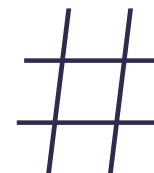
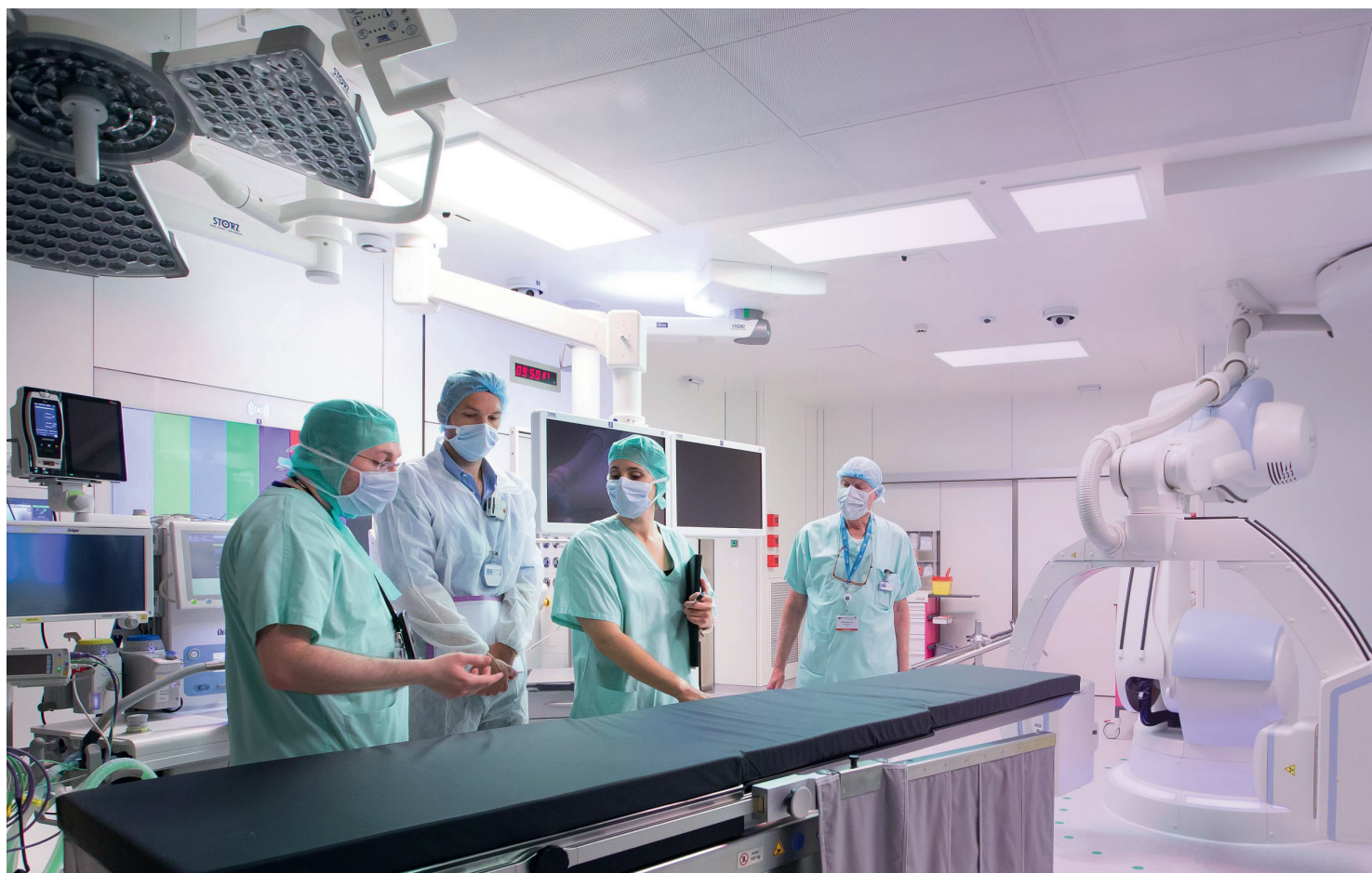


# PATIENT SAFETY

PAVING THE WAY FOR PROGRESS



May 2023



## MASTERING MEDICAL DEVICES IN FLUOROSCOPY-GUIDED INTERVENTIONAL PRACTICES: A COLLABORATIVE EFFORT

Newsletter for medical professionals involved in fluoroscopy-guided interventional practices



# EDITORIAL

**At a time when imaging devices using ionising radiation are becoming increasingly sophisticated, this newsletter urges the teams to recognise the importance of these medical devices (MD) for the safety of fluoroscopy-guided interventional practices.**

Misuse and errors in the management of MDs represent the second most frequent cause of patient significant radiation protection events (SRPEs) in interventional procedures notified to ASN.

