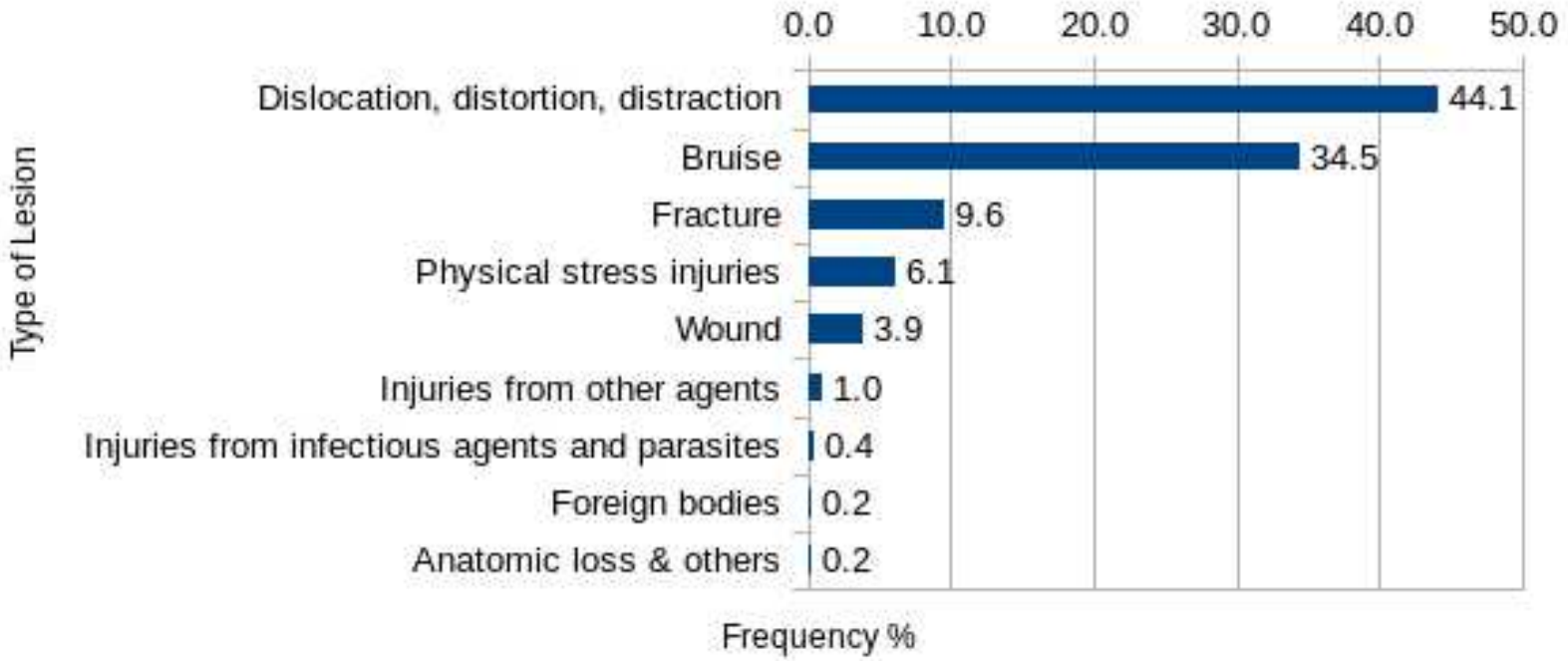
	2015	2016	2017
N. of cases	6724	7260	7784
Death cases	3	3	3

N. ow workers in the health sevices ca.	750000
N. of workers in social services ca.	350000

About 7 incidents/year every 1000 workers
Lethal incidents ~ 2.7E-06 per year

Incident in health services in Italy (2017)

data from the INAIL data base



Distribuzione per Regione (2017)

Regione	Numero casi	%
Piemonte	1.008	12.9
Valle D'Aosta	40	0.5
Lombardia	1.139	14.6
Bolzano - Bozen	81	1
Trento	140	1.8
Veneto	981	12.6
Friuli Venezia Giulia	243	3.1
Liguria	411	5.3
Emilia Romagna	1.493	19.2
Toscana	790	10.1
Umbria	82	1.1
Marche	282	3.6
Lazio	233	3
Abruzzo	81	1
Molise	9	0.1
Campania	121	1.6
Puglia	191	2.5
Basilicata	31	0.4
Calabria	84	1.1
Sicilia	101	1.3
Sardegna	243	3.1
Totale complessivo	7.784	100

~ 86% of reports in North and Center Regions

Prevention of accidents and incidents in NM

The BSS sets out requirements both for minimizing the likelihood of unintended and accidental medical exposures and for the ensuing investigation if such exposures occur.

Excerpted from SSG-46 Par. 4.250: A reduction in the probability of unintended or accidental medical exposures in Nuclear Medicine can be brought about by:

(a) The introduction of "**safety barriers**" at identified critical points in the nuclear medicine pathway, with specific quality control checks at these points.
(b) Encouraging a culture of always **working with awareness** and alertness.
(c) Providing **detailed protocols and procedures** for each process.
(d) Providing **sufficient** (educated and trained) **staff**, and an effective organization
(e) **Continuous professional development** and practical/applications training of all staff
(f) **Clear definitions of the roles**, responsibilities and functions of staff

Specific to NM

Imaging in Nuclear Medicine is much different, compared to Radiology and other modalities.

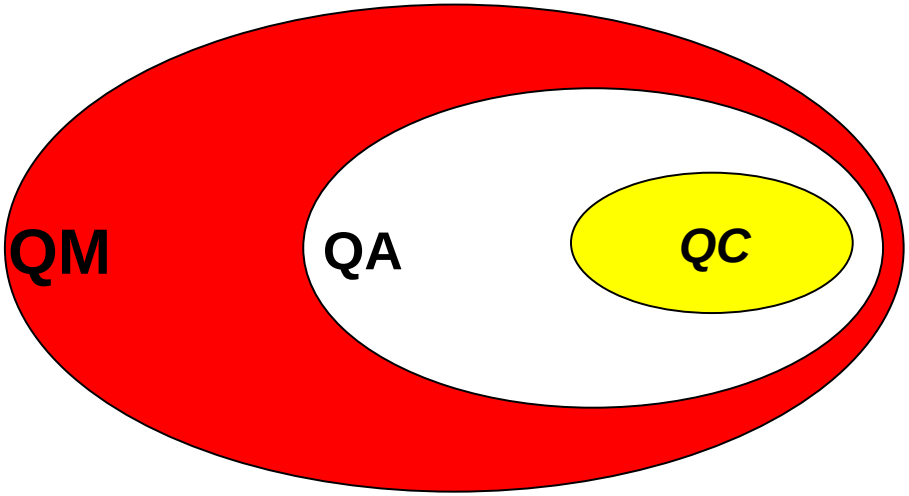
The fact that radiopharmaceuticals are used as tracers of metabolic functions, means that what we are imaging is not “the organ” or “a system”, intended as their physical morphology, but rather the metabolism of the cells of the organ or the functionality of a system.

For these reasons, it is not directly expected that the “quality” of the images, expressed by descriptors like the spatial resolution, would be optimal; rather, the quantitative aspects of organs and system function are expected to be imaged with sufficient accuracy.

This explains also how and why the process of patient's imaging is of paramount importance, included patient's preparation, timing and eventual “provocative” actions, aimed to stimulate response of the organs / systems.

