



HAUTE AUTORITÉ DE SANTÉ

Major concerns in quality and safety of radiation technology medical use

Example of the French perspective

Introduction to Session 3 “Quality and safety: improving medical practice”

Prof. Dominique LE GULUDEC
Haute Autorité de Santé

European Commission conference - 20th March 2018

Quality and safety of care : major challenges to improve medical practice

PREVENT RISKS

Risk assessment, integrating safety upstream, limiting exposure, optimizing doses...

SECURE HEALTH FACILITIES AND EQUIPMENT

via authorizations, accreditation

MANAGE SERIOUS ADVERSE EVENTS

400 000 serious adverse events for hospitalization/yr.
40% preventable.


IMPROVE APPROPRIATENESS OF MEDICAL CARE

Number 1 priority
“do no patient harm”
right health intervention,
right time, right place,
right patient

In a constrained environment, appropriateness of medical care needs to be actively pursued in the presence of continued innovation.

Societal component: public acceptability

Prior to questions pertaining to medical risk, medical use of radiation technology raises **the issue of public acceptability**.



This highly sensitive topic calls for combined and increased efforts with regards to:

- ✓ **Vigilance & Quality Assurance Safeguards**
- ✓ **Evidence-based Public Health Pedagogy**
- ✓ **Transparency**

Improving and securing RT medical use

Facilities and equipment

- ✓ **Declarations/ authorizations**
- ✓ **Developing standards** for installation
- ✓ **Classification rules** (« zonation »):
 - ❑ Specific restricted area according to doses
- ✓ **Accreditation of health facilities**
 - ❑ “Management of patient care in high-risk sector”

Professionals

- ✓ **Use of ionizing radiation on human body is restricted to medical specialized doctors**
- ✓ **Patient RP:**
 - ❑ Justification and optimization according to **professional guidelines**
 - ❑ Periodic evaluation of delivered doses
 - **Comparison to diagnostic reference levels**
 - **Annual values sent to IRSN**
- ✓ **Training in patient RP updated every 10 years¹**