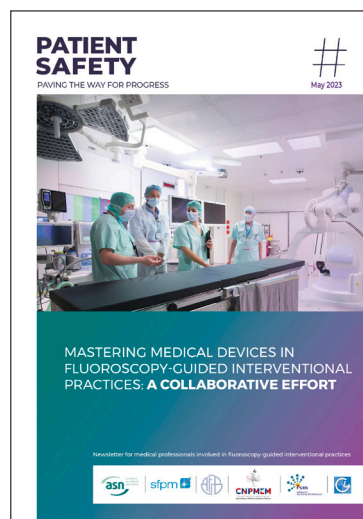
**These events highlight all the organisational difficulties, particularly with regard to training and co-ordination between the actors concerned.**

Incorrect parameter setting or inappropriate use of a function can lead to overexposure of patients. Vigilance is vital, because it is difficult to detect changes in dosimetric parameters and detection is often late if the medical device is not connected to a Dosimetric Archiving and Communication System (DACs), hence the potentially large number of patients concerned.

Many different members of hospital staff interact around a medical device (medical physicist, biomedical engineer and technician, medical staff who use it), along with personnel from various outside companies (application engineer, maintenance technician, external quality control organisation). **For each MD, the transmission of information between these various actors and the user services is a real safety issue!**

**Wishing you enjoyable reading!**

The Editorial Team



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## Key figures

During the period from 2016 to 2021, a total of 137 significant radiation protection events (SRPEs) were notified to ASN in fluoroscopy-guided interventional practices (FGIPs), i.e. about twenty SRPEs per year. Half of these events (60 SRPEs) involved patients.

The SRPEs are observed on MDs dedicated to neuroradiology, interventional radiology and coronary cardiology activities. These SRPEs result primarily from “difficulties specific to the examinations (procedures involving the highest exposures, sometimes performed in an emergency context), without there being any identified technical

malfunction” (notification criterion 6.1 on the initiative of the medical centre for sharing lessons learned).

In second place we find the application of parameters and protocols or errors in functions. **These MD misuses and management errors** result from organisational and human problems.

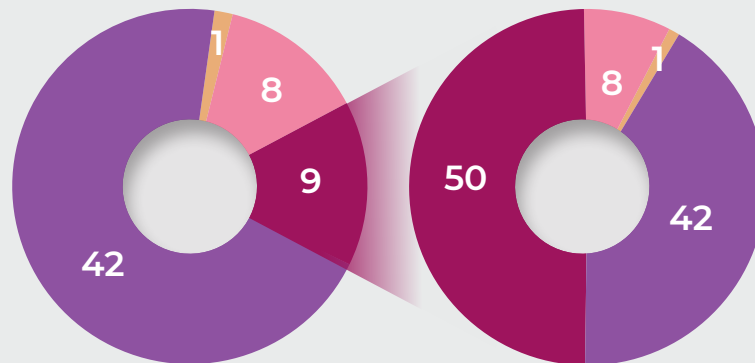
They can have consequences on the dosimetric parameters of the protocols (which can lead to higher than expected exposures) and on image quality (which can lead to difficulties in interpreting the results of the examination, or even render it unusable).

The later the discover of the consequences of the malfunction, the larger the number of patients concerned, hence the importance **Over the 2016-2021 period, 50 patients were concerned by the 9 SRPEs resulting from MD misuse or mismanagement.**

Lastly, just over 10% of the SRPEs are associated with a **problem of medical devices vigilance** (malfunction of the MD itself) and are notified to the ANSM.