Thus, the optimization process should not be applied only the imaging procedure, but to the whole process ...

QC, QA, QM



Quality control: is a part of quality assurance. The set of operations (programming, coordinating, implementing) intended to maintain or to improve quality. It covers monitoring, evaluation and maintenance at required levels of all characteristics of performance of equipment that can be defined, measured, and controlled.

Quality Assurance: all those planned and systematic actions necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily complying with agreed standards.

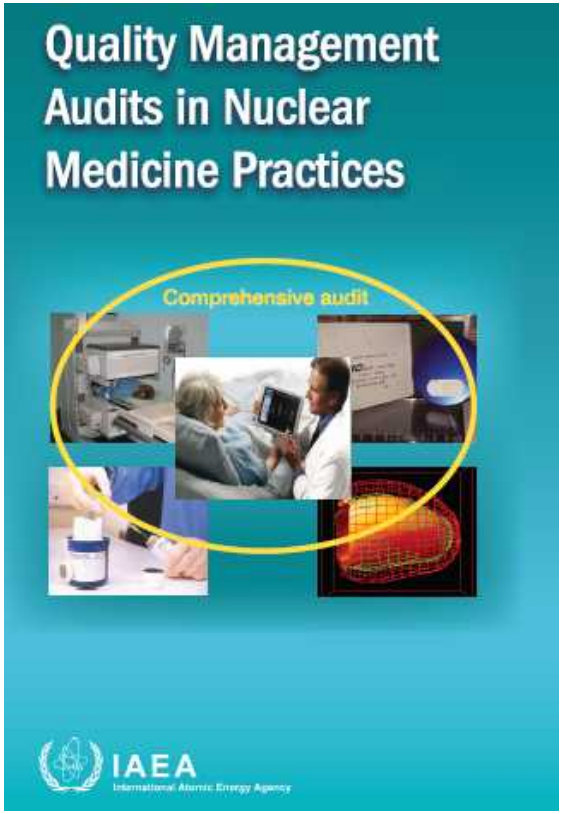
From EU Directive 97/43

***Quality Management*:** That aspect of the overall management function that determines and implements the *quality policy*

A comprehensive approach

- The IAEA has developed and introduced a comprehensive approach to Quality management in Nuclear Medicine
- This includes a checklist for assisting in the performance of audits (both internal and external)
- All the components of the process are checked (administration & management, human resources, radiation protection, equipment QA/QC, IT systems, clinical practice in diagnostic & therapeutic applications, radiopharmacy)

- Only a comprehensive approach can make possible a reliable process of optimization



Accidents in Nuclear Medicine routine activity
Safety of operators

Routine activity in Nuclear Medicine presents the possibility of some typical, and relatively frequent, accidents:

- Puncture with a syringe, during radiopharametucial preparation or following patient admimistration;
- Contamination in the management of body fluids
- Diffused “spray” contamination during injection;
- Irradiation in manipulation of sources (in particular therpeutic radiopharmaceuticlas)
- Mechanical injury by heavy lead shielding components (e.g. lead bricks; leaded transport containers; hot cell's portels, etc.);
- …

Puncture

- During some steps in the preparation of radiopharmaceuticals, it is necessary to recap syringes. This operations should be made ONLY in a safe way, using appropriate tools. However, operators may avoid this, to “save time” or for an excess of confidence.
- After administration to patients, syringes SHOULD NEVER be recapped, and be disposed as they are in an appropriate sharps container. However, some times this aspect is not fully conceived as exposing the operator not only to the risk of radioactive contamination (relatively modest), but also to a signifcant risk of microbiological contamiantion.

- These accidents should be immediately noticed and reported. A procedure for centralized reporting of all punctures should be active in any Hospital, and should be used also for events regarding radioactive pharmaceuticals.
- In most part of the cases (excluding some radionuclides for therapeutic use), the microbiological risk is much more significant than radiation risk.
- The subject should be immediately referred for appropriate tests and profilaxis against major infective risks.
- Systematic use of gloves, reduces signifcantly all risks of contamination.

Management of body fluids

- Procedures like White Blood Cells labelling and other, involve manipulation of blood samples.
- Urine bags, diapers and assistance to specific classes of patients presnte the risk of contamination.

- As in the case of puncture, these accidents should be immediately noticed and reported, according to the (existing) Hospital accident reporting procedure.
- In most part of the cases (excluding some radionuclides for therapeutic use), the microbiological risk is more significant than radiation risk.
- The subject should be immediately referred for appropriate tests and profilaxis against major infective risks.
- Systematic use of gloves, reduces signifcantly all risks of contamination.

Mechanical injury

- Even if referring to these risks may seem as not relevant, in a context mostly concerned with radiation protection, events such as crushing of the fingers with lead bricks or doors of hot cells, or crushing the toes due to drop of shielded transport containers, are relatively frequent.
- These events are not only painful, but can lead to permanent disability, and should be carefully prevented.
- It was reported at least one case of an operator killed by having the chest crushed by an hot cell, capsized during a shift.

- Preventive actions: all barriers should fixed and stable; periodical inspection.

- It essential focus the mind of workers to a general concept of safety, not considering ONLY radiation protection.

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Diffused radioactive contamination

- Even if infrequently, the needle of a syringe may get clogged during injection, producing a spray of radiopharmaceutical when the piston is pushed.
- The face, hairs and chest of the operator can be contaminated.
- Adopting proper injection procedure (e.g. using an i.v. line, aspiring blood prior to injecting etc.), these events can be avoided.

- In the case of such an event, care should be taken not to extend the contamination.
- Regular decontamiantion procedures should be followed.
- Monitoring of residual contamination should be performed by a MP / RPE.
- The accident should be reported, including an estimate of the effective dose to the skin.

Accidents in Nuclear Medicine routine activity
Safety of patients

Procedure	Incident / Accident
Request & scheduling	Wrong examination booked / Inappropriate examination booked / Repeated examination
Patient identification	Wrong patinet injected
Patient preparation	Contraindications to proceed not observed / unproper timing
QC of radiopharmaceuticals	Wrong radiopharmaceutical administered / Unexpected biodistribution
Traceability / identification of unit doses	Misadministration
Measurement of individual activity	Non correct activity injected / suboptimal imaging
Equipment QA and insection	Poor image quality / Mechanical injury of patient

Accidents in Nuclear Medicine routine activity
Safety of patients

Errors that may contribute to incidents during the preparation of radiopharmaceuticals

Component	Possible errors
Storage of precursors, kits, cassettes etc.	Wrong environmental conditions may alter the products A product may have expired and not be taken out of use Poor demarcation of storage areas
Biological contamination during synthesis	A module or vial may not have been sealed adequately or aseptic conditions in a hot cell or laboratory may not be adequate, resulting in contamination of the product
Synthesis / labelling of the radiopharmaceutical	Inaccurate colour coding or labelling of kits Incorrect set-up of synthesis module, e.g. the module is not tightened or wrong loading of reagents / cassette
Quality control (QC)	Errors in laboratory procedures Inaccurate calibrations or equipment with poor sensitivity Components of the QC checks omitted
Dispensing of radiopharmaceutical	Poor procedures or environmental conditions that contaminate the product Inaccurate activity or mixing up of different products resulting from simultaneous dispensing of many vials in advance of the administration Missing, inaccurate, or ambiguous labels on vials, suringe, or protective shields
Receipt and control of vials of radiopharmaceutical	Poor system for checking orders to confirm the correct radiopharmaceutical and activity of each vial has been delivered

