Recommendations of the working group on the conditions of implementation of « new techniques and practices » in radiotherapy
Report of the working group concerning the conditions of implementation of "new techniques and practices" in radiotherapy
SUMMARY

In August 2013, ASN asked the Advisory Committee of Experts in radiation protection for medical and forensic applications of ionising radiation to issue recommendations concerning the conditions of implementation of new techniques in radiotherapy and the associated practices, focusing in particular on the techniques of intensity-modulated radiotherapy and stereotactic irradiation, and on new treatment devices. A working group (WG) was set up for this purpose.

In the course of the various hearings held during its work, the WG observed that the new techniques in radiotherapy are developing with insufficient recommendations and with no specific supervision in the current radiotherapy licensing systems.

Further to its findings, the WG issues the following 12 recommendations:\footnote{The order of these recommendations is not an indication of their importance. They are presented in an order that goes from the most general to the most technical or practical.}

\begin{enumerate}
\item \textbf{R1: Create an Advisory Committee of Experts comprising professionals} having contact with representatives of the health and radiation protection authorities concerned
\item \textbf{R2: Organise clinical audits by peers}
\item \textbf{R3: Verify the prerequisites of a centre before} starting to implement the new technique or practice
\item \textbf{R4: Ensure rigorous and robust project management}, including the medical-economic aspect
\item \textbf{R5: Human resources:} adapt the human resources when setting up and using innovative or special techniques
\item \textbf{R6:} Integrate the changes in techniques and practices into the \textit{initial and continuous training} as soon as they arise, and \textbf{reinforce the role of the manufacturer}
\item \textbf{R7: Improve the testing of the technical and dosimetric performance} of new equipment or techniques at acceptance testing, and periodically thereafter (quality control)
\item \textbf{R8: Supervise external services in medical physics}
\item \textbf{R9: Develop the prospective collection and analysis of data} concerning radiotherapy patients for the new techniques
\item \textbf{R10: Enhance the informing and involvement of patients}
\item \textbf{R11: Revise the INCa approval criteria} for the practice of radiotherapy
\item \textbf{R12: Improve the dissemination of information relative to medical devices vigilance and experience feedback}
\end{enumerate}
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PART I: THE WORKING GROUP'S TASKS
I. Introduction - scope of reflection

- Referral

In December 2009, ASN organised - in collaboration with the IAEA (International Atomic Energy Agency), the WHO (World Health Organisation), the European Union, the SFRO (French Society for Radiation Oncology) and the SFPM (French Society of Medical Physics) - an international conference on modern radiotherapy in Versailles on the theme of "Advances and Challenges in Radiation Protection of Patients".

The conclusions of this conference underlined in particular that certain innovative techniques in radiotherapy could have major consequences, emphasizing not only the benefits but also the risks associated with the dissemination of these new techniques and the related practices if they are not fully mastered2.

The follow-up meeting to this conference, organised with the French radiotherapy stakeholders in November 2010, identified the need to define "the conditions of implementation of the new equipment and the associated new practices and the users' needs in terms of specific skills, training and good practice guides".

The radiotherapy accidents affecting patients in Epinay and Toulouse, although due to very different causes, brought home this fact. In the Epinay case specifically, experience has shown that minor modifications can have major consequences [Derreumaux 2008].

The majority of the lessons learned from the use of conventional radiotherapy techniques are applicable to the new technologies and treatment techniques. Additional experience feedback concerning the new technologies is now available [ICRP 112]. When new technologies and/or new practices are introduced, forward-looking approaches enable rational organisational choices to be made thereby acquiring an adequate level of safety for the risks.

In August 2013, ASN asked the Advisory Committee of Experts in radiation protection for medical and forensic applications of ionising radiation (GPMED)3 to issue recommendations concerning the conditions of implementation of new techniques in radiotherapy and the associated practices, focusing in particular on the techniques of intensity-modulated radiotherapy and stereotactic irradiation, and on the new treatment machines (see Appendix 1. Working group engagement letter.

- Tasks

The WG was therefore tasked with issuing recommendations intended for the radiotherapy professionals, license holders, medical health centres and institutions concerned. These recommendations concern in particular:

- project management by establishments involved in the implementation of the new techniques and practices in external-beam radiotherapy;
- the necessary human resources (radiation oncologists, medical physicists, radiographers, dosimetrists, quality specialists, measurement technicians);
- training prior to utilisation as well as the continuing professional development of the teams, ensured by the manufacturers in particular;

3 http://www.asn.fr/L-ASN/Appuis-techniques-de-l-ASN/Les-groupes-permanents-d-experts/Groupe-permanent-d-experts-radioprotection-medicales-medico-legales-GPMED
- the organisational conditions;
- the consequences on the equipment configurations of the technical platforms wishing to implement these new technologies;
- the necessary equipment, particularly for dosimetry and the quality controls of the devices used (including the software applications);
- the equipment and procedures for monitoring the quality of the treatments, including verification of the delivered dose;
- the assistance from external experts and the setting up of a quality assurance programme (including external audit by peers and dosimetric audit) during their deployment;
- the a priori risk analysis process.

The justification of the prescription of the radiotherapy procedure, whatever the technique, does not enter into the framework of this referral.

The WG will submit its report to the GPMED which will decide on the follow-up.

- **Scope of reflection**

A new radiotherapy technique and/or practice is defined as being a significant change that can concern treatment planning, the software, the performing/delivery of the treatment and the related quality controls. This notion of significant change corresponds to the processes which are not yet implemented in clinical practice at national level or in the centre concerned.

The recommendations set out in this report concern in priority the innovations (new equipment) or developments such as the introduction of intensity-modulated radiotherapy or stereotactic irradiation techniques.

On the other hand, developments such as the upgrading of software versions (TPS - treatment planning system, etc.) that are already in use are not considered.

Whatever the extent of the development or innovation, the level of vigilance must be identical.

**II. Working group composition and work method**

- **Composition of the WG**

The WG, coordinated by Eric Lartigau and Albert Lisbona, comprises experts from the GPMED, representatives of the SFRO, the SFPM, the AFPPE (French Association of Radiographers), IRSN (French Institute of Radiation Protection and Nuclear Safety), radiation oncologists, medical physicists, dosimetrists and radiographers. The list of members of the WG is appended to this report (appendix 2).

The technical secretariat was ensured by the Ionising Radiation and Health Department (DIS) of ASN.

- **Work method**

The WG met 11 times on the following dates:
- 8th November 2013
The group members:

- ensured the writing of and searches for documents, which were then validated in meetings and served as inputs for this report,
- conducted an international survey to find out the provisions that currently exist concerning the conditions of implementation of "new techniques and practices" in radiotherapy,
- conducted hearings (the persons met are listed in appendix 3).
PART II: SITUATION ASSESSMENT
I. National and international context concerning the implementation of new techniques

I.1. In France

I.1.1. Regulations and recommendations

- Licensing

Pursuant to Decrees 2007-388 and 2007-389 of 21st March 2007 [Decree 2007-388, Decree 2007-389], only healthcare establishments licensed by the ARS (Regional Health Agencies) can exercise cancer care activities.

The licence to exercise the activity of cancer treatment by external beam radiotherapy mentioned in 2° of Article R. 6123-87 of the Public Health Code can only be issued or renewed for applicants having a technical platform comprising at least two particle accelerators on the same site, at least one of which emits radiation energy of 15 MeV or more (Article R. 6123-93 of the Public Health Code).

This text stipulates the requirement for compliance with the approval criteria for practising external-beam radiotherapy (INCa Board of Directors' deliberation of 20th December 2007, Official Bulletin - Health and Social Protection - Solidarity No.2008/7) (Article R. 6123-88 of the Public Health Code).

Furthermore, the order of 29th March 2007 setting the minimum annual thresholds applicable to the cancer treatment activity sets a minimum threshold of 600 patients per year per radiotherapy centre [Order of 29.03.07].

This license is supplemented by a license to hold and use ionising radiation sources, issued by ASN in application of Articles R.1333-23 to R.1333-43 of the Public Health Code and the Order of 14th May 2004 relative to the general licensing and declaration system defined in chapter V-I "Ionising radiation" of the Public Health Code [Order of 14th May 2004].

- INCa approval criteria for the practice of external-beam radiotherapy

The INCa has defined 18 quality criteria specific to radiotherapy which have been applicable since 2011.

In accordance with the ministerial road map of national measures for radiotherapy adopted in November 2007, the implementation of these criteria should enhance treatment quality and safety and guarantee equal access to care in all the centres.

However, not one of these 18 criteria is specific to the new techniques or practices.
- Quality assurance

The health establishments and the persons licensed to practice radiotherapy must apply ASN Resolution 2008-DC-0103 concerning the quality assurance obligations in radiotherapy [DC-0103].

- Quality control

The medical devices used in radiotherapy are subject to maintenance and quality control obligations [Order of 3rd March 2003]. The decisions of the AFSSAPS (French Health Products Safety Agency) of 2nd March 2004 [DC(1) of 2nd March 2004] and 27th July 2007 [DC(1) of 27th July 2007] set the internal quality control conditions. The AFSSAPS decision of 2nd March 2004 [DC(2) of 2nd March 2004] and 27th July 2007 [DC(2) of 27th July 2007] set the external quality control conditions. An audit of the internal and external quality controls of the external-beam radiotherapy facilities must be carried out [DC(3) of 27th July 2007].

The AFSSAPS (now the ANSM - French Health Products Safety Agency) decisions do not cover all the medical radiotherapy devices currently in operation, and for those devices concerned, they cover only some of the characteristics used in clinics.

- Assessment of clinical practices

The clinical audit obligation provided for by the European directives\(^4\) has been transposed into French legislation by the clinical practices assessment system. This obligation is formulated in Article R.1333-73 of the Public Health Code. The conditions of implementation of this assessment must be defined by the HAS (French National Authority for Health) in conjunction with the professionals.

A first approach to the implementation of the professional practices assessment for training purposes was initiated in 2013 by the HAS (guide published in 2013) and involves self-assessments [HAS-EPP-2013]. Four programmes are proposed for radiotherapy.

- Guide to External-Beam Radiotherapy Procedures


The new technologies will be approached from two aspects, firstly in a chapter drawn up on the basis of the work of the GPMED WG devoted to the assistance with the implementation of the new techniques (IMRT, stereotactic irradiation), and secondly in the chapters organised by tumour location in which expert opinions will be given on the clinical indications and the conditions of use of each technique.

\(^4\) Directives 97/43/EURATOM and 2013/59/EURATOM setting out the basic safety standards for protecting health against the dangers arising from exposure to ionising radiation.
Guide to good medical physics practices

The SFPM's Guide to Good Medical Physics Practices [GBPPM 2012] recommends, in a specific chapter on attitudes and behaviour, the practices to adopt for the management of change and innovation in radiotherapy. Table 3.17 of the GBPPM gives the main steps for introducing a change or innovation in a practice associated with the medical use of radiation. The content of table 3.17 has to be adapted according to the situations.

Other reports published by the SFPM, which may be useful for the introduction of new technologies, are mentioned in appendix 8. These reports concern more specifically MLCs (multi-leaf collimators), IMRT (intensity-modulated radiotherapy) and IGRT (image-guided radiotherapy).

I.1.2. General information concerning radiotherapy equipment, personnel and the activity

The May 2014 edition of the National Observatory of Radiotherapy concerning the data available at the end of 2012 (last official figures) provides an overview of the equipment, the personnel and the radiotherapy activity in France as a whole:

- **Number of centres**: 172. Out of these 172 centres, 168 communicated their data for the purpose of the Observatory. 51% of these 168 centres are in private structures.