### Causes of the 60 patient SRPEs in fluoroscopy-guided interventional practices (criteria 2.2 and 6)

- Examination difficulty with no technical malfunction
- Misuse, errors in MD management
- Medical devices vigilance problem
- Identity monitoring problem



### Number of patients concerned according to the cause of the SRPEs

- Examination difficulty with no technical malfunction
- Misuse, errors in MD management
- Medical devices vigilance problem
- Identity monitoring problem

Statistics drawn from the healthcare centres' notifications via the ASN on-line services portal for the 2016-2021 period.



## Decoding the event

The events are mainly caused by a **change in exposure parameters** that has gone unnoticed due to a lack of communication between the people concerned (no knowledge of the performance or content of maintenance, quality control or updating work on the MD).

### Key actors in the MD monitoring chain

- External: the application engineer, the maintenance company and the external quality control organisation,
- Internal: the medical physicist, the biomedical engineer and technician, the radiation protection expert-officer (RPE-O) or the radiation protection organisation (RPO) in relation with the user services: supervisors, physicians, radiographers and state-registered operating theatre nurses.

### ■ Main organisational causes of SRPEs:

- the lack of risk mapping targeting the risk-prone maintenance operations (replacement of X-ray tube, software updating, urgent context at night or during the week-end);
- failings in the organisation put in place for the scheduling of inspections and the systematisation of information feedback;
- insufficient control and coordination of subcontracted activities:
  - late detection of a change in a protocol parameter by the medical physics team (internal or external service provider),
  - deficient circulation of information in a multiple outsourcing context,
  - maintenance staff, quality control organisations and physicists external

to the medical centre, without adequate supervision by a person from the centre;

- insufficient training of the users (physicians, radiographers) preventing them from detecting the modification of one or more key parameter(s) of a protocol;
- mismatch between the number of medical devices and medical physics staff numbers.

### ■ Contributing factors:

- the fact that the medical device is not connected to a Dosimetric Archiving and Communication System (DACs);
- the absence of a data watch and alerts from a DACs.



## Background: definitions

### ■ Fluoroscopy-guided interventional practices (FGIP)

The FGIPs group “*all the imaging techniques using ionising radiation to perform invasive medical or surgical procedures for diagnostic, preventive or therapeutic purposes, and surgical and medical procedures using ionising radiation for the purpose of guidance or verification*”. Appendix 13-7 first part of the Public Health Code.

### ■ The two categories of MD malfunction

**Malfunctions in the management of a functional MD** comprise the misuses and errors leading to the application of incorrect parameters, protocols or functions without the users being aware of them.

**Malfunctions of the MD itself** require the sending of a **medical devices vigilance notification to the ASN**. The aim of medical devices vigilance is to monitor MDs once they have been put on the market in order to prevent incidents and risks of serious incidents from occurring or reoccurring, by taking appropriate preventive and/or corrective measures.

### ■ What must be notified to ASN?

SRPEs concerning FGIPs must be notified to ASN under criterion 2.2 whatever the type of procedure, because

the ionising radiation is used for diagnostic or guidance purposes (and not for treatment as is the case with radiotherapy, brachytherapy and therapeutic nuclear medicine).

The SRPEs can result from an inappropriate practice, a utilisation error or even a malfunction of the MD that has caused or could cause exposures significantly higher than the diagnostic reference levels, or errors in performing the examination.

Furthermore, it is worthwhile notifying ASN, under criterion 6.1, of SRPEs that are not linked to a malfunction and which have led or could lead to overexposure, because a lot can be learned from such events.

### ■ Dosimetric archiving and communication systems

DACS-type software applications meet the obligation to put in place a “*system for the systematic collection and archiving of dosimetric data*” which is stipulated in the new healthcare licensing decrees, particularly for interventional practices using medical imaging in cardiology and neuroradiology, in an approach that is graded according to the radiation exposure risks for the patients.