Accidents in Nuclear Medicine routine activity
Safety of patients

Factors that could contribute to an incident during patient preparation and administration

Component of the process	Possible errors
Patient preparation	Wrong instructions given to the patient Fasting condition not checked at time of examination Pregnancy or lactation not verified at time of exam. Biochemical tests omitted (e.g. glucose level)
Stress testing / pharmacological stimulation	Errors in the procedure. Errors in timing.
Patient identification	Identification not confirmed Lack of physical tools for identification (e.g. wristband) Poor management of patients with same name
Administration of radiopharmaceutical	Errors in the procedure Wrong radiopharmaceutical / activity administered Extravasation of injection Contraindications not checked

Accidents in Nuclear Medicine routine activity
Safety of patients

Factors that could be neglected or set incorrectly during imaging

Component of the process	Possible errors
Gamma camera setup	Wrong collimator / energy window / imaging time / matrix size or other sampling parameters set. Inadequate QC for detection of faults (e.g. a photomultiplier not working).
PET scanner setup	Incorrect daily QC procedure (e.g. detector block is not working)
Multi-modality scans	Wrong or poorly optimized CT protocol selected
In all imaging modes	Wrong reconstruction algorithm chosen Balance between quality of the images, acquisition time, and administered activity sub-optimal
Scanner calibration	The scanner is not calibrated, or calibration has expired before imaging (e.g. sensitivity, standardized uptake value (SUV), centre of rotation, etc.)
Mechanical safety	Patient has not been secured to the imaging bed. Moving components of the scanner have not been checked. Tools, furniture or other objects lie in the trajectory of motion.

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ACCEPTED MANUSCRIPT

Guidance on prevention of unintended and accidental radiation exposures in nuclear medicine

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Seminars in
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Radiation Safety and Accidental Radiation Exposures in Nuclear Medicine

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Medical radiation accidents and unintended events may lead to accidental or unintended medical exposure of patients and exposure of staff or the public. Most unintended exposures in nuclear medicine will lead to a small increase in risk; nevertheless, these require investigation and a clinical and dosimetric assessment. Nuclear medicine staff are exposed to radiation emitted directly by radiopharmaceuticals and by patients after administration of radiopharmaceuticals. This is particularly relevant in PET, due to the penetrating 511 keV γ-rays. Dose constraints should be set for planning the exposure of individuals. Staff body doses of 1-25 μSv/GBq are reported for PET imaging, the largest component being from the injection. The preparation and administration of radiopharmaceuticals can lead to high doses to the hands, challenging dose limits for radionuclides such as ^{90}Y and even ^{18}F. The risks of contamination can be minimized by basic precautions, such as carrying out manipulations in purpose-built facilities, wearing protective clothing, especially gloves, and removing contaminated gloves or any skin contamination as quickly as possible. Airborne contamination is a potential problem when handling radioisotopes of iodine or administering radioaerosols. Manipulating radiopharmaceuticals in laminar air flow cabinets, and appropriate premises ventilation are necessary to improve safety levels. Ensuring patient safety and minimizing the risk of incidents require efficient overall quality management. Critical aspects include: the booking process, particularly if qualified medical supervision is not present; administration of radiopharmaceuticals to patients, with the risk of misadministration or extravasation; management of patients' data and images by information technology systems, considering the possibility of misalignment between patient personal data and clinical information. Prevention of possible mistakes in patient identification or in the management of patients with similar names requires particular attention. Appropriate management of pregnant or breast-feeding patients is another important aspect of radiation safety. In radiopharmacy activities, strict quality assurance should be implemented at all operational levels, in addition to adherence to national and international regulations and guidelines. This includes not only administrative aspects, like checking the request/prescription, patient's data and the details of the requested procedure, but also quantitative tests according to national/international pharmacopoeias, and measuring the dispensed activity with a calibrated activity meter prior to administration. In therapy with radionuclides, skin tissue reactions can occur following extravasation, which can result in localized doses of tens of Grays. Other relevant incidents include confusion of products for patients administered at the same time or malfunction of administration devices. Furthermore, errors in internal radiation dosimetry calculations for treatment planning may lead to under or over-treatment. According to literature, proper instructions are fundamental to keep effective dose to caregivers and family members after patient discharge below the Dose constraints. The IAEA Basic Safety Standards require measures to minimize the likelihood of

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Misadministration

A misadministration happens when:

- A different radiopharmaceutical is administered instead of the intended one
- A different activity is given instead of the prescribed
- A unit dose prepared for Patient A is administered to Patient B, even if it is the correct radiopharmaceutical and activity (sentinel event)
- A wrong administration route is used

Even in the case of limited activity of a short lived NM radionuclide, a misadministration is considered a serious event, since the exposure of the patient in this case is completely **un-justified**.

Patient's identification

As a difference compared to Radiology, in Nuclear Medicine the exposure of the patient happens at the time of the administration of the radiopharmaceutical, typically well in advance respect to the time of the examination.
An effective system for the correct identification of the patient prior to administration is therefore a fundamental requisite of patient's radiation protection (IAEA SRS no. 40, par. 5.3.1 and 5.3.2).

There are several methods to properly identify patients:

- Confirm the patient's name by asking at every step of the process; the question should be “Can you please tell me your name ?” and not “Are you Mr. John Wayne ?”
- Assign to every patient an identification number and cross-check the number at every step of the process.
- Assign to each patient a wristband or equivalent, with an identification bar code; colours of the wristband can help to identify specific groups of patients.

Management of same name patients

A very specific problem of patient identification may arise with homonymous (same name) patients.

Several approaches are possible, and wristbands can be a substantial improvement.

However, in several centres, it is preferred to avoid booking same name patients in the same day; in these case a software rule is added in the RIS system, making impossible to add in the worklist a patient that has the same name as another already accepted. The new patient is booked the following day or ASAP.

Since NM examinations rarely are urgent, this is typically an accepted delay.

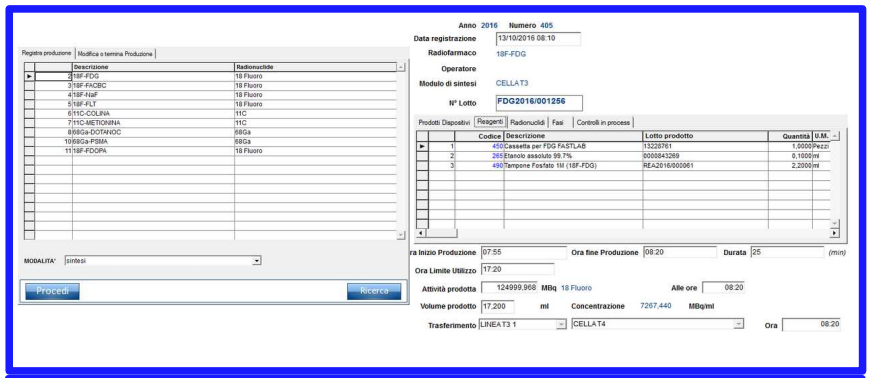
Patient's identification & traceability

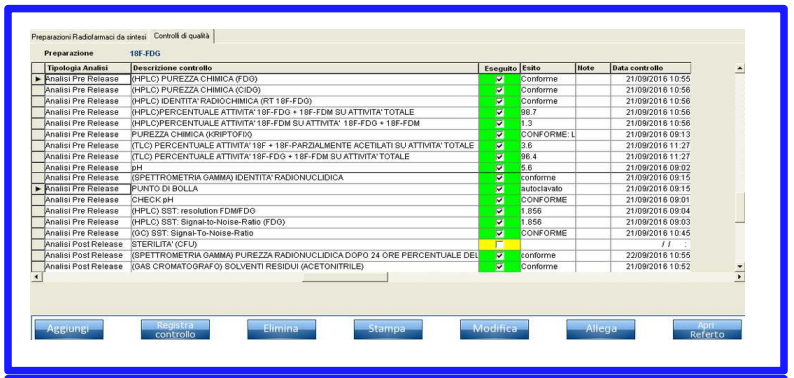
For proper **traceability**, it is suggested to adopt a specific paper module that follows the patient in every step of the process, and report on it all the passages, operations and the responsible operator e.g. :