- **Number of external-beam radiotherapy devices**: 470 including:
  - multipurpose accelerators: 421
  - dedicated accelerators (Cyberknife®, Novalis®, TomoTherapy®): 25
  - gamma Knife®: 4
  - orthovoltage equipment: 11
  - dedicated intraoperative devices: 7
  - cyclotrons: 2.

A 16% increase in the number of linear accelerators between 2007 and 2012 has been recorded for the 140 centres having responded to all 5 survey years.

In 2012, 50% of the accelerators were less than 6 years old and 80% were less than 10 years old.

Approximately 50% of the centres have 2 accelerators.

The accelerators in the respondent centres have:

- a multi-leaf collimator: 93%
- portal imaging: 94% (84% amorphous silicon)
- additional imaging devices to monitor patient positioning: 47%

- **personnel** (responses from 168 centres):
  - radiation oncologists: 654 FTEs (full-time equivalents)
  - medical physicists (in radiotherapy): 525 FTEs
  - radiographers (in radiotherapy): 2268 FTEs
  - dosimetrists: 403 FTEs
  - quality specialists: 0.4 FTEs per centre on average
- activity:
  - incidence of cancer in France: estimated at 355,000 cases in 2012 (InVS report 2013),
  - number of patients receiving radiotherapy treatment: 175,000 in 2012 (in 168 centres),
  - number of external-beam radiotherapy sessions per year: 3.9 million (in 168 centres),

Developments in equipment, practices and personnel

According to the data published by the National Radiotherapy Observatory in May 2014, the developments are as follows:

- Equipment with intensity-modulated volumetric arc therapy

In 2012, out of 167 having responded to the Radiotherapy Observatory, 31% of the accelerators have the intensity modulated volumetric arc therapy option. This figure was 16% in 2010.

- Inverse planning dosimetry

The proportion of centres equipped with inverse planning dosimetry software increased from 43% in 2009 to 72% in 2012.

The proportion of centres using inverse planning for volumetric arc therapy increased from 11% in 2010 to 35% in 2012. The proportion of treatments carried out with inverse planning alone or by volumetric arc therapy increased from 5% in 2010 to 13% in 2012.

However, in 2012, only 32% of the centres used inverse planning in more than 10% of their treatment preparations.

- Personnel

The number of FTE radiation oncologists remained stable between 2009 and 2012. The number of FTE medical physicists in radiotherapy increased by 38% between 2007 and 2012. The number of FTE radiographers increased by 22% between 2007 and 2012.

I.1.3. Current situation of training of professionals

a. Initial training

The initial qualification is associated with the diplomas held by the professionals since the end of their studies. These diplomas ensure that the persons holding them have adequate basic knowledge to exercise a given profession.

However, during or by the end of initial qualification, the notions of "knowledge" (fundamental knowledge) and "know-how" (utilisation or application of this fundamental knowledge) must result in the notion of "skills". The "skill" is the faculty a person has to use his or her "knowledge" and "know-how" according to the situations and circumstances encountered in the exercise of the profession. This notion of "skills" is acquired through putting into practice (courses), experience, and complementary practical training courses if necessary.
Although the initial qualification is vital, as it represents the prerequisite in terms of "knowledge" and "know-how" in order to acquire the "skills", it is the skills that will enable a technique, whatever it is, to be implemented with the best possible standard of quality and safety in the treatment of patients.

Radiation oncologist:

Specialist post-graduate diploma (DES) in Oncology
The initial training of hospital interns comprises theoretical instruction and practical training through six-month internships (four semesters in approved departments for the DES in oncology - radiotherapeutic oncology option, two semesters in departments approved for the DES in oncology - medical oncology option, and four free semesters). Compliance with a programme comprising compulsory and optional modules, as well as a minimum number of internships in specific departments is necessary. The intern is monitored throughout the curriculum by fulfilling the objectives defined in the Intern's Logbook. On completion of 10 semesters, the oncological radiotherapy intern obtains the DES in oncology, allowing that person to practise in the field of oncology.
The core common to the three oncology specialties (medical oncology, onco-haematology and oncological radiotherapy) plans addressing all the general principles of oncology.
The teaching specific to radiation oncology is not dispensed by the faculties but during the national radiotherapy lectures organized each year by the SFjRO assisted by the SFRO.
The growing number of interns undergoing training poses a problem in the regions with the fewest internship centres. Furthermore, not all the training centres can offer access to stereotactic radiotherapy, which can be a real problem in the training of interns who will never have practised stereotaxy even though this technique is destined to become increasingly important in their future practices.

University diploma courses teaching stereotactic irradiation
Several courses currently teach the techniques of stereotaxy apart from the DES. The first is the Inter-University Diploma (DIU) in High-Tech External-Beam Radiotherapy (Nice, Lille, Paris, Nancy & Bordeaux) which comprises a theory part (100 hours) and a practical part (one-week internship). The second is the University Diploma of Radiosurgery and Intra- and Extra-cranial Stereotactic Radiotherapy which proposes 54 hours of theory instruction and 15 hours of practical demonstrations. Other courses dedicated to stereotactic irradiation have now been developed.

Medical physicist:

The initial training as a medical physicist comprises a master's degree in medical physics supplemented by the DQPRM (Medical and Radiological Physics Qualifying Diploma) in accordance with the Order of 6th December 2011 [Order of 06.12.11].
The DQPRM course duration was recently extended to 28 months, thereby bringing the level of training of medical physicists in France closer to that of the European recommendations for the training of these professionals. The theory instruction is spread over various modules based on the Core Curriculum of the EFOMP (European Federation of Organisations for Medical Physics) and on the IAEA's recommendations for the training of medical physicists. It is dispensed over two periods: in first year, before starting the practical training and at the beginning of second year.
The new techniques and practices are taught chiefly during the first period of theory instruction. About forty hours are devoted specifically to new techniques and practices (IGRT, IMRT/VMAT, stereotaxy, etc.), plus the same number of hours again of lectures in the more general subjects. The second-year lectures are devoted to emerging or less widely used techniques (such as hadron therapy).

The theory instruction is supplemented in the internship centre where the student, during the 24 months of practical training, can observe and take part in the application of these techniques. IMRT is practised by all the internship centres (mandatory approval criterion) and stereotactic radiotherapy is practised in the large majority of them. Whatever the case, it is recommended for second-year students to go to other departments to get training in the techniques that are not used or are different on their internship site.

Radiographer:

The training of radiographers has recently been integrated in the LMD (License (Bachelor)-Master-Doctorate) programme. Following this change, the theory instruction in radiotherapy is 195 hours and the duration of internships in radiotherapy has been reduced by 140 hours (falling from 350 hours in the former reference system to a minimum of 210 hours). Depending on the sites that students work on during their training, they may or may not have seen devices that incorporate a new technology.

The theory instruction in radiotherapy includes an introduction to new technologies. About ten hours in all are allocated specifically to the introduction of new techniques in radiotherapy.

The initial training aims at delivering a diploma enabling the holder to work as a "novice" radiographer. The training in new technologies constitutes a foundation which must be supplemented by methods that have not been defined so far. At present this training is highly dependent on the institutions and the persons that dispense it. Work is currently in progress to render the training content and practices more uniform.

b. Continuous training

Different types of training can be identified:
- theory, by reading books or dispensed by the learned societies,
- proposed by organisations / training institutes/ universities / schools / healthcare establishments,
- training by the manufacturers in the use of the medical equipment and devices,
- practise in the clinical environment proposed within centres that use the technology or technique in question.

At national level, the learned societies (accredited with a continuous training number), such as SFPM, AFCOR, SFRO, propose courses in the new techniques. These courses, which are based on voluntary participation and do not result in a diploma, are nevertheless strongly recommended.

At European level, the ESTRO (European Society for RadioTherapy and Oncology) proposes theory courses lasting 3 to 4 days (IMRT and stereotactic irradiation in particular) which are recognised by the UEMS (European Union of Medical Specialists) but not in the current continuous professional development (CPD) system. These courses seem to be rarely attended by the French professionals.
At international level, the learned societies or federations of learned societies also propose instruction courses.

For radiation oncologists:
Since 2011, the SFPM, AFCOR and SFRO have organised the first training courses intended to train a two-person team (not an individual person) per healthcare facility, comprising a radiation oncologist and a medical physicist. These courses concern the techniques of IMRT (3 courses have been held) and stereotactic radiotherapy (first course in 2013, repeated in December 2014).

The first theory session concerning stereotactic radiotherapy lasted 3 days and was attended by 20 medical physician-physicist pairs. The subjects addressed the principles of this technique, the delineations, the quality controls, the therapeutic results and the limits of the technique.

One of the objectives of this training course is to create, for a given centre, a two-person team comprising a radiation oncologist and medical physicist, thereby forming a "central core" (of project leaders) around which the technique will be put in place in that centre.

A practical session was organised for each two-person team in 2014 in the expert centres with a view to validating this national training course. The participants will then be able to continue their training by submitting their first treatments to their training centre if they wish. A second theory training course was held in December 2014, followed by practical courses in 2015 for 20 new two-person teams. For the physicians, this training shall be part of their CPD obligation.

A new delineation and radioanatomy aid is going to be developed. This tool (SIRIADE 2.0) follows on from the SIRIADE website which was created in 2010 and has been made available as a book of radioanatomy and as free applications for smartphone and tablets. This new tool will feature a web-application interface enabling junior and senior physicians to delineate clinical cases on any type of location from any supporting medium (MAC, PC, tablet) by logging in to a dedicated server via a simple Internet address. Each clinical case will first be contoured by two experts, and the contours produced by the user physician will be compared in real time with those of the experts, enabling the contours of each participant to be analysed individually.

For medical physicists:
The lack of recognition of medical physicists as health professionals in the Public Health Code (action in progress conducted by the DGOS within the framework of the Cancer Plan 2014-2019) implies that they are not eligible for the mandatory CPD training programme. Access to training is therefore strongly dependent on the employer's continuous professional development policy.

Apart from the joint AFCOR/SFRO/SFPM physician-physicist training described above, postgraduate courses are organised by the SFPM for its members, but are also open to other professions. The subjects addressed more specifically concern the aspects and problems of dose measurement, dose calculation and the associated quality assurance means and methods for the preparation and utilisation of advanced radiotherapy techniques.

To give an example, since 2010 the SFPM has organised training courses on IMRT and VMAT (held 3 times, renewed in 2014), IGRT (held 2 times, renewed in 2014), on the new dose calculation and measurement algorithms. Since 2002, 10 sessions focusing on IMRT (and VMAT in the last few years) have been organised successively in Dijon, Saint-Cloud and Rennes.

The SFPM moreover organises "Scientific days" each year intended primarily for physicists but also for medical physics technicians, dosimetrists or radiographers, with a common session since June 2013.
For radiographers:

Radiographers have access to the mandatory CPD training programme, but the training offering in radiotherapy specific to the new technologies is still poorly developed. When the offering exists, it generally proposes introductory modules, information concerning new technologies - all technologies combined - and without providing opportunities to use the systems. No assessment is carried out at the end of this type of training. Since 2011, a DIU (Inter-University Diploma) in high-tech external-beam radiotherapy exists; at present this course is only open to dosimetrists with more than 5 years' experience in dosimetry.

Since 2013, several regional training sessions in IGRT have been proposed by AFPPE, AFCOR and SFRO (in the Nord, Bourgogne and Provence-Alpes-Côtes d'Azur regions). Based on presentations, these sessions addressed the implementation of this technology and the associated problems.