## Steps for progress

### Innovative initiative

From left to right: **Mailys MICHEL** and **Christelle GALLAIS**, medical physicians, **Fabien VOIX**, medical centre senior supervisor, **Nathalie CAYOT** and **Sandrine BRUNETEAU**, health supervisors  
**Poitiers University Hospital**

“No (re)starting of a machine without prior verification by the medical physicist and without a suitable protocol”



In June 2020, the University Hospital of Poitiers set up an monthly coordination meeting on medical devices

### In practice

#### ■ What organisation has been put in place?

Following a significant event that occurred in March 2020 due to a parameter setting problem and repeated situations where only the service supervisor was informed of

the corrective updating of a medical device, we decided to change our organisation to guarantee that the medical physicists are available when they are needed.

Since then, on the first Monday of each month, all the people concerned meet to review the medical devices of the Poitiers University Hospital,

including the supervisors of the two outlying sites of Montmorillon and Châtelleraut.

The meeting is attended by the two imaging physicians, the two biomedical engineers and all the management staff: the senior supervisor, the three radiology supervisors and the nuclear medicine

supervisor. The meeting agenda is prepared by the medical physicist.

### ■ **What is the purpose of this meeting?**

The prime aim is to plan the medical device inspections and preventive or corrective maintenance operations. Planning ahead in this way guarantees that the medical physicist is properly informed, particularly for operations to be carried out during the week-end or unconventional hours. It has enabled us to institute a systematic quality control before any device is returned to service.

The meeting also addresses the tracking of failures and nonconformities and reviews the results of the interventions. It provides the opportunity to give

feedback on the operation of the devices, and the support and training of the teams.

Today the discussions have widened to cover a watch on equipment problems, the management of new equipment projects and clinical studies, for example.

### ■ **After two years, what benefits have been drawn?**

The requirements of each person involved are better known. Genuine relations of trust have been established between the supervisor and the medical physicist who is now unquestionably an integral part of the team.

The meeting has highlighted the importance of the medical physicist's equipment optimisation work and the added value it brings.

The medical physicist is present at the installation of the medical device to gather all necessary information from the application engineer, supplement it if necessary and then be the resource person for all the radiographers.

Thanks to this organisation, no machine is restarted without adapting the manufacturer's protocol and the medical centre's parameters are integrated by the manufacturer during equipment acceptance testing.

In addition, the medical physics criteria are taken into account from the outset in the choice of new medical devices.

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## Good practices - Recommendations

Formalise a robust organisation between the various actors involved in the quality management system, based on the following fundamentals:

### ■ **MAP THE RISK**

- Identify the medical devices on which the most highly exposing procedures are performed (procedures with diagnostic reference levels (DRLs), treatment of patients at risk or undergoing iterative procedures);
- Prioritise the monitoring actions on this type of MD throughout its service life (choice of MD, user training, connection to the DACS, determining the risky maintenance operations, quality controls and coordinating with the periodic radiation protection verifications);
- Identify any points requiring vigilance (relations between external service providers for example).

### ■ **ORGANISE INFORMATION SHARING AND MAKE IT SYSTEMATIC**

Within the medical centre, provide means of sharing information between the actors in order to:

- Define the organisation, including in case of failure (division of roles and tasks between the different actors);
- Communicate the maintenance operations and inspections schedule;
- Distribute the intervention reports;
- Examine the data collected if a specific monitoring system has been put in place.

With outside personnel (suppliers and maintenance service providers in particular), define the conditions for ensuring traceability and effective communication concerning the work interventions:

- the technical information necessary for drawing up the intervention report;
- the deadlines for obtaining the reports;
- the points of contact for the application engineer and the maintenance technician;
- the information transmission circuit.

### ■ **TRAIN THE VARIOUS USERS**

When purchasing a new medical device, plan with the supplier for training the teams in its use, in order to ensure:

- that its utilisation is mastered by the medical, paramedical, medico-technical and technical personnel (including newcomers);
- that the actions having an impact on patient safety are identified.

The in-person training during the installation of the MD can be usefully supplemented later on by digital training courses.

To learn how to use complex MDs rapidly and without apprehension, users may be proposed an immersion course in a reference centre.

As a complement, providing **operational support media in French** enables:

- the radiographer resource persons to pass on the information to their colleagues and to newcomers;
- the service supervisor to define the specific work tasks qualification criteria.