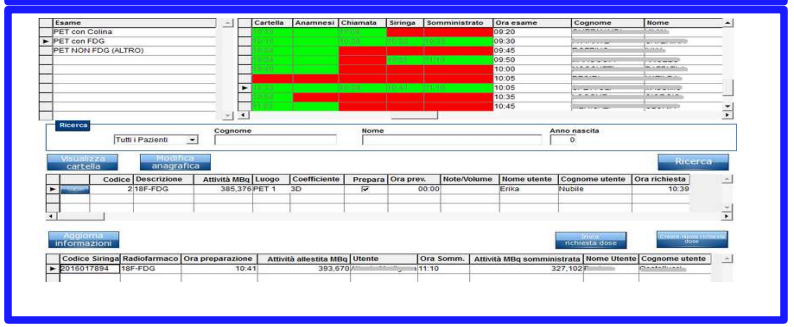
- time of arrival;
- patient's response to specific questions;
- time of administration, exact activity administered, type of radiopharmaceutical and batch number (best made by sticking in the module a sticker that should came with every individual syringe)
- time of beginning of the imaging
- time of release from the Department

Different steps are under the responsibility of different operators (secretaries, nurses, technologists, physicians); a signature or code number of the operator in charge should be included.

Sofware to support traceability



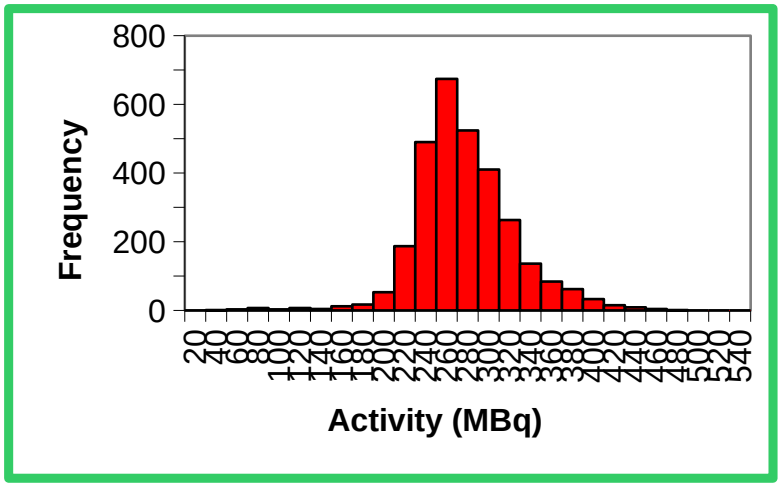


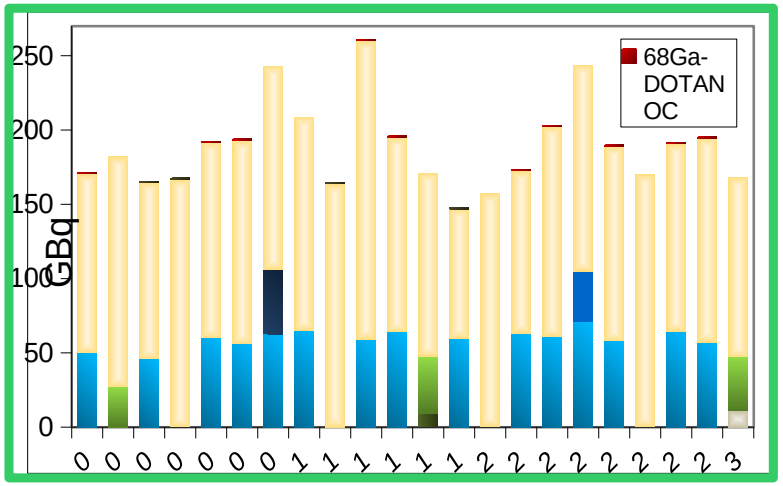


- Specific sofwares to support traceability are nowadays available
- Allow to trace all the process, from radionuclide productio, to synthesis, QC and release of radiopharamceuticals batches, patint's administration, image acquisition etc.

Malizia C et al, Eur J Nucl Med Mol Imaging (2016) 43 (Suppl 1):S666-S667

Sofware to support traceability





- an additional benefit that traceability software bring, is in the ease of obtaining statistics, for example, data useful for assessing the Diagnostic Reference Levels

Corrective actions following a misadministration

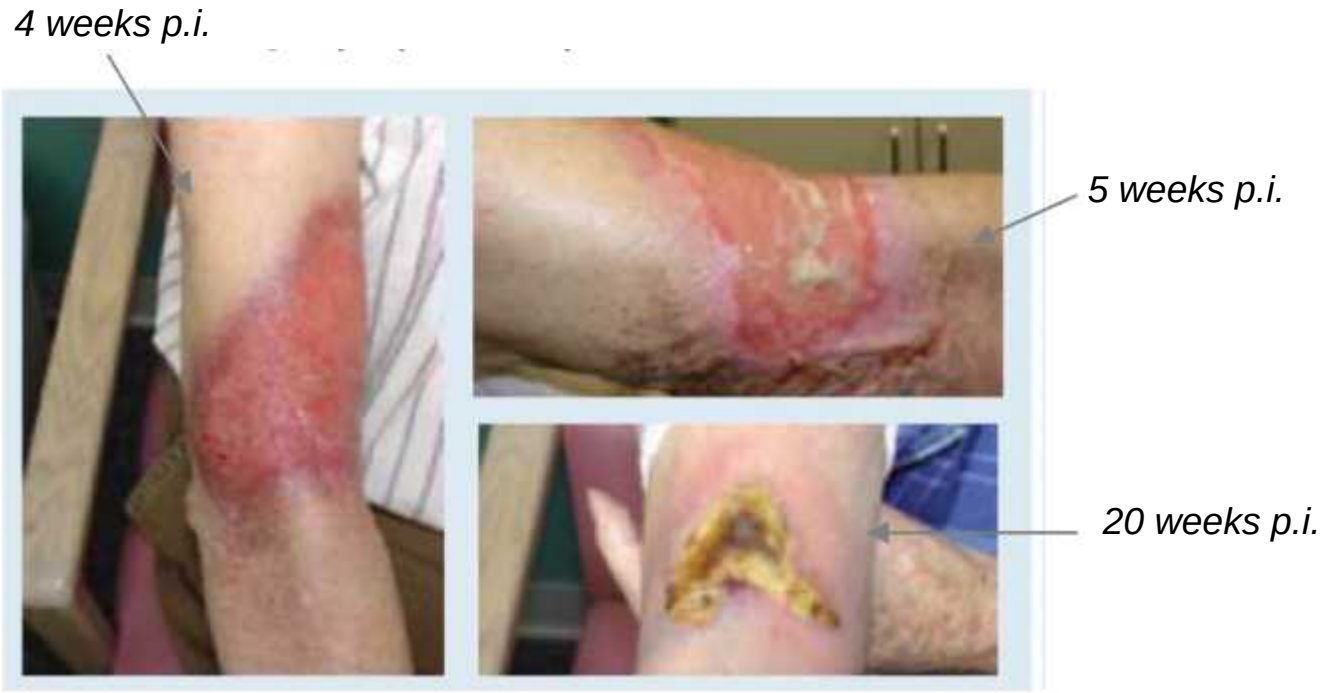
The correct identification of patients and radiopharmaceuticals, and the traceability of the process should ensure the substantial reduction of the risk of misadministration. However, in practice errors may happen.