Certain cancer centres also propose complete training courses (theory and practice) of 1 to 2 days on their radiotherapy platforms that use new technologies.

The main difficulties with giving access to this type of training result from the need for the radiotherapy departments to make personnel available and from the costs (direct and indirect) induced by the courses.

In May 2014, the AFPPE conducted a survey on the training of radiographers in new techniques and practices by having them respond directly to a questionnaire.

The main conclusions of this survey show that the new techniques and practices are already very widely used (VMAT, IMRT, IGRT in particular); 93% of the radiographers have already used this type of technology since they began their activity.

Only half of them (48%) received formally organised initial training from the manufacturers when a new technique was introduced.

The technological, dosimetric and safety aspects are not always addressed. In 72% of the cases, the training sessions provided by the manufacturers are not renewed periodically despite the fact that such needs are felt.

The main drawbacks of manufacturer-provided training concern the practical exercises which are often insufficient and the considerable variability in the duration of training for which there is no final validation.

Lastly, the training by mentoring is mainly ensured by another system user (65%) and/or an identified coordinator (26%). This type of less formal training leads to a deterioration and/or a loss of the original information and deviations in utilisation. Training by mentoring is also rarely assessed and not formally validated, despite the availability of utilisation baselines in the departments.

c. Other sources of continuous training:

Radiotherapy departments in various medical establishments (cancer centres, university hospital centres, etc.), whose knowledge and competence is acknowledged in the radiotherapy profession, offer training courses in the new techniques they have put in place (helical tomotherapy, etc.), often in the form of workshops.
Some universities also propose courses (DIUs). For example, the DIU in high-tech external-beam radiotherapy. These courses are open to radiotherapy professionals but are oriented more particularly towards medical physicians.

Lastly, certain manufacturers propose workshops on very specific subjects or particular techniques with partner medical establishments.

I.1.4. Current situation regarding the use of external service providers

The members of the WG conducted a survey with 12 centres that had used an external service provider when implementing a new technique/practice.

The large majority of the centres called upon an external service provider because they lacked time and/or human resources. Few professionals lack knowledge but many needed assistance because the proposed training courses (manufacturers, post-graduate education) do not seem to suit everybody as they do not cover all the aspects and their timing does not necessarily coincide with the project in question. Furthermore, the regulatory external checks are absent or insufficient.

This led the physicists (from the respondent centres) to want to use an external service provider, which generally does not substitute for the recruiting of a physicist or participating in congresses or post-graduate education.

Several difficulties concerning the metrology of clinical beams are reported. The most serious difficulty however, lies in the configuring and validation of the TPS, for which the questioned physicists do not always master all the processes involved (the persons questioned often mention the "black box" effect). This point provides the opportunity for many of them to challenge the manufacturers' training sessions which do not sufficiently describe the detailed principles of operation of the software programs. Similarly, the outside assistance is appreciated in clinical application of treatment planning and validation, as a complement to the training courses which are considered too theoretical.

The service, which lasts two weeks on average, is intended primarily for the physicists and secondly for the physicians and dosimetrists, though it can involve the entire local team.

Even if a service report is nearly always provided, along with numerous procedures, the training is only rarely assessed and when it is, nothing is really formalised. Follow-up after starting is not always ensured either, although some instructors offer remote assistance.

The assessment of the external services highlights the time-saving aspect. The keenness of the physicists to benefit from the experience of other sites and the opinion of other physicists is also observed.

The use of a service provider results from an initiative on the part of:
- the supplier of the new technique: in this case the external service is included directly in the initial commercial proposal, or
- the user.

To conclude, the reasons given for using an external service provider during acceptance of the machine or the implementation of a new technique are primarily:

1. the lack of time or personnel,
2. the lack of experience and/or skill of the teams (for example, questions on the detectors to use),
3. economic reasons: the cost of a physicist on a limited-term contract without being certain of their ability to deploy the technique, compared with the cost of paying an external service provider for a few weeks,
4. the software parameters are not known (the manufacturers sometimes give default values for the software parameters to use, but without providing further explanations),
5. delineation demands from the clinicians,
6. the need for assistance during start-up.

I.1.5. Orientations of Cancer Plan 3

On 4th February 2014, the President of the Republic presented the third Cancer Plan 2014-2019, developed on the basis of Professor Jean-Paul Vernant's guideline report.

The Cancer Plan 2014-2019, coordinated by a committee co-chaired by the ministers responsible for research and health, is organised around four major priorities:

- Cure more sick people
- Preserve continuity and quality of life
- Invest in prevention and research
- Optimise the coordination and the organisations

These four priorities are broken down into 17 operational objectives.

Among the objectives figuring in this third Cancer plan are several actions that concern radiotherapy directly.

**Objective 2**, "Guarantee the quality and safety of treatments", includes 2 actions in particular:

- **Action 2.6**: Update the scope of cancer treatment licenses to integrate the changes in the treatment techniques and access to innovation.

  The defining of the conditions of activity of oncology teams is a key issue. It is important to manage the situations where the literature evidences potential loss of chance of cure and **to ensure the necessary safety in a context of significant technical innovations**.

- **Action 2.9**: In each treatment discipline, define what is classified as "local centre" equipment and what is classified as a "referral" structure integrating highly specialised techniques. Define the referral radiotherapy centres at national level (France) for particularly complex techniques (proton therapy, intraoperative radiotherapy) and organise their collaboration with the local centres.

**Objective 3**, "Accompany the technological and therapeutic developments", includes 6 actions "to ensure that each person has access to the most appropriate radiotherapy technique":

- **Action 3.11**: Guarantee a suitable offering of radiotherapy equipment in France and improve its clarity in order to facilitate appropriate patient referrals and reduce waiting times.
  - Identify with the professionals the indications that require treatment with specific types of radiotherapy equipment.
  - **Assist and ensure safety of deployment of high-precision radiotherapy equipment** as and when the professionals are trained in the corresponding technique and the quality procedures - for which national recommendations are
required - are put in place: speed up the deployment of IMRT accompanied by IGRT.

- **Action 3.12:** Harmonise and bring closer together the system for coding radiotherapy procedures in the public and private sectors so that a national radiotherapy policy can be coordinated.

- **Action 3.13:** Experiment the implementation of fixed-rates reimbursement fees for radiotherapy treatments taking into account the number of sessions but also other criteria to incite the establishments to invest in innovative techniques such as hypofractionation for the benefit of the patients.

- **Action 3.14:** Make an overall assessment of the quality approach / risk analysis put in place and supported in the context of the Cancer Plan 2009-2013, and encourage the teams to buy into a medico-economic evaluation approach.

- **Action 3.15:** Organise appropriate national meshing for the high-tech equipment based on recommendations concerning the indications for which they should be used.

- **Action 3.16:** Regulate the offering for particularly costly major equipment items at national level (example: proton therapy).

**Objective 4**, "Make oncology training and activities evolve", includes 2 actions in particular (actions 4.2 and 4.3) aiming at recognising the professions of medical physicist and dosimetrist has health professions.

**Objective 5**, "Speed up the emergence of innovation for the benefit of the patients" includes three actions "to create the conditions for rapid dissemination of the technological innovation" (actions 5.11, 5.12, 5.13).

**Objective 17**, "Adapt the modes of funding to the challenges of oncology" includes 1 action aiming at promoting the development of hypofractionated treatments.

- **Action 17.2:** Experiment the implementation of fixed rates reimbursement fees for radiotherapy treatments to encourage the establishments to invest in innovative techniques such as hypofractionation for the benefit of the patients.

Several objectives emerge from the actions set out in Cancer Plan 3:

1. Allow the development of new treatment techniques, including radiotherapy, in a safe environment (actions 2.6 and 3.11),
2. Define referral radiotherapy centres at national level for the particularly complex techniques (action 2.9) and organise national meshing for the high-tech equipment (action 3.15),
3. Encourage the deployment of innovative and high-precision techniques (IMRT - action 3.11, and hypofractionation - actions 3.13 and 17.2, actions 5.11, 5.12 and 5.13),
4. Develop the professions that are involved in radiotherapy (actions 4.2 and 4.3).
I.2 At international level

In 2014, the WG sent a questionnaire to the Heads of European Radiological Protection Competent Authorities (HERCA\(^5\)).
The aim was to gather information on any national regulations or recommendations concerning
the implementation of new techniques and practices in radiotherapy.
Eleven countries responded. The points common to this survey in terms of recommendations concern the medical physics personnel numbers, quality control and the clinical audit. The survey did not reveal an overall and conclusive reflection on the new techniques. The detailed responses are presented in appendix 7 and concern:
- the quality control protocols of the linear accelerators, including complex equipment or techniques,
- the dosimetric audit,
- the external clinical audit by peers,
- the licensing of new techniques in radiotherapy,
- the personnel numbers in medical physics.

I.2.1. Recommendations from international organisations

Several international organisations, the ICRP, the ICRU (notably in report 83), the IAEA and learned societies or their federations (including ESTRO, EFOMP, AAPM, ASTRO and the ACR) have issued recommendations or published documents aiming to help implement technological developments in radiotherapy centres on the world scale.

The IAEA has thus published numerous reports and recommendations (see bibliographic references in appendix 8) addressing cross-cutting themes that are absolutely essential when implementing new technologies in radiotherapy:
- Metrology (dosimetry), planning (calculation), level of precision, etc.
- Quality Management, Quality Assurance, Quality Control and the new approaches to them, documentation, procedures, change, optimisation
- Specifications, "commissioning" / acceptance tests, implementing and evaluating
- Human resources, organisation, monitoring
- Training, communication, human-machine interface
- Qualifications / training programmes / accreditations, continuous training,
- Roles and Responsibilities
- Accident/incident analysis and prevention (minimise the risk), draw lessons and learn from mistakes, accident prevention and analysis procedure
- Evaluations, monitoring
- Audit, peer review, references to standards, etc.
- Radiation protection, safety
- …

\(^5\) http://www.herca.org/
I.2.2. United States of America

There does not seem to be any federal regulations or recommendations providing a general coverage of the new techniques in radiotherapy as a whole, or definitions thereof. However, there are documents issuing recommendations for each technique, produced by the professional bodies: the Practice Guidelines/Technical Standards of the ACR/ASTRO (American College of Radiology, American Society for Therapeutic Radiology and Oncology), the ASTRO Safety White Papers (IMRT, IGRT, SRS/SBRT) and the reports of the AAPM, which are usually technical (IMRT, SBRT, SRS, robotised radiotherapy, helical tomotherapy, IGRT, TPS with Monte Carlo) (appendix 5 provides a list of documents published by the ACR and the ASTRO with the address of the website at which they are accessible, references of the AAPM reports for various techniques).

A summary document entitled "Safety is no accident" (2012), has been produced by all the professional and institutional bodies involved, sponsored by ASTRO. This document takes up the recommendations concerning safety in radiotherapy and makes reference to the abovementioned documents (Practice Guidelines/Technical Standards, ASTRO Safety White Papers, AAPM reports). The main recommendations issued concern:
- The calculation of the human resources (physicists and dosimetrists) required according to the techniques (equipment and procedures);
- The appropriate personnel training and accreditation;
- The collaboration between the supplier and the users;
- The independent external audits concerning the calibration of the treatment device, the treatment protocols and procedures;
- The minimum Quality Assurance (QA) requirements and the QA specifics for IMRT, SRS, SBRT and IORT;
- The embedded imaging devices;
- The dose planning systems.