Major players in quality and safety : IR medical use

*Dedicated players
in nuclear and radiation risk management*



Scientific body



Regulatory body

*Dedicated player
in quality and safety of care*

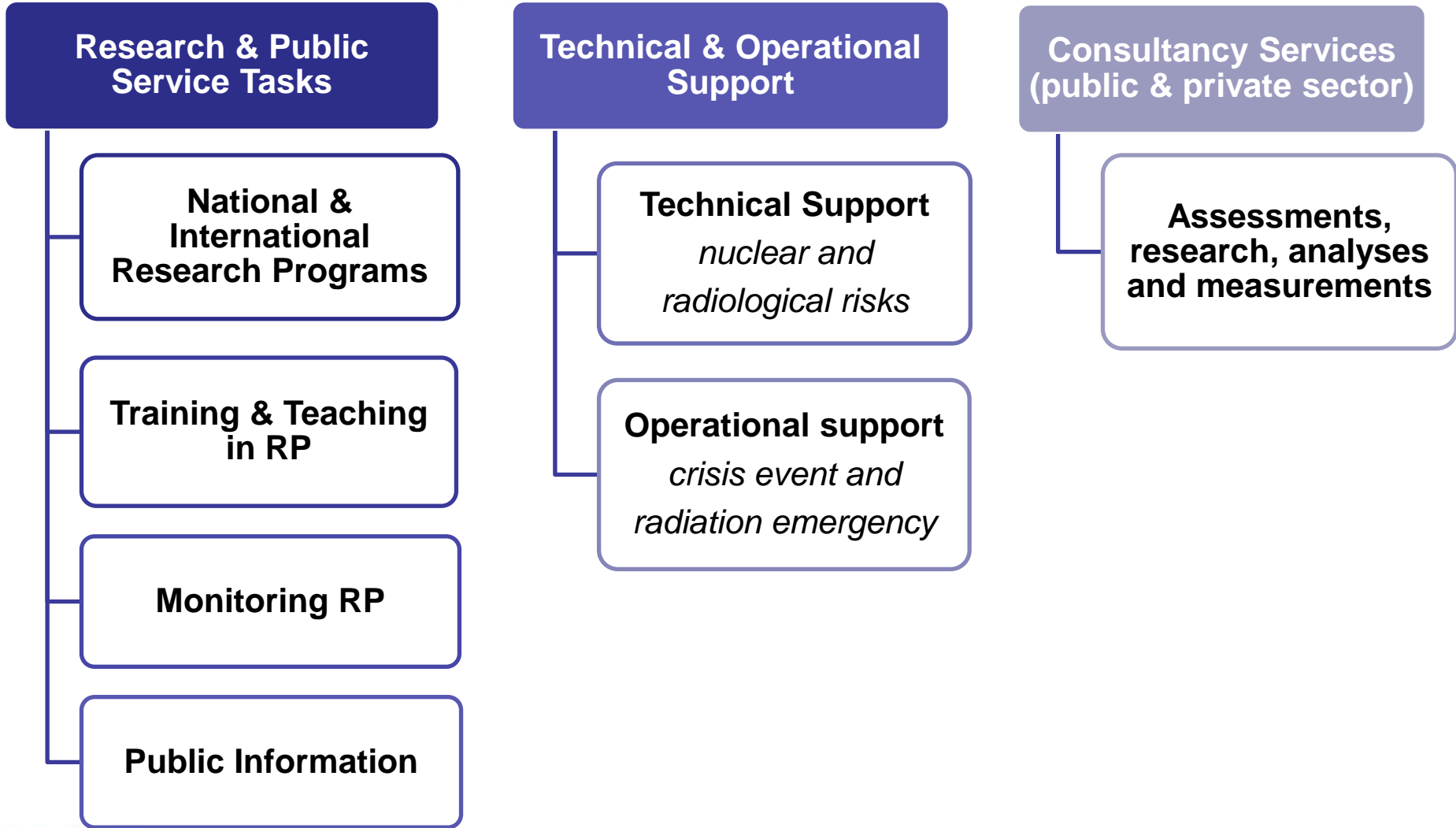


Scientific body



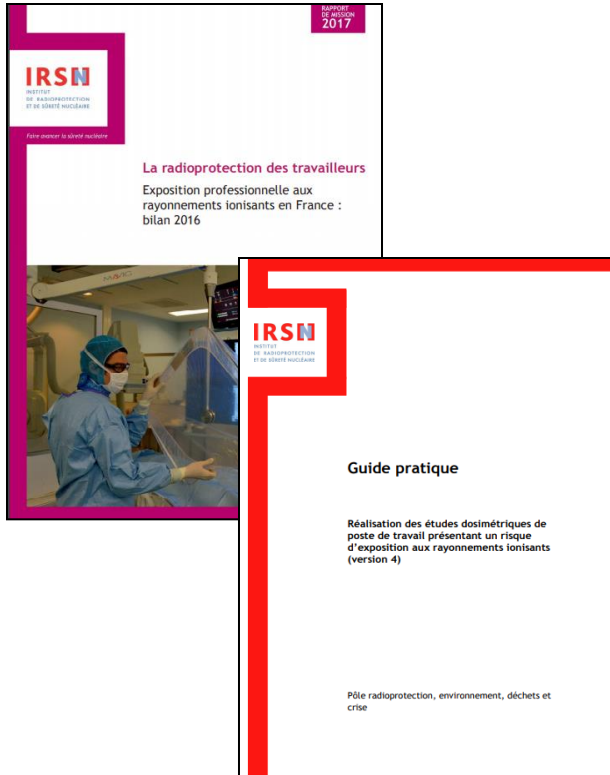
*includes
radiation technology activities*

France's public service expert in nuclear and radiation risk



Developing and Building on RP expertise

IRSN Publications



- Review on Workers RP Professional exposure to ionizing radiation in France (2016)
- Practical Guide on Performing dosimetric studies for occupational exposure to ionizing radiation

Associated Networks



European Radiation
Dosimetry Group



International Commission on
Radiological Protection

France's Regulatory Body: The Nuclear Safety Authority

Regulation

- Issues opinions on decrees and ministerial orders
- Issues technical regulatory decisions
- Makes individual decisions