It is the request that specific procedures exist, in order to be promptly applied in the undesired event of a misadminisration; the procedures should include:

- Formal registration of the event
- Modality of communication of the event to the patient and the referring physician
- Any treatment that can be applied in order to reduce patient's absorbed dose
- Actuation of a Corrective Action, in order to identify the reasons for the deviation and adopt the necessary solutions in order to avoid a repetition
- Periodic review of all adverse events

Example: a patient referred for bone scan, at the time of examination do not show proper biodistribution. Only limited renal activity was present. It was realized the patinet was administered with DTPA instead that with MDP. The technologist in charge of preparing the radiopharmaceuticals was re-entering at work after a long maternal leave and has confused the vials. Corrective action was taken in order to grant a proper re-training and temporary coaching when staff re-enters after a long leave.

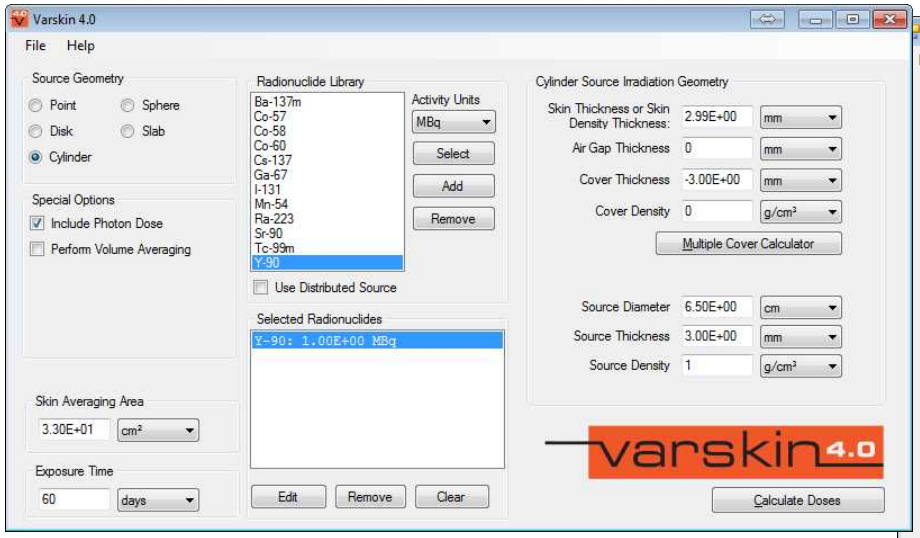
Extravasation of therapeutic radiopharmaceuticals

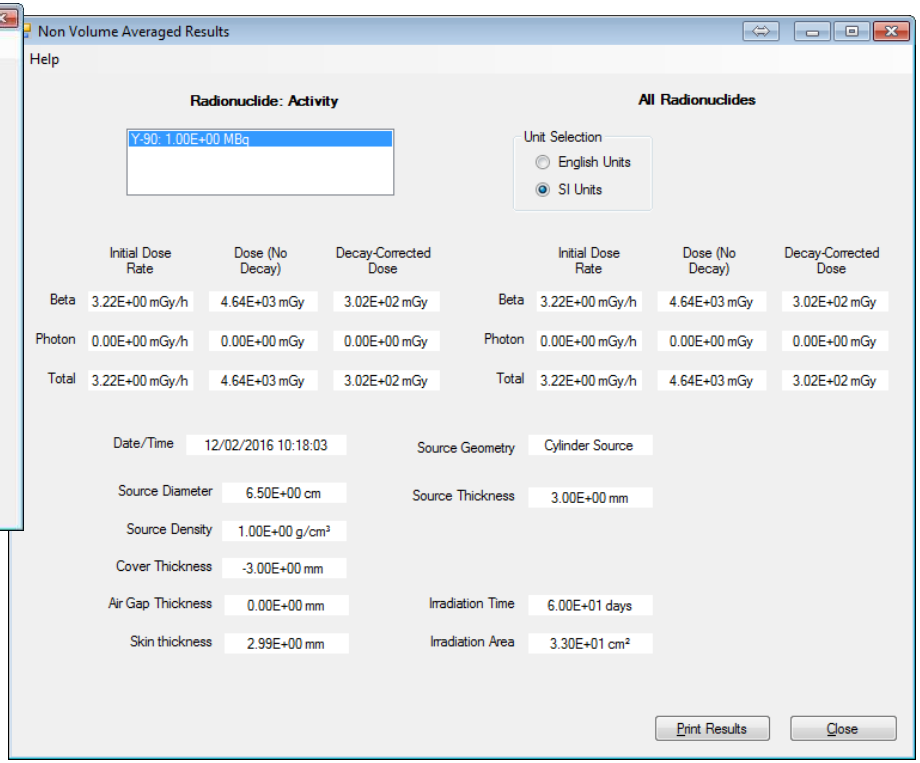


Extravasation of yttrium 90–ibritumomab tiuxetan.
Siebeneck B., Clinical Journal of Oncology Nursing, (12) 2, 2008

- Specific care should be adopted in administration of beta emitting and in particular of new alpha emitting radiopharmaceuticals

Estimate of skin dose in the case of extravasation





Be prepared

	ISTRUZIONE OPERATIVA AZIENDALE GESTIONE DEI CATETERI VENOSI PERIFERICI E DELLO STRAVASO NEL PAZIENTE ADULTO	IOA85 Rev. 1 Pag. 1/42

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11.0 PREVENZIONE E GESTIONE DEGLI STRAVASI DA RADIOFARM

11.1 CLASSIFICAZIONE DEI FARMACI

Come definito dal D.Leg. 24/04/2006 n. 219, si intende per radiofarmaco qualsiasi medicinale che, quando e' pronto per l'uso, include uno o piu' radionuclidi (isotopi radioattivi) incorporati a scopo sanitario.
I radiofarmaci sono impiegati sia a scopo diagnostico, sia per finalità terapeutiche.
Nella tabella 1 vengono elencati i principali radiofarmaci, classificati in base alla loro tossicità tissutale.
Le **sostanze irritanti** causano una reazione infiammatoria con dolore, bruciore, senso di oppressione e flebite, sito di inserzione e lungo la vena, che te risolversi velocemente in quanto sono sostanze rapidamente inattivate o velocer metabolizzate.
Le **sostanze vescicanti/necrotizzanti** causano necrosi tessutale fino a perdi spessore totale della cute e gravi danni alle strutture sottostanti in quanto, per i meccanismo d'azione, rimangono a lungo nel tessuto.