II. Current situation concerning recommendations on personnel numbers in medical physics

Several studies or international reports show that the medical physics personnel numbers (medical physicists, dosimetrists) are lastingly affected, particularly during the putting into service, clinical use, evaluation and deployment of innovative special techniques. The personnel numbers are associated firstly with the part concerning medical devices (in the broad sense) and secondly with the number of patients concerned by the technique.

II.1 American recommendations

The "Safety is no accident" report published by ASTRO in 2012 [ASTRO-2012] presents a table for calculating the human resources in medical physics necessary in radiotherapy. For example, a centre with 2 helical tomotherapy units treating 400 patients per year requires 0.6 FTE medical physicists and 0.06 FTE dosimetrists for the equipment, and 3.2 FTE medical physicists and 2 FTE dosimetrists for the 400 procedures it performs.
**II.2 European recommendations**


The results of the *European project HERO* (Health Economics in Radiation Oncology), sponsored by the ESTRO were published in 2014, providing an assessment of the recommendations concerning personnel numbers in radiotherapy [HERO-guidelines-2014]. Nineteen of the 29 respondent countries have quantitative recommendations for human resources in medical physics, with figures of up to 2.75 physicists per machine or from 400 to 750 patients per physicist per year.

The survey conducted by the WG with HERCA enabled some of these recommendations to be detailed (see appendix 7).

The table below presents an extract of the European, American, British and German recommendations concerning the calculation of medical physicist personnel numbers according to the available equipment and techniques and the clinical activity. This table does not present the recommendations that depend on the activities of the medical physicist other than the new techniques (organisation of the department, management, teaching, etc.).

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>European (RP174)</th>
<th>American (ASTRO)</th>
<th>British (IPEM)</th>
<th>German</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTE Physicists per machine:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multi-energy accelerator</td>
<td>0.6</td>
<td>0.25</td>
<td>0.8</td>
<td>1 (+ 1 out of total)</td>
</tr>
<tr>
<td>Single-energy accelerator</td>
<td>0.2</td>
<td>0.08</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td>Dedicated accelerators (Tomotherapy, Cyberknife, Gammaknife)</td>
<td>0.2</td>
<td>0.3</td>
<td>N/A</td>
<td>1</td>
</tr>
<tr>
<td>Options on machines (IGRT, IMRT, MLC, EPID, etc.)</td>
<td>0.05 to 0.2</td>
<td>0.05 to 0.3</td>
<td>0.2</td>
<td>1 for 2 techniques</td>
</tr>
<tr>
<td>Brachytherapy (per technique: LDR, PDR, HDR, etc.)</td>
<td>0.1 to 0.2</td>
<td>0.2</td>
<td>0.2</td>
<td>1 minimum</td>
</tr>
<tr>
<td>Planning system (per system)</td>
<td>0.1</td>
<td>0.05</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>FTE Physicists per patient:</td>
<td>RP174</td>
<td>ASTRO</td>
<td>IPEM</td>
<td>Germany</td>
</tr>
<tr>
<td>Conformal radiotherapy</td>
<td>0.001</td>
<td>0.0003</td>
<td>0.0008</td>
<td>0.003</td>
</tr>
<tr>
<td>IMRT, SRS, SRT, SBRT, TBI</td>
<td>0.004</td>
<td>0.008</td>
<td>0.003</td>
<td>0.003</td>
</tr>
<tr>
<td>Brachytherapy</td>
<td>0.004</td>
<td>0.008</td>
<td>0.003</td>
<td>0.003</td>
</tr>
</tbody>
</table>

**II.3 French recommendations**

In France, circular "DHOS-2002-299 of 3rd May 2002 relative to the organisation of care in oncology" specifies, taking into account the implementation of special techniques in addition to
the standard techniques, the teaching and training functions, the innovation and research activities and participation in the multidisciplinary discussion meetings:
- 1 FTE medical physicist for 300 to 400 annual treatments of external-beam radiotherapy and
  1 FTE for 250 brachytherapy treatments per year,
- 1 dosimetrist for 300 to 500 treatment plannings per year.

At the time of writing this report, an SFPM working group has been set up to establish recommendations concerning medical physics personnel numbers in radiotherapy. This work, which will be materialised in the months following publishing of the GPMED WG's report, will consider the implementation of new techniques and/or practices in a quantitative manner. The readers will find figures relative to this in the future report.

At the time of writing this report, the SFPM working group proposes the following information on the implementation of new techniques and/or practices.

It is necessary to distinguish the various aspects:
1) The implementation of the new technique or practice, its follow-up (updating, etc.), the associated training to master it, etc.
2) The clinical activity resulting from this new technique.

The first point concerns the need for human resources in medical physicists, their number being clearly dependent on the technique and the number of devices involved in the technique. Additional human resources specifically trained in the new technique or practice are vital for their implementation, particularly for the development of the project itself.
The second point concerns the need for human resources in the medical physics department as a whole (involving other professions such as dosimetrists and medical physics technicians). The evaluation will therefore depend in principle on the activity for the new technique in question; a quantification of the needs per multiple of 100 patients for example may be proposed (for treatment planning, quality assurance of treatment plans, etc.).

The notion of expert for the new technique must be included alongside the evaluation of the needs for the implementation of that technique. Part of the additional medical physicist personnel for the implementation, monitoring and maintaining of the new technique cannot be reduced in number. A medical physicist can be the expert for several techniques, but probably not for all the new techniques of a given centre.

III. Current situation concerning external dose control in radiotherapy

In France, the external quality control of radiotherapy facilities is defined in accordance with ANSM (formerly AFSSAPS) decision of 27th July 2007 setting the conditions for external quality control of external-beam radiotherapy facilities (NOR: SJSM0721863S) amending the amended decision of 2nd March 2004 setting the conditions for external quality control of external-beam radiotherapy facilities (NOR: SANM042085S).

The controls referred to in these decisions concern the standard utilisation of the radiotherapy devices and equipment with regard to the photon beams:
- Reference dose rate of the beam: under the reference conditions of the operator (and at a depth of 10 cm if different) for a 10 cm x 10 cm field
- Dose at 10 cm and 20 cm depth for field sizes of 10 cm x 10 cm and 20 cm x 20 cm
Variation in beam dose rate according to the aperture of the collimator with and without MLC
- Transmission factor of the wedge filters

The operators are obliged to have the external control performed before starting treatment of the first patient, then every three years thereafter for all photon energies and the three most commonly used electron energies.

When implementing a new technique or practice, several cases of application of the AFSSAPS decision of July 2007 can be encountered:

- New technique or practice on a conventional linear accelerator already in operation: in this case the operator has already validated the external control in application of the decision of 27th July 2007 amending the decision of 2nd March 2004,
- New technique or practice on a conventional linear accelerator which has not yet started service: the operator must validate the external control in accordance with the abovementioned decision,
- New technique or practice on a non-conventional machine: in this case, the operator cannot satisfy all the parts of the external control (for example, it is impossible to perform an irradiation with a field of 10x10cm² on a tomotherapy machine or on a Cyberknife). The current text does not mention partial performance of the external quality control.

SFPM survey conducted in 2013

In February 2013, the SFPM had questioned its members during joint work with ANSM, IRSN, ASN and the learned societies on the action to take for application of the abovementioned decision of 27th July 2007.

The last questions of the survey concerned the need to extend application of external quality control to the particular cases not provided for by the current measures: intensity-modulated radiotherapy and stereotactic radiotherapy (intracranial and extracranial). 120 responses were obtained.

In the very large majority of the cases the medical physicists answered in the affirmative: yes for more than 87% of the responses for intensity-modulated techniques and for more than 90% of the responses concerning stereotactic radiotherapy.

The comments relating to these items of the questionnaire bring out the fact that the current controls do not permit strict application of this text and a modification would be necessary.
SFPM survey, February 2013. "Do you think that external QCIs should be made mandatory in the practice of intensity modulated radiotherapy and intracranial and extracranial stereotactic radiotherapy?" (120 responses).

The solutions available for the new techniques

Several dosimetry and audit laboratories propose dosimetric audit services. In the majority of cases the protocol includes the sending of equipment (test object, detectors) to be irradiated following a strict procedure. The laboratory ensures off-line reading and results analysis by comparison with the calculated doses given by the audited centre. Some laboratories propose, in addition to the dosimetry audit, an on-site audit of the practices and the equipment.

France:

In France, the measurements laboratory EQUAL-ESTRO is currently the only laboratory accredited as an external control body in accordance with the decision of 27th July 2007 amending the decision of 2nd March 2004 (COFRAC Tests Accreditation No.1-2165).

For several years now EQUAL-ESTRO has also been proposing a dosimetric control protocol for IMRT and helical tomotherapy based on measurement by thermoluminescent detectors and/or radiochromic films. There is also a specific protocol for brachytherapy.

The laboratory is in the process of developing an external control protocol for modulated volumetric arc therapy and for the use of small irradiation fields.
A protocol for Cyberknife treatments is also undergoing validation (Guinement et al. Cancer Radiother. 2013, Marchesi et al. ESTRO Congress 2013).

**Belgium:**

In Belgium there is no accredited laboratory or mandatory systematic official procedure.

The BELdART project was initiated in 2009, resulting in a collaboration between the Nuclear Technologisch Centrum (NuTeC) of the XIOS Hogeschool Limburg, the College of Radiotherapy Physicians and the Belgian Society of Hospital Physicists.

This national audit was set up at the request of the FANC (Federal Agency for Nuclear Control) for a 3-year period. It consisted in conducting a basic on-site dosimetry audit of all the external-beam radiotherapy devices in Belgium.

The BELdART1 project was followed by the ALdART project, which involved a site visit by experts (basic mechanical quality controls of the accelerators) and a dosimetric audit. These two projects are now both finished.

The basic audit (BELdART1) was funded by the FANC. The funding has now been taken over by the Federal "Public Health" service (multi-year anti-cancer plan) within the framework of overall management of quality in radiotherapy.

The BELdART2 project planned for the period from 2012-2015 follows on from the first audit and will enable the entire treatment chain to be taken into consideration and give an overview of the quality of IMRT treatments.

**United Kingdom:**

There is no legal inter-comparison or dosimetric audit obligation, therefore there is no structure for managing this type of control. External audit procedures by inter-comparison exist in a regional format with the participation of a centre in the audits of other regions, probably to ensure some uniformity in practices.

The National Physical Laboratory (NPL), which is also the secondary national calibration laboratory, takes part in these regional audits.

**Netherlands:**

The Netherlands Commission of Radiation Dosimetry (Nederlandse Commissie voor Stralingsdosimetrie) participates in the defining of the dosimetric standards, the promotion of dosimetric intercomparisons and the defining of dosimetric protocols.

It carries out its work within sub-commissions (stereotaxy, helical tomotherapy, modulated arc therapy, cone-beam computed tomography imaging, IMRT audit) which are tasked with establishing recommendations for good practices in terms of implementation, utilisation and controls.

Thus, the "Auditing of IMRT and Modulated Arc Therapy procedures" commission is tasked with conducting audits on a voluntary basis, on intensity-modulated irradiation by static beams or arcs in medical establishments in the Netherlands. The aim of this audit is to verify the consistency between the calculations and the measurements taken on the audited centre's machines - by ionisation chamber, radiographic films or matrix detectors - with respect to acceptable tolerances.
This commission officially started its activity on 18th February 2014.

**United States:**

The Radiological Physics Center (RPC, rpc.mdanderson.org) proposes quality assurance services for radiotherapy treatments and clinical tests, and is associated with the MD Anderson Dosimetry Laboratory (MDADL), the North-American equivalent of the EQUAL-ESTRO laboratory, situated in the premises of the MD Anderson center in Houston (Texas). It proposes both measuring instrument calibration and anthropomorphic phantoms in which dosimeters are inserted (TLD and films).