### ■ **PUT IN PLACE A DOSIMETRIC ARCHIVING AND COMMUNICATION SYSTEM (DACs)**

For the MDs representing significant radiation risks listed in the risks mapping, define a calendar for connection to a DACS, associated with a reflection on:

- the adequacy of the medical physics resources to be able to use the data in an acceptable time frame;
- the dose alert thresholds;
- the methods of informing the users before and after intervention on the MDs;
- the type of information to give to the users;
- any studies required according to the user's needs;
- the conditions of annual information feedback as part of the analysis of the local reference levels (LRLs);
- the collection of data for the DRLs.



## The experience of the centres

“Coordinating the quality control and radiation protection verifications increases our vigilance with regard to parameter setting errors”



From left to right: *Xavier TABEY* and *Valentin BOUTARD*, radiographer and RPE-O - *Pr Denis ANGOULVANT*, head of the Cardiology Service - *Emmanuel GÉMON*, health supervisor, Haemodynamics and interventional cardiology laboratory - *Maguelonne JALBY*, quality and radiation protection engineer - *Dr Serge MAIA*, PH - SCR supervisor - *Hélène BOUSCAYROL*, medical physicist - **Tours Regional University Hospital**

### ■ The Regional University Hospital of Tours detected a parameter setting error in 2021. Under what circumstances was the SRPE discovered?

In early June 2021, on a medical device used for vascular functional explorations, the medical physicist found dose values that were three times higher than the reference values. This nonconformity was detected on reception of the report on the quarterly internal quality control carried out one month earlier by an outside company on a complete treatment protocol.

The medical device was stopped. The manufacturer's technician came the next day and found that the “low dose” block was unticked. The date and cause of the modification were not clearly identified but could date back to early April when preventive maintenance and software reloading were carried out. According to the information available on the planning software, 36 patients were involved in short procedures with low exposure levels, such as cardiac biopsies.

### ■ How was the SRPE analysed?

The SRPE was analysed with the support of the Quality Department in accordance with the root causes analysis method, ALARM. The cardiologists were particularly closely involved along with the biomedical

services, the physicians, the supervisors, the radiographers and the radiation protection service. This greatly helped to emphasise the importance of radiation protection and each person's role in giving the alert when necessary.

### ■ What lessons were learned from this SRPE?

The quality control barrier allowed retrospective detection of the error. This prompted us to harmonise the radiation protection verifications between the various medical devices, always using the same parameters. The verifications are now carried out using the same protocols, which enables dose values to be compared over time and any drifts to be detected. In addition, the event highlighted the risk associated with belated transmission of information on the maintenance operations performed, as well as a problem with patient file traceability on the cardiology doses archiving software.

### ■ What measures have you taken?

We have improved coordination within the teams and with the external service providers in charge of quality control and maintenance. We have asked that reports be more detailed and be submitted more quickly in order to rapidly identify any “risky” maintenance work and any significant deviation in the quality controls.

An e-mail list common to the biomedical and medical physics teams makes for better circulation of information.

In addition to this, the medical physics function has put in place a training course on localising the low dose module and filtration for the operators using the medical device in order to encourage verifications if there is the slightest doubt. Two radiographer resource persons dispensed the manufacturer's specific training course internally.

Lastly, the medical devices used in cardiology, which present the greatest radiation exposure risks, were connected to the DACS in priority in early 2022.

## The point of view of the National Union of the Medical Technologies Industry (SNITEM)

“Share user practices to improve application follow-up”

Jérôme CHEVILLOTTE  
Chairman of the SNITEM  
imaging group



engineering, medical physicist or supervisor - that person receives a copy.

However, it is not always possible to verbally communicate the significant aspects of the intervention, particularly if it took place at night or during a week-end when the customer is absent.

### WHAT DO YOU PROVIDE FOR THE USERS?

The user support is above all relational, through the application engineer and telephone support. The law requires an approved user manual to be provided in French, along with on-site training. However, the manufacturers increasingly develop varied teaching aids: quick guides, technical data sheets, FAQs or training material for newcomers.

A third of our customers benefit from increased on-site presence and access to classroom training under an application follow-up contract. Lastly, national or regional users' clubs provide greatly appreciated feedback for the radiographers and physicians.