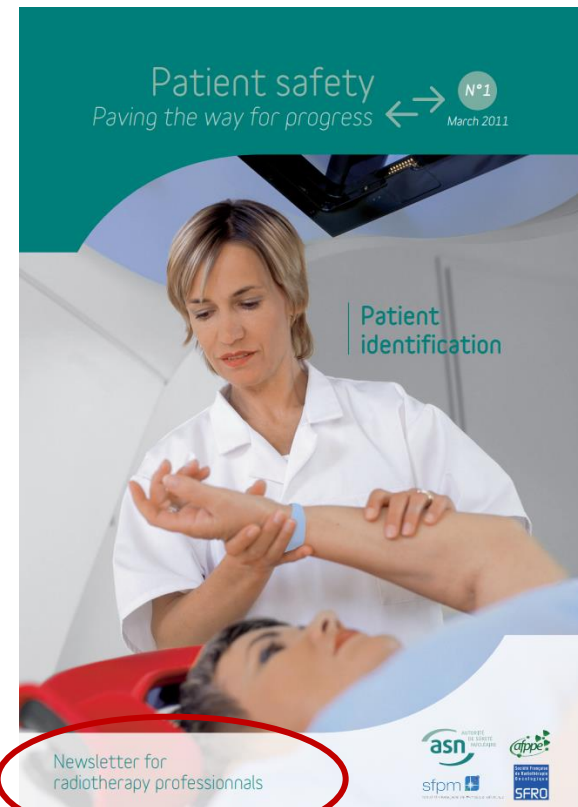
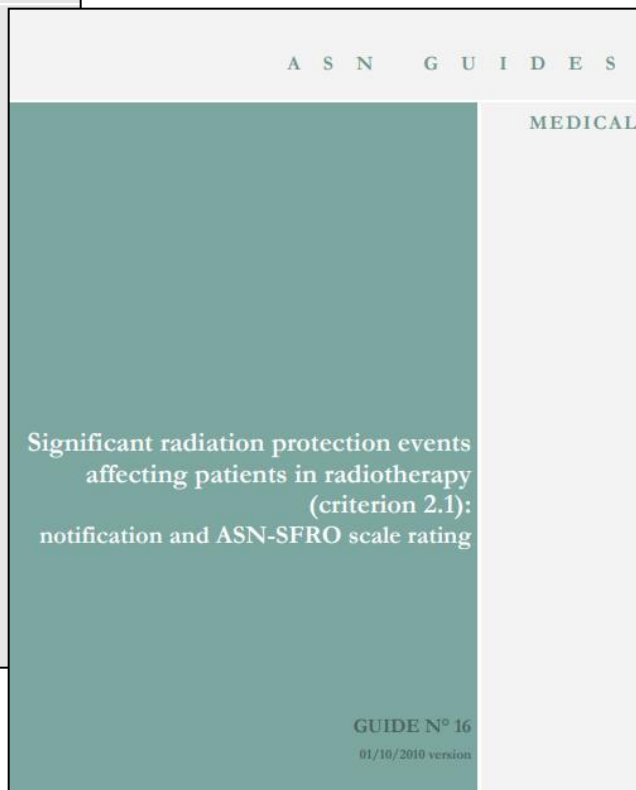
Inspection

- Ensures compliance with rules and specifications
- Empowered to enforce and sanction