The proposed external dosimetric controls are of the end-to-end type and allow the reproduction of a complete treatment procedure from the dosimetric computed tomography scans through to the irradiation of the treatment session.

In addition to the irradiation of detectors in an anthropomorphic phantom, the local quality assurance procedures are also required for IMRT treatments.

The proposed audit protocols concern:

- The reference dose rate,
- IMRT: head and neck, prostate/pelvis,
- Pulmonary treatments, with or without a mobile platform,
- Intracranial stereotaxy,
- Proton therapy: head, vertebral column, liver, prostate/pelvis, lungs, etc.

**IAEA:**

The IAEA recently created a commission for external audits of innovating techniques; a complete system comprising several tests (including the "final" end-to-end level) has been devised. This project is still being finalised but should be available as of 2015.

In all, the obligation - when one exists - to participate in external dosimetric audits, only concerns the standard irradiation conditions. Complex radiotherapy techniques are only concerned in the case of clinical tests or targeted campaigns and for a given period.

Solutions currently exist for the techniques of IMRT, arc therapy and helical tomotherapy through the EQUAL-ESTRO laboratory, RPC/MDADL, and shortly the IAEA. For the stereotactic irradiation techniques, the protocol of the RPC/MDADL is now available, and will soon be available for EQUAL-ESTRO.
IV. Current situation concerning the performance of clinical audits by peers

- IAEA

The IAEA guide QUATRO has been published for the auditing of radiotherapy departments⁶.

- In Europe:

With regard to health protection of persons against ionising radiation resulting from medical exposure, Article 6.4 of Directive 97/43 obliges the performance of clinical audits. This obligation is taken up in Article 58 (e) of Council Directive 2013/59/EURATOM of 5th December 2013 [DIR 2013/59].

In 2009, to facilitate the implementation of these clinical audits, the European Commission published Guide No.159 entitled "European commission guideline on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy)" [Guide-RP159].

Several European countries have put in place clinical audits (by peers) in radiotherapy. This is the case in Belgium for example. During his hearing by the WG, Pierre Scalliet presented the method used for conducting clinical audits in radiotherapy in Belgium, along with the results of the last campaign. The clinical audits have been carried out by a team (radiation oncologist, medical physicist, radiographer) since 2007. They are organised using the IAEA methodology. A document available on the Internet ⁷ gives practical directives for the clinical audits in Belgium.

Appendix 7 provides additional information.

- In France:

In France, Article R.1333-73 of the Public Health Code introduces the elements relative to the evaluation of clinical practices that expose individuals to ionising radiation for medical purposes. A first approach to the implementation of the professional practices assessment for training purposes has been initiated by the HAS (guide published in 2013, 4 programmes for radiotherapy) and involves self-assessments⁸.

At the time of writing this report, the SFRO and SFPM were preparing a procedure for the performance of clinical audits based, to begin with, on voluntary participation of the radiotherapy centres and modern radiotherapy techniques.

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V. Findings concerning the current situation in France

It is observed too frequently when implementing new radiotherapy techniques that the project-mode organisation of the centres could definitely be improved. As a general rule, the project organisation is rarely defined and coordinated.

It is noted that radiotherapy centres have difficulty in precisely determining the work load associated with the implementation of a new technique. This question is generally underestimated by the radiotherapy centres.

The acquisition of certain items of equipment, particularly those used for performing the quality controls specific to a technique, is sometimes postponed, as such equipment can be considered like a budget adjustment variable and not a necessity. A "risk management" approach is deployed rarely if at all, and the impact of these new techniques on the organisation and professional practices is often underestimated by the medical administrative decision-makers.

The professionals often express their needs for training and mentoring with other centres that have already implemented the new techniques. Some centres, considered by the professionals as being technically advanced and experienced but which do have the official status of reference centre, accept to integrate personnel from a centre wishing to acquire the new technique in their teams.

It is moreover sometimes difficult to find a training plan for new techniques that is consolidated for the whole team.

The requirements of ASN Resolution 2008-DC-0103, such as the writing of treatment protocols, specific quality controls, a priori risk analysis, or the updating of procedures, are not necessarily foremost among the concerns of the departments. Quality control still remains highly dependent on the manufacturer's recommendations. It appears necessary to set up a reference system and appropriate guidelines specific to the techniques/equipment in question.

No particular regulatory text exists for IMRT with linear accelerators or the recent machines such as Tomotherapy (Accuray), Cyberknife (Accuray) or Vero (Brainlab). The ANSM decisions relating to quality controls do not provide for these equipment items even though one of the major guarantees of the system seems to be the initial external quality control which at present does not cover the dynamic configurations such as IMRT.

Some of the INCa approval criteria for the practice of radiotherapy are not adapted to the new techniques (e.g.: double calculation of MUs, in vivo dosimetry). The recent developments will enable the objective to be achieved (particularly the development of transit dosimetry and the existence of software for the double calculation of MUs appropriate for IMRT).

With regard to the organisation of centres described for medical physics, difficulties are recurrently observed in evaluating the impact of the new techniques on the internal organisation. It appears that it is essential to provide information on the additional work load related to the medical physics, the new methods of collaboration to be put in place between the professionals.
(dosimetrists, medical physicists, radiation oncologists), and the impact on the practices resulting from the implementation of new techniques. Today there is no enforceable criterion for assessing the capacity of a centre to implement a new technique.

Furthermore, the WG notes that, unlike several European countries, France has not always organised clinical audits by peers for either its organization or its funding.

It emerges from these findings that the new techniques are currently developing with insufficient recommendations and with no specific supervision in the present radiotherapy licensing system.
Report of the working group concerning the conditions of implementation of "new techniques and practices" in radiotherapy
PART III: OPINIONS AND RECOMMENDATIONS
Opinions and recommendations of the WG concerning the conditions of implementation of "new techniques and practices" in radiotherapy

When a new technique or practice is implemented, whether at national level or in a centre, the WG recommends that particular attention be devoted to the subjects developed below.

1. Project management: a defined aim and means

A rigorous and robust project management organisation must be established to guarantee the successful implementation of any new technique. In effect, the balance of a department is often upset when a new technique or practice is implemented.

Project management consists in controlling costs, time frames, quality, risks and personnel training.

The first step consists in answering the question about the appropriateness of deploying the new technique/practice in the centre in question. Which technique or practice for which patients? The defining of the initial medical project is essential for the choice of the technique and therefore its successful conduct. A medical-economic study shall always be associated with the preliminary project: cost/efficiency of implementation. This step will serve to evaluate the involvement of the administrative services of the centre in question (human resources, financial, legal departments etc.).

This step may necessitate the formalising of pre-requisites.

It would seem necessary to establish prerequisites for the implementation of the envisaged new technique. The pre-requisites can be used to assess any shortcomings to be remedied beforehand and thus adopt a gradual, unbrushed approach, without any "forgotten" steps, comprising an assessment of each step performed. For example, it would not be recommended to validate a new technique using a new measurement method for which there is no hindsight in the centre in question, or if it has not been put in place and validated using more conventional and mastered techniques and been compared with other validated measurement methods.

The WG recommends verifying the pre-requisites of a centre through an internal or external audit before implementing new techniques.

The WG recommends:

- setting up a limited multidisciplinary and experienced team (senior radiation oncologists, senior physicists, radiographers with at least 5 years' experience) dedicated to the implementation of a new technique for a minimum period - to be defined - with the aim of mastering all the functions and processes associated with the new technique before opening the team to other people. This team must bring together all the professional categories linked to the new technique implemented, as well as the persons responsible for quality management and risk management,
- to promote the emergence of coordinator/expert personnel in the use of these techniques,
- to perform an a priori risk analysis,
- to gradually increase the number of patients and the complexity of the treatments. This will limit the stress associated with the newness of the technique and leave free slots on the new equipment in the early stages for personnel training and quality controls,
- that the experts be present in the radiotherapy department during the learning phase, and present on the treatment station for the first patients treated,
- to disseminate the new technique or practice to the entire team through continuous training, the content of which must be traced and course attendance validated.

2. Human resources: personnel numbers to match the implications

Whatever the case, implementing a new technique involves an additional work load which may be too great to be absorbed by the existing personnel numbers. The WG thus recommends that this work load be assessed in project management in order to plan for additional human resources as required and adapt them to the project objectives. It is recommended to ensure that the human resources match the needs of the "new development".

The human resources, which are heavily dependent on the project, its size and duration, must be sufficient to allow the acceptance testing and deployment of the technique in question, and then to make it function with the previously set clinical objectives.

The dimensioning must be based on the existing regulatory provisions and recommendations, the good practices baselines set by the learned societies and involve the management of the structures concerned.

3. Training: trained professionals

In the recent past, in Deliberation 2011-DL-0025 of 30th August 2011 relative to the improvement of radiation protection in the exercise of stereotactic radiotherapy, ASN issued several recommendations relating to proficiency and safety in the use of these practices. These recommendations focus in particular on the initial and continuous training of professionals.

*The WG recommends that the initial and continuous training of the professionals should integrate the developments in techniques and practices as soon as they arise. To this end, the learned societies and training organisations will ensure that a training offering appropriate for these developments is maintained.*

a. Involvement of the manufacturers:

*The involvement of the manufacturers is vital* and must supplement the training of the professionals, particularly regarding the use of the medical devices and software.

*The WG recommends that the supply of equipment should be tied to the delivery of a minimum amount of prior training by the manufacturer to the different professional categories concerned. The training in the use of the machine must be applied to the different methods of treatment that the machine can deliver.*

*The WG recommends that the customer training be provided in French.*

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9 INCa (National Cancer Institute) approval criteria for the practice of radiotherapy No. 4 and No. 5 relative to personnel
The manufacturers should also assist the professionals with the implementation of these devices and their upgrades.

**The WG recommends that the medical teams be assisted by the manufacturer in the short and medium term following the installation of a facility under a contract with the management of the medical center.**

The training must not be used as an economic adjustment option when implementing a new technique; it must be part of the basic commercial proposals when purchasing a new machine. The WG underlines the inadequacy of the services (training, quality controls, etc.) provided by certain manufacturers during installation and/or after work interventions (preventive actions, maintenance, etc.).

**b. Radiographers:**

**The WG recommends reinforcing the initial training in the new technologies.**

**The WG recommends designating at least 2 treatment station radiographers as long-term experts in the new techniques or practices.** They must receive specific and complete training. The content of the training must be tracked and course attendance must be validated by the expert professionals who are competent with respect to the content. The dissemination of the new technique or practice to the entire team must obligatorily be achieved through in-house training, the content of which must be tracked and course attendance validated.

The main knowledge necessary for the use of a new technology can be summarized as follows:

- Technology: Operation, utilisation and safety.
- Dosimetric particularities and points of vigilance.
- Therapeutic indications, protocols used and patient follow-up.

A professional practices assessment shall be carried out periodically taking up the subjects from the in-house continuous training and the skills booklet.

The WG also recommends that the continuous training offering organised by the AFPPE should be developed and enable the radiographers to train themselves or enhance their skills in the area of new techniques and practices.