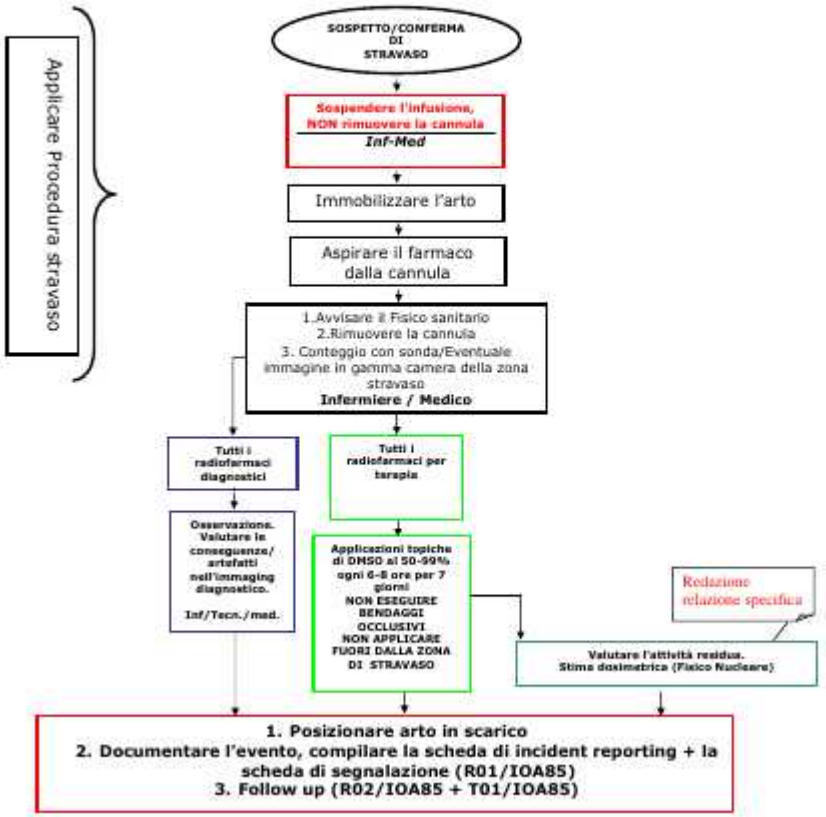
In linea generale, si ritiene di considerare irritanti i radiofarmaci per imp diagnostico caratterizzati da breve tempo di dimezzamento fisico. I radiofa per impiego terapeutico devono invece essere considerati vescicanti/necrotizzanti.

TABELLA 1: classificazione dei **radio-farmaci irritanti**, vescicanti/necrotizzanti

IRRITANTI	VESCICANTI / NECROTIZZANTI
^{99m}Tc - Pertecnetato	^{223}Ra – Dicloruro (Xofigo)
^{99m}Tc - MDP	^{90}Y - Zevalin
^{99m}Tc - MIBI	^{131}I - NaI
^{99m}Tc - MAG3	^{131}I - MIBG
^{99m}Tc - DMSA	Altri per farmaci impiegati per terapia
^{99m}Tc - MAA	
^{99m}Tc - Nanocoll	
^{18}F - FDG	
^{18}F - FLT	
^{18}F - NaF	
^{18}F - DOPA	
^{11}C - Colina	
^{11}C - Metionina	
^{68}Ga - DOTANOC	
Altri per farmaci impiegati per la diagnostica	

	ISTRUZIONE OPERATIVA AZIENDALE GESTIONE DEI CATETERI VENOSI PERIFERICI E DELLO STRAVASO NEL PAZIENTE ADULTO	IOA85 Rev. 0 Pag. 36/42

11.3 TRATTAMENTO

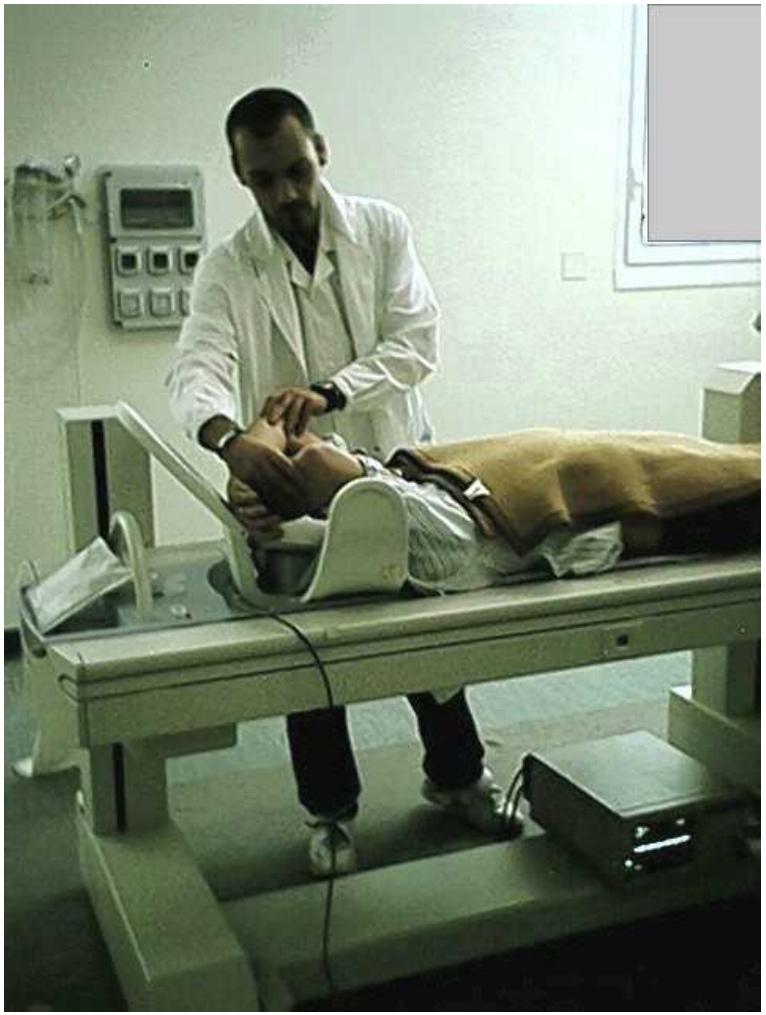


Patient fall / other mechanical injury

- Patient fall from the bed of scanners is the most frequent accident in diagnostic imaging Depts.
- This does not involve a dose absorpition.
- ... It is the same !!!

Note that:

- The patient carrier bed and its accessories (mats, belts, other objects useful for immobilization) are components of the medical device
- They shoudl be appropriately used
- Maintenance and periodical replacament are necessary