### WHO ARE THE MEDICAL CENTRE'S CONTACTS FOR MEDICAL DEVICE FOLLOW-UP?

The follow-up of medical devices - installation, parameter setting and user training - is ensured by the **application engineer**. This specialist in a medical imaging method, who is a trained radiographer or biomedical engineer, answers questions concerning the use of the medical device. The application engineer receives in-depth internal training on the manufacturer's medical devices. Their know-how is attested by internal certification which is renewed annually.

The “**remote maintenance**” support engineer resolves some failures remotely, diagnoses failures and determines the spare parts to be delivered for on-site interventions.

The **technician** ensures the preventive maintenance (checking correct operation of the system) or corrective maintenance

(resolving problems) while the application engineer is called for operations involving significant parameter changes.

### HOW IS THE TRAINING ON THE MEDICAL DEVICES DELIVERED?

The training is progressive. It begins with a half day without patients, then continues over one to two weeks with a gradual increase in the number of patients. After this, another session is organised remotely to answer the users' questions.

### HOW ARE WORK INTERVENTIONS REPORTED?

Any intervention is duly documented. The report is drawn up and transmitted to the requesting person or entity within 24 hours for a technical intervention or within 5 days for work on the application. If there is a resource person - biomedical



## Further reading

### FLUOROSCOPY-GUIDED INTERVENTIONAL PRACTICES

■ **French Cardiology Society** - Interventional group: Guide to good patient radiation protection practices in interventional cardiology, 2015



■ **French National Authority for Health (HAS)** Improving patient follow-up in interventional radiology and fluoroscopy-guided procedures, May 2014



■ **ASN** : Risk mapping for activities involving high radiation exposure risks for patients. ASN resolution 2019-DC-0660 of 15 January 2019 setting the quality assurance obligations in medical imaging using ionising radiation and in diagnostic nuclear medicine



### MEDICAL DEVICES (MD)

■ **French Health Products Safety Agency (ANSM)** Recommendations concerning the acceptance testing of MDs used for fluoroscopy-guided interventional procedures, April 2018

Clarification on the maintenance of medical devices, October 2011

■ **ASN**: Recommendations concerning training in the use of MDs established with AFIB, AFPPE the G4, SFPM and SNITEM with the participation of ANSM, June 2016

Maintenance and quality control of medical devices. Appendix 8 of the ASN guide to the main regulatory provisions, October 2021



## PATIENT SAFETY

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**MARCH 2011** - PATIENT IDENTIFICATION

**NOVEMBER 2011** - THE FIRST VERIFICATION SESSION

**JULY 2012** - HOW DO YOU ANALYSE YOUR SIGNIFICANT RADIATION PROTECTION EVENTS?

**APRIL 2013** - WHAT EVENTS MUST BE NOTIFIED TO ASN?

**DÉCEMBER 2013** - IN-VIVO DOSIMETRY

**MAY 2014** - LATERALITY ERRORS

**MACH 2015** - RECORD AND VERIFY: RECORDING ERROR!

**JUNE 2015** - PULSED DOSE-RATE AND HIGH DOSE-RATE BRACHYTHERAPY

**MAY 2016** - HIGH-PRECISION HYPOFRACTIONATED IRRADIATION

**JANUARY 2017** - DOSE PROTRACTION / FRACTIONATION

**SEPTEMBER 2017** - MAKING THE PATIENT A PARTNER IN TREATMENT SAFETY

**JUNE 2018** - PATIENT REPOSITIONING IMAGING: VERTEBRA IDENTIFICATION ERROR

**MARCH 2019** - EXPERIENCE FEEDBACK IN OTHER COUNTRIES

**JULY 2019** - IMPROVING THE USE OF CT SCANNER FUNCTIONS

**MARCH 2020** - SAFETY OF THE RADIOPHARMACEUTICAL CIRCUIT IN NUCLEAR MEDICINE

**SEPTEMBER 2021** - IONISING RADIATION: LIMITING THE EXPOSURE OF WOMEN UNAWARE OF THEIR PREGNANCY

**OCTOBER 2021** - PATIENT FOLLOW-UP FURTHER TO RADIOTHERAPY INCIDENTS - REVIEW OF 10 YEARS OF USE OF THE ASN-SFRO SCALE