Appendix 6 provides an example of project management for the training of radiographers.

c. Radiation oncologists

- **Adaptation of the DES to emerging technologies:**

The main medical knowledge necessary for the implementation of a new technology can be summarized as follows:

- Indications: type of cancer, stage, compatible history of the illness,
- Definition of the target - radioanatomy: imaging work-up necessary to optimally define the target volume, delineation
- Prescription: total dose, fractionation, protraction, dose constraints on specific organs at risk
- Basic specific medical physics knowledge: conformation index, dose uniformity, non-coplanar treatments, dose calculation algorithms,
- Basic radiobiological knowledge: dose equivalence models, vascular effect.

d. Medical physicists

The WG recommends that the professionals and the training organisation of medical physicists adapt the content of the theory teaching to the developments in techniques and practices as rapidly as possible.

Particular attention must be paid to ensure that the students have access to these techniques during their internships in the host departments, essentially for the IMRT and stereotactic irradiation techniques.

The WG also recommends that the continuous training offering organised by the SFPM should enable the medical physicists, or even all the health professionals concerned, to train themselves or enhance their skills in the new techniques.

The WG recommends that at least two medical physicists be trained on the new equipment by the manufacturer. These 2 physicists shall be the experts for the new technique. These training courses must enable the medical physicists to acquire the necessary knowledge of the equipment, its functioning and its utilisation. The training must also provide precise knowledge of the calculation algorithms used in order to avoid the "black box effect" as much as possible.

Access to a new technology must be accompanied by training for all the professionals mentioned, with an assessment and maintaining of skills over time (continuous professional development).

These training courses are complementary. It could be damaging to only consider one type of training, with the risk of causing potential shortcomings (for example, omitting training in the use of medical equipment and devices could induce a risk).

4. Technical and dosimetric performance: tested equipment

- Acceptance

Even if the end-user remains responsible for the measurements taken, the manufacturers have a preponderant role in accompanying the teams through the supply of methodologies and/or verification or measuring devices dedicated to their equipment, along with access to all the theoretical and practical dosimetric data measured in other centres that have installed this equipment.

The WG recommends that the manufacturers make available to the users generic reference data ("golden data") resulting from measurements taken on equivalent equipment so that the new user centre can compare them with its own measurements.
The practice or technique implemented can constitute part or all of the treatment chain, the individual elements of which must undergo appropriate verification. However, a verification of the entire treatment chain that led to the dose being obtained must be performed by end-to-end dosimetric tests reproducing a "standard" of the technique considered and using all the planned methods and procedures for the clinic, as described in appendix 4.

The WG recommends verifying the entire treatment chain through end-to-end dosimetric tests.

- Quality controls

When any new machine is introduced, the teams of the radiotherapy departments must be able to familiarise themselves with it by validating - if necessary with respect to the initial specifications - the technical, practical and dosimetric aspects of its characteristics, parameters and performance. In this latter domain, the expertise of the medical physicist will make it possible, from the start of project management, to make the technical and methodological choices necessary for mastering measurement of the delivered dose and performance of the quality controls. Thus, before the new equipment arrives, the team will install its tools, acquire training in their use and validate its competence for their implementation.

In certain cases the newness of the technique will mean that the team cannot refer to texts such as the decisions of the AFSSAPS of 2nd March 2004 and 27th July 2007, or that the ANSM cannot publish a specific decree. This being said, French publications (the SFRO Guide to External Beam Radiotherapy Procedures - 2007, SFPM Guide to Good Medical Physics Practices, etc.) or international publications (ICRU 83, IAEA, ACR/ASTRO, etc.), and scientific publications should be able to guide the reflection of the teams in the choice of equipment and methods of measuring the basic dosimetric data (acceptance) and the determining of the internal controls of the treatment chain as a whole.

The WG recommends that, as soon as a new machine or technique is introduced in France, the professionals (SFPM) initiate work on the entry into service and the quality control of the new machines and techniques in order to establish national recommendations. The work to perform will be specified by the committee of experts (see point 11 below) on the basis of any publications and the manufacturers’ recommendations.

The difficulties in applying the controls mentioned by the decision of 2nd March 2004 (amended by the decision of 27th July 2007) must not be an obstacle to the performance of the external dosimetric controls. These must be revised and adapted to the technique in question by:

- the development of specialised services or companies for these external services,
- having these services or companies develop and provide aids that are better suited or complementary to those used at present (thermoluminescent dosimetry), such as ionisation chambers, detector matrices, films or alanine.
- the involvement of the LNHB (national metrology laboratory) for the calibration and validation of the above-mentioned tools, and for conducting dosimetric audits in France for complex techniques (example of the NPL in the United Kingdom which participates in external regional audits).
Thus defined, these controls - when available - must be carried out before the first entry into service, then periodically thereafter or after making any major modifications to the equipment. As a minimum, when the proposed dosimetric control protocols do not satisfy the ongoing external control requirement, the centres will have to either:
- call upon an external organisation to check a final prescribed dose, as close as possible to the reference protocol, or failing this, as close as is technically achievable for the service provider. This implies that the external companies must propose simple and adaptable tests (utilisation of simple dosimeters such as the TLDs, alanine or dosimetric films in relative and absolute mode) other than their standard protocols,
- call upon a dosimetric audit by peers or call upon learned societies or national or regional associations,
- approach "expert" centres or centres that routinely use the equipment,
- participate in the production of new dosimetric protocols under development.

Consequently, the WG recommends:
- extending the framework and conditions of performance of the external dosimetric control to complex and innovative techniques over and beyond the controls mentioned in the decision of 2nd March 2004 (amended by the decision of 27th July 2007) and involving the national metrology structures.
- that the dosimetric controls already available from recognised laboratories (EQUAL ESTRO, RPC/MDADL, etc.) be carried out before the first entry into service, then periodically, without waiting for the regulatory framework to evolve,
- the performance of dosimetric inter-comparisons between user centres.

5. Clinical audit by peers: validated practices

The WG recommends the setting up of clinical audits by peers. These clinical audits will be based on the recommendations and baselines established by the learned and professional societies. This audit by peers would be carried out during the first entry into service (before the 1st patient) then during routine use (periodic visits).

The recommendation initially concerns the performance of audits for the new techniques, then extending this principle to all radiotherapy practices.

The WG recommends:
1. setting up the clinical audit by peers led by a multidisciplinary team, as is done in several European countries.
2. performing an audit before treating the 1st patient then during routine use (periodic visits).

6. External services in medical physics

Considerable disparity is observed today in the external medical physics services for putting a new technique into service, in terms of the measurements taken, the equipment proposed or the training provided and the assessment of the people trained.
The WG recommends clarifying the framework of involvement of external medical physics service providers, to define in particular the necessary skills and the responsibilities.

7. Collection and analysis of the data concerning the first patients treated

The collection and analysis of data will enable the centre to compare itself with the national and/or international baselines. The collection of data in the national databases (like the one that is going to be set up for stereotactic radiotherapy) and the inclusion in the clinical research protocols which feature a quality control section part must be encouraged. These projects can only be envisaged with the aid of institutional bodies and hospital federations. The WG recommends constituting a prospective database of the first patients treated with a new technique for the purpose of analysis, follow-up and assessment of the clinical results.

8. Patients: informed and involved

Patients can be informed in several ways:
- handing over an information letter and collection of the signed consent form for patients treated in the context of clinical research protocols or whose data are colligated in a database,
- providing booklets on the pathology and the treatment techniques, etc.
- giving the contact details of the nearest meeting and information area,
- giving the contact details of the websites that can provide information on the illnesses and the treatments: learned societies, patient associations, etc.
- proposing a paramedical consultation with a radiographer in addition to the medical consultation.

The WG recommends placing the patient at the centre of the system with information feedback by the patients themselves. The information delivered to the patient must be clear and appropriate. Its traceability is recommended for the medical file and the quality system of the medical centers.

9. INCa approval criteria for the practice of radiotherapy

The guide published by INCa in 2008 concerning In Vivo Dosimetry in external-beam radiotherapy must be updated to take into account the technological developments and practices that have emerged in the last few years. The WG recommends that the INCa criteria be revised regularly in order to integrate the particularities of the new techniques and practices.

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10 Guide to the daily practice of in vivo dosimetry in external beam radiotherapy drawn up under the aegis of the INCa (National Cancer Institute), with the collaboration of the SFPM (French Society for Medical Physics) and ASN (French Nuclear Safety Authority). October 2008.

http://www.google.fr/url?q=http://www.sfpm.fr/download/fichiers/docs_sfpm/200810_guide_dosi_in_vivo.pdf&sa=U&ei=EojJUc7cOuW80QX6_IDYBA&ved=0CBwQFjAA&usg=AFQjCNGbzYe96RdP-ncNdQy0En-E9seWNw
10. Medical devices vigilance / experience feedback

Establishments having made medical device vigilance reports express regularly their desire to have feedback from the ANSM on the investigations of these reports.

The WG recommends:
1. better dissemination by the ANSM of the information relative to the reporting of medical devices vigilance events directly to the radiotherapy professionals,
2. better coordination at European and International level with regard to lessons learned from events concerning new techniques.

Organisations such as the IAEA or HERCA could be called upon in this respect.

11. Creation of an Advisory Committee of experts

The WG observes that in view of the current national (French) organisation, it is impossible to define precise technical and functional recommendations encompassing all the techniques being deployed at present or in the future.

Consequently, the WG recommends the creation of an Advisory Committee of Experts comprising professionals proposed by the learned societies, in relation with representatives of the health and radiation protection authorities concerned.

This committee would be tasked with:
- determining which device or technique requires new provisions,
- defining the prerequisites before implementing a new technique,
- detailing what new measures must be developed (training, quality control, informing patients, etc.),
- organising the development of these provisions,
- monitoring application of these provisions,
- issuing recommendations for the implementation of external audits.

This committee would meet at the request of one of its members and at least once a year.

Material and financial resources must be planned for within the health system to enable this committee to continue to exist over the long term.
Report of the working group concerning the conditions of implementation of "new techniques and practices" in radiotherapy
PART IV: SUMMARY OF THE RECOMMENDATIONS
The WG observes that new techniques are developing with insufficient recommendations and with no specific supervision in the present radiotherapy authorisation system.

Consequently, it is moved to issue the following recommendations.

The order of these recommendations is not an indication of their importance. They have been taken up in an order that goes from the most general to the most technical or practical.

R1: Create of an Advisory Committee of experts
The WG recommends the creation of an Advisory Committee of Experts comprising professionals proposed by the learned societies, in relation with representatives of the health and radiation protection authorities concerned.
This committee would be tasked with:
- determining which device or technique requires new provisions,
- defining the prerequisites before implementing a new technique,
- detailing what new measures must be developed (training, quality control, informing patients, etc.),
- organising the development of these provisions,
- monitoring application of these provisions,
- issuing recommendations for the implementation of external audits.

This committee would meet at the request of one of its members and at least once a year.

Material and financial resources must be planned for within the health system to enable this committee to continue to exist over the long term.

R2: Organise clinical audits by peers
The WG recommends the setting up of clinical audits by peers, led by a multidisciplinary team. This recommendation is initially aimed at the new techniques, but must ultimately be extended to all radiotherapy techniques.
With regard to the new techniques, the WG recommends the performance of an audit at the first entry into service (before the 1st patient) then periodically during routine use.

R3: Verify the pre-requisites
The WG recommends verifying the pre-requisites of a centre through an internal or external audit before implementing the new technique or practice.

R4: Project management
A rigorous and robust project management organisation must be established in order to guarantee the successful implementation of a new technique or practice in radiotherapy, including the medical-economic aspect.

The WG recommends:
1. the setting up of a limited, multidisciplinary and experienced team and to promote the emergence of expert personnel in the use of these techniques, with the designation of at least 2
expert professionals per discipline maintained over the long term, and the involvement of the persons responsible for quality and risk management from the project preparation stage,

2. the performance of an a priori risk analysis,

3. a learning phase comprising a gradual build-up in the number of patients and treatment complexity. The experts are present in the radiotherapy department during the learning phase and present at the treatment station for the first patients treated,

4. the dissemination of the new technique or practice to the entire team through continuous training, the content of which must be recorded and course attendance validated.