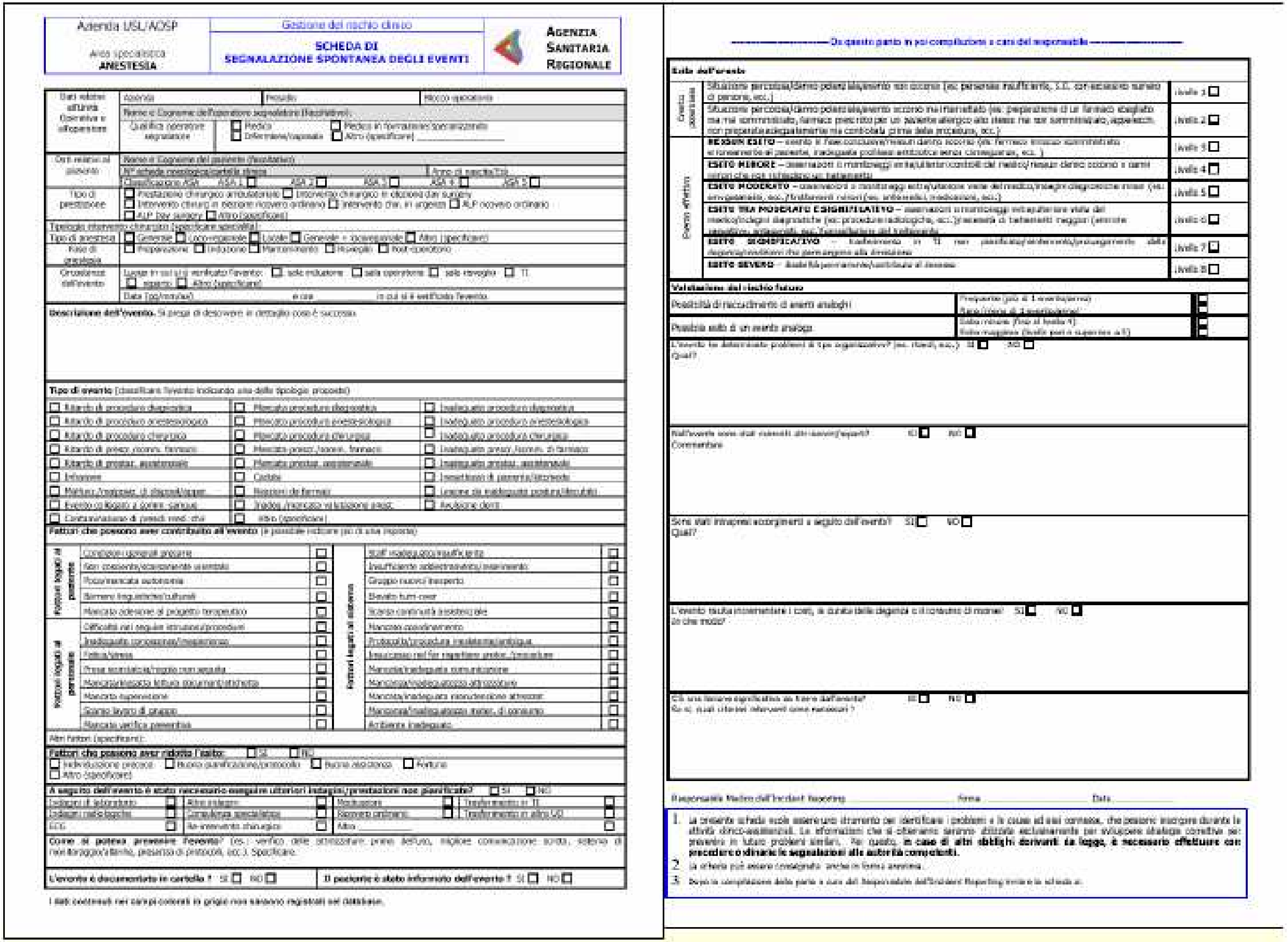
Reporting of accidents / Incidents

Significant problems remain with local and national incident reporting systems. These include:

- Fear of punitive action
- Poor safety culture in anorganization
- Lack of understanding among clinicians about what should be reported,
- Lack of awareness of how the reported incidents will be analysed,
- Lack of awareness on how will the reports lead to changes which will improve safety.

In the medical context, in particular, lack of systematic analysis of the reports and feedback directly to the clinicians and professionals is probabily one the major barriers to engagement.

Unified Incident Reporting form in Emilia Romagna



Azienda USL/AOSP | Gestione del rischio clinico | **SCHEDA DI SEGNALAZIONE SPONTANEA DEGLI EVENTI** | Agenzia Sanitaria Regionale

Area specialistica ANESTESIA

Dati relativi all'Unità Operativa e all'operatore: Azienda | Presidio | Blocco operatorio

Nome e Cognome dell'operatore segnalatore (facoltativo)

Qualifica operatore segnalatore: ☐ Medico ☐ Medico in formazione specialistica ☐ Infermiere/caposala ☐ Altro (specificare)

Dati relativi al paziente: Nome e Cognome del paziente (facoltativo); N° scheda nosologica/cartella clinica; Anno di nascita/Età; Classificazione ASA: ASA 1 ☐ ASA 2 ☐ ASA 3 ☐ ASA 4 ☐ ASA 5 ☐

Tipo di prestazione: ☐ Prestazione chirurgica ambulatoriale ☐ Intervento chirurgico in regime day surgery ☐ Intervento chirurgico in regime ricovero ordinario ☐ Intervento chir. in urgenza ☐ ALP ricovero ordinario ☐ ALP Day surgery ☐ Altro (specificare)

Tipologia intervento chirurgico (specificare specialità)

Tipo di anestesia: ☐ Generale ☐ Loco-regionale ☐ Locale ☐ Generale + locoregionale ☐ Altro (specificare)

Fase di anestesia: ☐ Preparazione ☐ Induzione ☐ Mantenimento ☐ Risveglio ☐ Post-operatorio

Circostanze dell'evento: Luogo in cui si è verificato l'evento: ☐ sala induzione ☐ sala operatoria ☐ sala risveglio ☐ TI ☐ reparto ☐ Altro (specificare); Data (gg/mm/aa) e ora in cui si è verificato l'evento

Descrizione dell'evento. Si prega di descrivere in dettaglio cosa è successo.

Tipo di evento (classificare l'evento indicando una delle tipologie proposte)

Fattori che possono aver contribuito all'evento (è possibile indicare più di una risposta)

Fattori che possono aver ridotto l'esito: ☐ SI ☐ NO

A seguito dell'evento è stato necessario eseguire ulteriori indagini/prestazioni non pianificate? ☐ SI ☐ NO

Come si poteva prevenire l'evento?

L'evento è documentato in cartella? SI ☐ NO ☐ **Il paziente è stato informato dell'evento?** SI ☐ NO ☐

I dati contenuti nei campi colorati in grigio non saranno registrati nel database.

Da questo punto in poi compilazione a cura del responsabile

Esito dell'evento

Livello 1 ☐ Livello 2 ☐ Livello 3 ☐ Livello 4 ☐ Livello 5 ☐ Livello 6 ☐ Livello 7 ☐ Livello 8 ☐

NESSUN ESITO – **ESITO MINORE** – **ESITO MODERATO** – **ESITO TRA MODERATO E SIGNIFICATIVO** – **ESITO SIGNIFICATIVO** – **ESITO SEVERO**

Valutazione del rischio futuro

Possibilità di riaccadimento di eventi analoghi; Possibile esito di un evento analogo

Responsabile Medico dell'Incident Reporting — Firma — Data

See also Di Denia et al., Pratica Medica & Aspetti Legali, V. 6, N. 1 (2012)