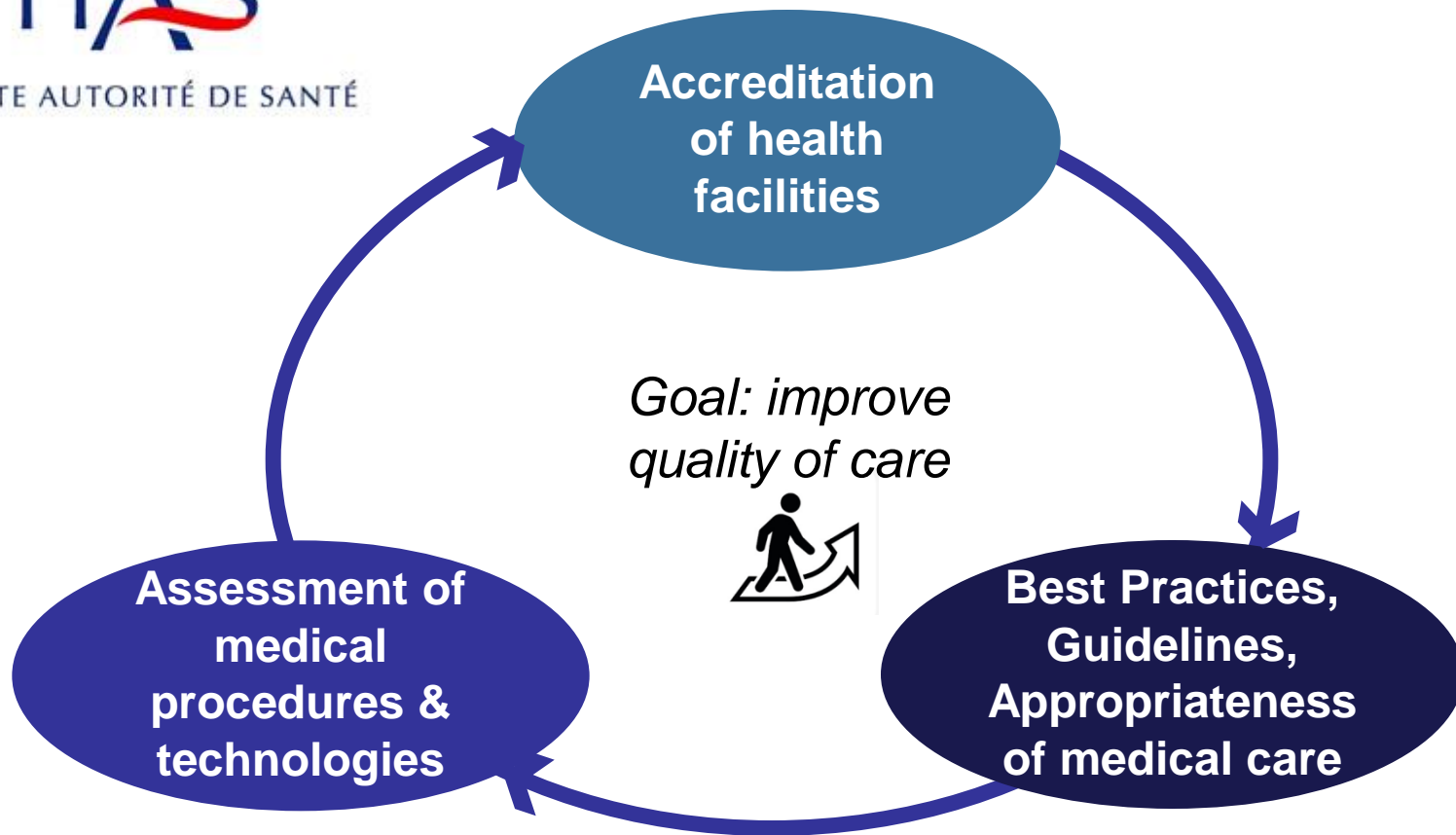
Information

- Keeps the public and stakeholders informed
- Assists in emergency situations

Publications on quality and safety (in English)



French National Authority for Health (HAS): its broad scope of activities



HAS' activities contributing to quality and safety of RT medical use

Accreditation of health facilities

Quality and safety indicators

Patient safety, Accreditation of health professionals

Continuing Professional Education (CPE)

CPE: HAS in charge of validating and providing methods to help professionals implement continuing professional education programs

Best practices, Guidelines, Appropriateness of medical care

HTA
Focus on health procedures

3 Health Sectors using IR and European Legislation



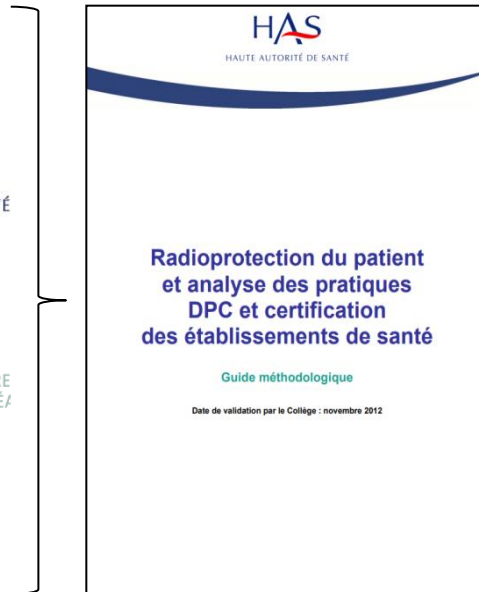
Radiology

Nuclear
medicine

Radio-
therapy

- In transposing the European directive EURATOM 97/43, **HAS was mandated in France to define** (with health professionals) **how to implement** assessment of clinical practices exposing people to IR for medical purposes.
- Since, Council **directive 2013/59/EURATOM** established uniform basic safety standards for the protection against the dangers arising from IR, repealing several Directives (including 97/43).

HAS Methodological Guide developed in partnership with ASN for the 3 sectors using IR



- ❑ 20 practice improvement programs elaborated with all professionals involved in RP
- ❑ **Goal : better secure patient radiation exposure pathways**

Implementation of the programs across the following activities:

- ✓ Accreditation of health facilities
- ✓ Accreditation of health teams or professionals in high-risk medical specialties such as radiotherapy
- ✓ Continuing Professional Education (DPC)
- ✓ And ASN inspections

Appropriateness of medical care and optimization of resources

“Right health intervention, right time, right place, right patient”

Need to mobilize and encourage health professionals and patients on the use of appropriate medical care

current challenges

Over-use

+

Under-use

Multi-Institutional Program

Participation in a national program (DGOS, CNAMTS, ATIH, HAS) and response to referrals

+

HAS Program

Launch of a specific appropriateness program with health professionals

HAS, together with health professionals, acting as a driving force of change

A national priority « health system transformation strategy » : putting quality and appropriateness of medical care at the heart of organizations and practice

Innovation for continuous improvement

- ✓ The entire **quality and safety process** *appears* somewhat **cumbersome**
- ✓ Nonetheless, such a process is **necessary for safety and acceptability** when dealing with high radiation doses

Growing need for **research**, technological advances and **optimization doses**

Constraints represent both a challenge and an opportunity to encourage **best practices and innovation**



Thank you for your attention