R5: Human resources

The implementation and clinical application of a new technique require additional human resources to guarantee treatment quality and safety. It may be justified to call upon external resources from time to time during the deployment phase.

The WG recommends adapting the human resources, particularly in medical physics, when setting up and using innovative or special techniques.

The human resource recommendations issued by the learned societies concerned according to the technique involved and the number of patients treated must be applied.

R6: Training

Initial and continuous training

The WG recommends that the initial and continuous training of the professionals should integrate the changes in techniques and practices as soon as they arise.

To this end, the training organisations and learned societies will ensure that a training offering appropriate for these developments is maintained.

Role of the manufacturer

The WG recommends:

1. that the supply of equipment should be tied to the delivery of a minimum amount of prior training by the manufacturer to the different professional categories concerned. The training in the use of the machine must be applied to the different methods of treatment that the machine can deliver,

2. that the customer training be provided in French,

3. that the manufacturer assists the teams until the end of the learning phase, which shall include the first patients (see R4).

R7: Improve the testing of the technical and dosimetric performance

Acceptance:

The WG recommends:

1. that the manufacturers make available to the users generic reference data ("golden data") resulting from measurements taken on equivalent equipment so that the new user centre can compare them with its own measurements,

2. verifying the entire treatment chain by performing end-to-end dosimetric tests.
Quality control:
The WG recommends:

1. that as soon as a new machine or technique is introduced in France, the professionals initiate work on the quality control of the new machines and techniques in order to establish national recommendations,

2. extending the framework and conditions of performance of the external dosimetric control to complex and innovative techniques over and beyond the controls mentioned in the decision of 2nd March 2004 (amended by the decision of 27th July 2007) and involving the national metrology structures,

3. that the dosimetric controls already available from recognised laboratories (EQUAL ESTRO, RPC, etc.) be carried out before the first entry into service, then periodically, without waiting for the regulatory framework to evolve,

4. the performance of dosimetric inter-comparisons between user centres.

R8: Supervise external services in medical physics

The WG recommends supervising the external medical physics service providers in order to define the necessary skills and the responsibilities, for example.

R9: Develop the prospective collection and analysis of data concerning the radiotherapy patients

The WG recommends constituting a prospective database of the first patients treated with a new technique for the purpose of analysis, follow-up and assessment of the clinical results.

R10: Enhance the informing and involvement of patients

The WG recommends placing the patients at the centre of the system with information feedback by the patients themselves. The information delivered to the patient must be clear and appropriate. Its traceability is recommended for the medical file and the quality system of the medical centers.

R11: Revise the INCa approval criteria for the practice of radiotherapy

The WG recommends that the INCa criteria be revised regularly in order to integrate the particularities of the new techniques and practices.

R12: Improve the dissemination of information relative to medical devices vigilance and experience feedback

The WG recommends:
1. better dissemination by the ANSM of the information relative to the reporting of medical devices vigilance events directly to the radiotherapy professionals,
2. better coordination at European and International level with regard to lessons learned from events concerning new techniques.
Glossary

The French terms are indicated in italics when the French acronym is used.

AAPM: American Association of Physicists in Medicine
ACR: American College of Radiology
AFCOR: Association of Continuous Training in Oncology Radiotherapy (Association de Formation Continue en Oncologie Radiothérapie)
AFPPE: French Association of Radiographers (Association Française du Personnel Paramédical d'Electroradiologie)
ANSM (formerly AFSSAPS): French Health Products Safety Agency (Agence Nationale de Sécurité du Médicament et des produits de santé)
ARS: Regional health agency (Agence Régionale de Santé)
ASTRO: American Society for Therapeutic Radiology and Oncology
CHU: University Hospital Centre (Centre Hospitalier Universitaire)
CPD: Continuous Professional Development
DGOS: General Directorate for Healthcare Provision (Direction Générale de l'Offre de Soins)
DIU: Inter-University Diploma (Diplôme inter-universitaire)
DQPRM: Qualifying diploma in radiological and medical physics (Diplôme de Qualification en Physique Radiologique et Médicale)
EFOMP: European Federation of Organisations in Medical Physics
ESTRO: European Society for RadioTherapy and Oncology
FTE: Full-Time Equivalent
GPMED: Advisory Committee of Experts in Medical radiation protection. Chaired by Mr. Bernard Aubert, the GPMED is called upon by ASN to give its opinions and, where applicable, recommendations in the field of radiation protection of professionals and the public for medical and forensic applications of ionising radiation.
HAS: French National Authority for Health (Haute Autorité de Santé)
HERCA: Heads of European Radiological Protection Competent Authorities. A voluntary association within which the heads of the European radiological protection authorities work together to identify shared problems and propose practical solutions to these problems. HERCA works on subjects that are usually covered by the provisions of the Euratom treaty. In 2014, HERCA comprised 51 radiation protection authorities from 31 European countries (including the 28 EU member countries).
IAEA: International Atomic Energy Agency
ICRP: International Commission on Radiological Protection
ICRU: International Commission on Radiation Units and measurements
IGRT: Image-Guided Radiation Therapy
IMRT: Intensity-Modulated Radiation Therapy
INCa: French National Cancer Institute (Institut National du Cancer)
InVS: French health monitoring institute (Institut de Veille Sanitaire)
IORT: Intra-Operatory RadioTherapy
IRSN: French Institute for Radiation Protection and Nuclear Safety (Institut de Radioprotection et de Sûreté Nucléaire)
MLC: Multi-leaf collimator
MPE: Medical Physics Expert
MU: Monitor-Unit
SBRT: Stereotactic Body Radiation Therapy
SFPM: French Society of Medical Physics (Société Française de Physique Médicale)
SFRO: French society for radiation oncology (Société Française de Radiothérapie Oncologique).
SRS: Stereotactic radio surgery
TBI: Total body irradiation
TLD: ThermoLuminescent Dosimetry
TPS: Treatment Planning System
UEMS: European Union of Medical Specialists (Union Européenne des Médecins Spécialistes)
VMAT: Volumetric-Modulated Arc Therapy
WHO: World Health Organisation
APPENDICES

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- Appendix 3. List of persons met during the hearings
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- Appendix 5. References relative to the recommendations issued by the learned societies in the USA
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APPENDIX 1. Working Group Engagement

Letter

Montrouge, 8 August 2015

Deputy Director-General of ASN
(Nuclear Safety Authority)

To,

The Chairman of the GPMED

Subject: Recommendations on the conditions of implementation of "new techniques and practices" in radiotherapy

Dear Chairman,

Since the 1990’s, external-beam radiotherapy has seen the introduction of a great number of innovations and technological advances, accompanied by imaging techniques with improved performance. The dissemination of these techniques, which are vital to improve clinical benefits for patients, necessitates a number of prerequisites for the centres that implement them and must take into account experience feedback from the first users.

The conference organised by ASN in collaboration with the IAEA, the WHO and the European Union in December 2009 in Versailles enabled certain radiotherapy techniques to be identified as having major implications by underlining not only the benefits but also the risks associated with the dissemination of these new techniques and the related practices if they are not fully mastered. The follow-up meeting to this conference with the French radiotherapy stakeholders, held in November 2010, identified the need to define “the conditions of implementation of the new equipment and the associated new practices and the users’ needs in terms of specific skills, training and good practice guides”.

The generic term "new techniques and practices" includes in particular:

- new functions of isocentric accelerators such as intensity-modulated radiotherapy, including volumetric arc therapy and stereotactic irradiation;
- new treatment devices such as helical tomotherapy and robotic radiotherapy, etc.

Consequently, I would ask the GPMED (Advisory Committee of Experts on Medical Questions) to establish recommendations on the conditions of implementation of new techniques in radiotherapy and the associated practices, based on the best practices existing in France and abroad, and to undertake a reflection on the regulatory framework applicable to the implementation of these techniques.

These recommendations, intended for the establishments and institutions concerned, which will have to draw from the experience of the centres that have acquired proficiency in the use of these techniques, may notably concern:

...
- project management by an establishment involved in the implementation of a high-precision technique in external-beam radiotherapy;
- the necessary human resources (radiation oncologists, medical physicists, radiographers, dosimetrist);
- training prior to utilisation as well as the continuing professional development of the teams, assured by the manufacturers in particular;
- the organisational conditions;
- the consequences on the equipment configurations of the technical platforms wishing to implement these new technologies;
- the necessary equipment, particularly for dosimetry and the quality controls of the devices used (including the software applications);
- the equipment and procedures for the quality control of the treatments, including verification of the delivered dose.
- the assistance from external experts and the setting up of a quality assurance programme (including external audit by peers and dosimetric audit) during their deployment;
- the a priori risk analysis process.

These recommendations, which are of a general nature, must focus more particularly on the techniques of intensity-modulated radiotherapy and stereotactic irradiation. If necessary, certain specific techniques may form the subject of particular recommendations.

I propose that you submit recommendations to me by October 2014 at the latest.

The recommendations of the GPMED will take into account the opinions of the professionals, manufacturers, institutions and bodies concerned by the new techniques and associated practices in external-beam radiotherapy, as well as the European and international recommendations when they exist.

Yours sincerely,

The Deputy Director General
of ASN (Autorité de Sûreté Nucléaire - Nuclear Safety Authority)

Jean-Luc LACHAUME
APPENDIX 2. Composition of the Working Group

Coordinates: Pr. Eric Lartigau and Mr. Albert Lisbona

Members of the WG:

Mr. Eric LARTIGAU  Member of GPMED, WG coordinator
Mr. Albert LISBONA  Member of GPMED, WG coordinator
Mr. Bernard AUBERT  Chairman of GPMED
Mr. Jean-Pierre GERARD  Member of GPMED
Mr. Marc-André MAHE  SFRO
Mr. Dominique LEDU  SFPM
Mr. Vincent MARCHESI  SFPM
Mr. Aurélien DE OLIVEIRA  AFPPE
Ms. Jocelyne MAZURIER  Oncorad Garonne Group, Toulouse
Mr. Olivier PHARE  Bordeaux Nord Clinic
Mr. Olivier DUPUIS  Jean Bernard Centre, Le Mans
Mr. Philippe CADOT  ICO, Nantes
Ms. Sylvie DERREUMAUX  IRSN

ASN Staff:
Ms. Aurélie ISAMBERT (ASN/DIS, technical secretary)
Ms. Marielle FAYOL (observer)
### APPENDIX 3. List of persons met during the hearings