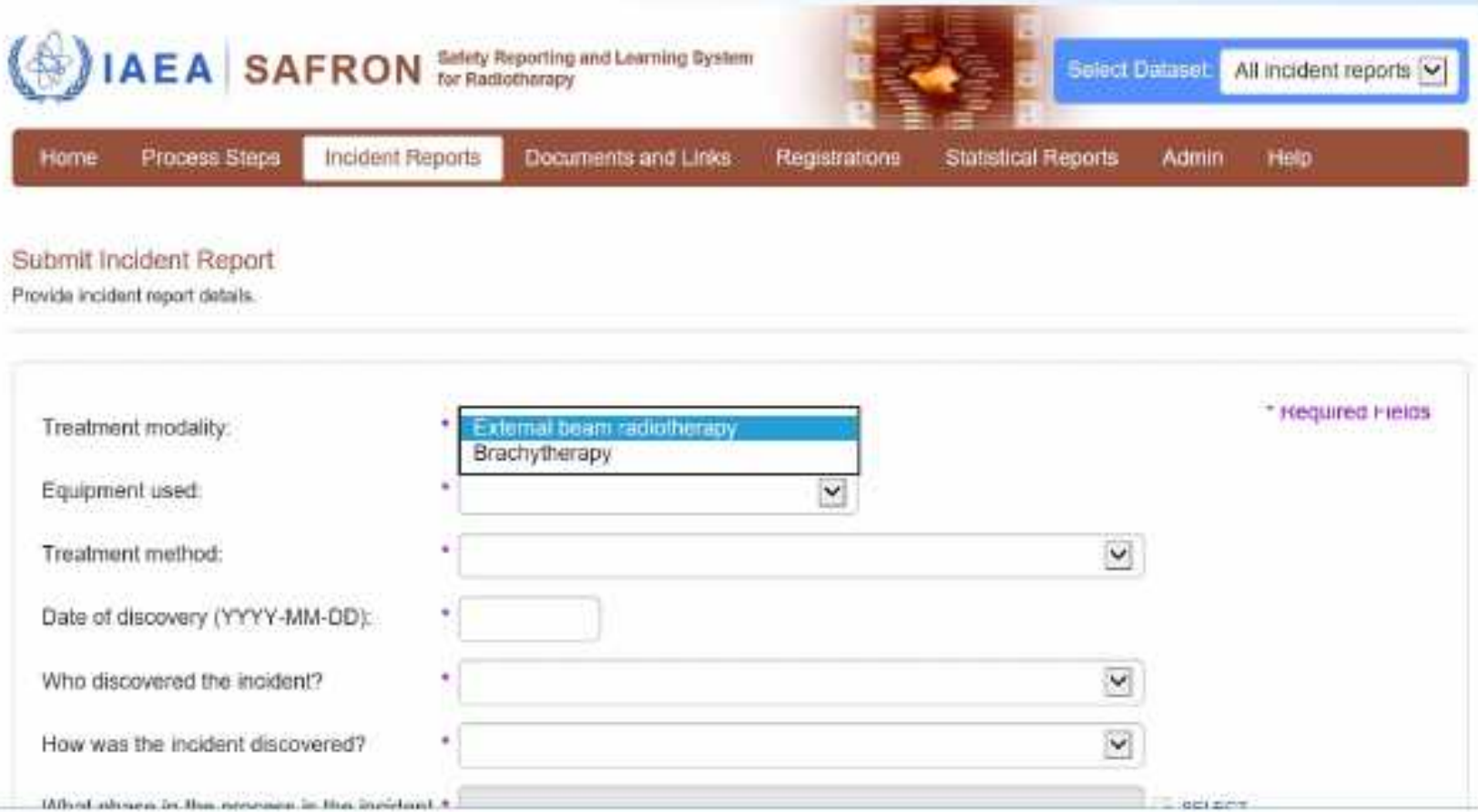
International System SAFRON - Features

SAFRON reporting system:

- is non-punitive, anonymous, voluntary, educational and international system
- does not replace the regulatory reporting requirements of an institution
- collaborates with other reporting systems, and contains incident information gathered by the IAEA, ROSIS,CRCPD, ASN, Norway, Spain, and registered participants
- Currently has aver 1500 events from 4 regulatory authorities and 102 facilities worldwide

Credits to Debbie Gilley

Adding Radiopharmaceutical Therapy Events to SAFRON



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Adding Radiopharmaceutical Therapy Events to SAFRON

Home | Process Steps | Incident Reports | Documents and Links | Registrations | Statistical Reports | Admin | Help

Browse Process Steps

You can view all the process steps for a selected treatment modality.

Please choose your preferred dataset in the top right corner of this screen. Based on this selection, you can browse your own or all incident reports.

All process step for: External beam radiotherapy / Brachytherapy

- 1. Non-clinical phase
  - 1.1. Equipment and software specific activities
    - 1.1.1. New equipment
      - 1.1.1.1. Installation
      - 1.1.1.2. Acceptance tests
      - 1.1.1.3. Customization and configuration of equipment
      - 1.1.1.4. New equipment - Commissioning
      - 1.1.1.5. Data recording
      - 1.1.1.6. Preparation of data files for planning computers
      - 1.1.1.7. Other
    - 1.1.2. Routine machine QA
      - 1.1.2.1. Daily consistency checks
      - 1.1.2.2. Planned QA programme checks

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Adding Radiopharmaceutical Therapy Events to SAFRON

What safety barrier	failed to identified the incident?	identified the incident?	might have identified it?
Verification of patient ID	☐	☐	☐
Verification that pretreatment condition have been taken into account	☐	☐	☐
Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)	☐	☐	☐
Verification reference points	☐	☐	☐
Physician peer review	☐	☐	☐
Review of treatment plan	☐	☐	☐
Independent confirmation of dose	☐	☐	☐
Time out	☐	☐	☐
Use of record and verifying system	☐	☐	☐
Verification of treatment accessories	☐	☐	☐
Image based position verification	☐	☐	☐
In vivo dosimetry	☐	☐	☐
Intra-treatment monitoring	☐	☐	☐
Regular independent chart checks	☐	☐	☐
Regular clinic patient assessment	☐	☐	☐
Post treatment evaluations (evaluation of clinical and process)	☐	☐	☐
Independent review of commissioning	☐	☐	☐
Regular internal audit	☐	☐	☐
Regular external audit	☐	☐	☐
Regular equipment performance verification	☐	☐	☐
Other, please specify	☐	☐	☐

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(Some) Conclusions

- Prevention of accidents, their management and reporting require not only appropriate provisional risk analysis, but also a properly organized Quality Systsem, with detailed and cross-linked procedures, and a functional reporting system

- The whole process should be under strict control, starting from the mechanism of patient referral

- An accurate identification of the patient and of the unit doses to be administered is necessary; the concept of traceability should be applied

- The process should be developed and monitored in order to avoid mis-administrations; in the case such an event happens, there should be in place procedures aimed to proper communication and to limit the unjustified dose absorbed by the patient

- Each activity administered to patients should be individually measured and be conforming to international guidelines, the SPC of the radiopharmaceutical and the Diagnostic Reference Levels

- In the case of multi-modality imaging, the CT component should be properly tuned; if only non-diagnostic CT is required, for attenuation correction and navigation in the image set, limited current data can be used satisfactorily

- ...

Tbd ...

Errors in medicine are common, and reporting them is a crucial component in their management and building the capacity to prevent them and being ready to react, in the undesirable occasion of an incident

Hospitals and health institutions should encourage the reporting of incidents and “near misses”, and investigate them promptly looking for causes. Various methods and platforms are available and many hospitals use software tools for online reporting, which facilitate efficient data collection. Despite these efforts, there is still resistance to reporting in some organizations.

A “no blame” environment should be created while balancing safety and accountability.

Learning from errors that do occur is a key factor in reducing the risk of repetition of similar mistakes, or at least decreasing their severity and maintaining and improving the quality of healthcare.

In addition to the internal reporting within the NM department, **a large scale gathering of experiences from events** is beneficial in looking for trends that extend beyond a facility and so helping to improve safety culture.