<table>
<thead>
<tr>
<th>Guest</th>
<th>Subject</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pascal François</td>
<td>What is the innovation?</td>
<td>10 December 2013</td>
</tr>
<tr>
<td>Medical physicist and risk manager</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFQSR (French Association for Quality and Safety in Radiotherapy)</td>
<td>Internal audit of practices / approach when implementing new techniques / documentary aspects, etc.</td>
<td>20 January 2014</td>
</tr>
<tr>
<td>Manufacturers (Varian, Elekta, BrainLab, Accuray)</td>
<td>Training / assistance / maintenance approach</td>
<td>20 February 2014</td>
</tr>
<tr>
<td>HAS</td>
<td>External audit of practices</td>
<td>18 March 2014</td>
</tr>
<tr>
<td>Pierre Scalliett (Belgium)</td>
<td>Audit by peers</td>
<td>18 March 2014</td>
</tr>
<tr>
<td>INCa</td>
<td>Approval criteria</td>
<td>18 March 2014</td>
</tr>
<tr>
<td>ANSM</td>
<td>Medical devices vigilance / possible modification of AFSSAPS quality control decisions</td>
<td>1 April 2014</td>
</tr>
<tr>
<td>Approved organisations (external quality control)</td>
<td>Solutions available for the external quality control of new techniques/practices</td>
<td>1 April 2014 (EQUAL –ESTRO)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Beld'Art (in writing)</td>
</tr>
<tr>
<td>ARS Bretagne</td>
<td>Impact on the authorisation criteria</td>
<td>15 May 2014 (by telephone)</td>
</tr>
<tr>
<td>ASN (DIS)</td>
<td>Presentation of the difficulties identified by the ASN divisions</td>
<td>15 May 2014</td>
</tr>
<tr>
<td>Service providers</td>
<td>Acceptance / implementation of a new techniques (e.g. IMRT)</td>
<td>15 May 2014 (Seven sigma)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19 June 2014 (Radiation Therapy Consulting)</td>
</tr>
<tr>
<td>AFIB</td>
<td>The biomedical engineer and innovations in radiotherapy</td>
<td>23 September 2014</td>
</tr>
<tr>
<td>Customers of service providers (non-exhaustive list)</td>
<td>Reasons for using a service provider / performance of the service / experience feedback</td>
<td>In writing between 15 May and 3 July 2014</td>
</tr>
<tr>
<td>FHP/ Unicancer</td>
<td>hindrances / incentives / motivation / prioritisation for the implementation of new techniques in radiotherapy</td>
<td>February - March 2014 (in writing)</td>
</tr>
<tr>
<td></td>
<td>Organisation of training courses</td>
<td>No reply from the FHF (French Federation of Hospitals)</td>
</tr>
</tbody>
</table>
APPENDIX 4. The "end-to-end" tests

The aim of the end-to-end tests is to verify the ability of a treatment chain, for the technology in question, to compliantly deliver an appropriate treatment plan corresponding to a "reference standard" of the technique. It is a question of developing a test procedure from the CT scan for dosimetric purposes and treatment planning through to irradiation and verification of the irradiation.

The elements that can be evaluated are:

- The treatment plan: possibility of comparison with respect to a "reference" treatment plan developed by an "expert" team ⇒ treatment plan calculation and preparation step,
- The ability of the system to deliver the planned treatment without any blockage or error during the procedure ⇒ treatment step,
- The ability of the machine to deliver the dose compliantly: comparison of the delivered dose distribution with the planned dose distribution ⇒ comparison step.

Remarks:

- The defining of the volumes by a team is presumed to be outside the framework of the "end-to-end" test since this concerns medical aspects linked to the prescribing of the treatment and not its delivery.
- Whether it involves the imaging of a patient or of a test object, the "end-to-end" test can include either the on-site acquisition of the dosimetric imaging or the external supply of the imaging.

The tests performed can be conducted with different strategies. They can involve tests presumed to be identical and carried out in parallel in different services under the aegis of an organisation / coordinator / sponsor as is often the case before starting a new protocol or clinical test, or else an audit constructed from images of an anonymous patient or an anthropomorphic phantom, with imposed organs at risk and target volumes. It could also consist of a test carried out on a one-off basis on the initiative of a given department and for which the result will be assessed either by an external entity or within the department in question as part of a quality control procedure.

If a specific test object is used, it must be compatible with the different imaging methods that could be used when applying the technique (CT, MRI, PET for example).

The treatment plan is devised by reproducing the standard clinical protocols in order to be as close as possible to the actual conditions of use of the treatment chain, or else from particular instructions given to the user concerning, for example, the dimensions of the irradiated field, the total dose and dose per fraction, the dose gradients necessary to meet the dosimetric requirements, etc. The plan is calculated on the treatment planning system used for the technique in question with the calculation model used in practice.
The irradiation step will be carried out on a "test object" simulating a patient and with the envisaged treatment characteristics, particularly in terms of geometry and anatomy of the envisaged patients (form, size, presence of tissular heterogeneities, etc.), method of repositioning and monitoring during the session, mobile to simulate breathing if necessary, etc. Irradiation must be carried out under clinical conditions, that is to say using the radiotherapy information system and the record and verify system.

The treatment must be delivered without being disturbed by events (errors, interruptions, etc.) that could jeopardize the satisfactory administering of the treatments.

The irradiation is verified using detectors positioned inside the test object and which may be chosen according to the desired or imposed goals. They can be 1D, 2D or even 3D detectors. The test often comprises several measurement methods. For example, for a 1D measurement, the detector must be chosen according to the type of treatment performed, the size of the fields, the energy level or the dose rate so that the measured dose is as representative as possible of the dose actually delivered. A two-dimensional measurement using radiochromic films is to be favoured in order to evaluate the dose distribution when using complex treatment techniques such as IMRT or stereotactic irradiation.

The acceptance criteria for the observed deviations shall be chosen such that they are appropriate for the test objective. For example, the gamma index (Low et al., Med Phys 1998) is often used to assess dose distributions. The dose criterion varies between 3 and 5\%, while the distance criterion varies between 2 and 5 mm depending on the desired geometrical precision.
APPENDIX 5. References relative to the recommendations issued by the learned societies in the USA

Documents published by ACR and ASTRO: Practice Guidelines/Technical Standards:

General
ACR Practice Guideline for Continuing Medical Education Res. 53 – 2011
ACR–ASTRO Practice Parameter for Communication: Radiation Oncology CSC/BOC 2014
ACR Practice Guideline on the Physician Expert Witness in Radiology and Radiation Oncology Res. 38 – 2012

Practice Guidelines
ACR–ASTRO Practice Parameter for Radiation Oncology CSC/BOC 2014
ACR–ASTRO Practice Guideline for 3D External Beam Radiation Planning and Conformal Therapy CSC/BOC 2011
ACR–ASTRO Practice Guideline for the Performance of High-Dose-Rate Brachytherapy Res. 3 – 2010
ACR–ASTRO Practice Guideline for the Performance of Low-Dose-Rate Brachytherapy Res. 4 – 2010
ACR–ASTRO Practice Parameter for Image-Guided Radiation Therapy (IGRT) CSC/BOC 2014
ACR–ASTRO Practice Guideline for Intensity Modulated Radiation Therapy (IMRT) CSC/BOC 2011
ACR–ASTRO Practice Guideline for the Performance of Proton Beam Radiation Therapy CSC/BOC 2013
ACR–ASTRO Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer Res. 2 – 2010
ACR–ASTRO Practice Guideline for the Performance of Stereotactic Radiosurgery CSC/BOC 2011
ACR–ASTRO–SIR Practice Guideline for Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignancies Res. 2 – 2008
ACR–ASTRO Practice Parameter for the Performance of Stereotactic Body Radiation Therapy CSC/BOC 2014
ACR–ASTRO Practice Guideline for the Performance of Total Body Irradiation CSC/BOC 2011
ACR–ASTRO Practice Guideline for the Performance of Therapy with Unsealed Radiopharmaceutical Sources Res. 26 – 2010
ACR Technical Standard for the Performance of Radiation Oncology Physics for External Beam Therapy Res. 7 – 2010
ACR Technical Standard for Medical Physics Performance Monitoring of Image-guided External Beam Radiation Therapy (IGRT) Res. 5 – 2009
ACR Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics Res. 5 – 2010
ACR Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics Res. 6 – 2010

ASTRO: ASTRO Safety White Papers:
https://www.astro.org/Clinical-Practice/White-Papers/Index.aspx

**AAPM reports**

APPENDIX 6. Project management and phase of initial and progressive training of radiographers for the implementation of an isocentric gantry in proton therapy: Experience of the Curie Institute - Proton Therapy Centre of Orsay

Description of the project:
- Change of accelerator (Cyclotron 230 MeV manufactured by IBA)
- Addition of a treatment room (isocentric gantry)
- Reconfiguring of the 2 fixed lines
- Extension of the medical wing
- Maintaining of the clinical activity

Project management and organisation:
Project management for the radiographers has been broken down into 5 sequences:
- Technical and organisational prerequisites
- Initial Internal Training (3 lines)
- Implementation of the first treatments
- Experience feedback
- Long-term Continuity and Continuous Internal Training

Working groups:
Creation of multidisciplinary working groups integrating radiographers and creation of specific working groups (organisation by head radiographer):
- Working group dedicated to positioning:
  - Choice and test of contention systems (ergonomic constraints and upgradability)
  - New locations (feasibility tests)
- Working group on the ergonomics of treatment rooms and safety:
  - Drawing up work procedures (process mapping) in order to optimise treatment times.
  - Verification of translations and manufacturers' procedures associated with the treatment.
  - Addition of complementary safety devices (positioning of cameras, positioning of emergency stop buttons, "roundsman" function, gamma probe, etc.).
  - Computing ergonomics and work station organisation.
  - Layout of the treatment room.
- Group dedicated to setting up the paramedical consultation:
  - Determining the information to deliver
  - Creation of supporting material (questionnaires, follow-up, etc.)
- Risk management working group: Failure Modes, Effects, Criticality Analysis
- Initiating working group, which will be responsible for establishing the working routine in the new treatment room.

Organising regular discussion meetings to foster the cross-disciplinarity of multidisciplinary groups.

Description of the "Initiating" radiographer group:
Team proposed head radiographer and physics team, after individual interviews.

- Group selection criteria (3 radiographers):
  - Experience, technical and dosimetric knowledge
  - Initial involvement in project
  - Motivation and availability
- Linguistic capabilities (for visiting foreign sites)
- Teaching capabilities
- Volunteership

○ Roles:
- Ensure the first treatments,
- Give the first experience feedback and determine the most blocking factors,
- Training of other radiographers (skills assessment),
- Setting up activity indicators (improving positioning times and treatment times)

○ Duration of the group: 6 months then initial internal training for the whole team.

Initial Internal Training
3 initial internal training lines to be validated by the radiographers:

○ Manufacturer – Technical Service:
  - System description,
  - Interfaces,
  - Specific safety devices,
  - VERISUITE positioning software,
  - Robots (coupling, decoupling, acknowledgements and defects)
  - One week's training in a foreign centre (2 radiographers + 1 medical physicist + 1 healthcare manager)

The manufacturer integrates an internal continuous training program for the site personnel in the service contract.
Experience feedback from the user to the manufacturer is set up.

○ Physics department:
  - Quality Controls and daily Reference Check,
  - Dosimetry,
  - New OIS version and organisation of information transfers between the various interfaces.

○ Radiographer (initiating group):
  - Verification sessions (practice runs)
  - Acquired skills booklet,
  - Protocols,
  - What to do if a problem arises,
  - Familiarisation with the manufacturer's treatment manual (translation / translation of clinical screens, etc.).

Agreement for work in pairs given by: Initiating radiographer and medical physics group, the paramedical team manager produces the summary.

Planning of training courses:

○ Radiographer team in place:
  - Initial Internal Training:
    - 3 lines
  - Continuous Internal Training (annual):
    - Manufacturer: specific training on demand.
    - Physics: Annual evaluation of accuracy of positioning by medical physics (comparative and reproducibility), quality controls.

  Radiographers meeting every two months to improve practices (meeting held as a matter of course as soon as a formal request is made by the radiographer team)
  - Head radiographer: Acquired skills (continuous training) and complementary internal and external training courses (cranial anatomy training, etc.). The paramedical team manager ensures the traceability of training courses and skills.
In case of recruitment:
- Initial Internal Training:
  - 3 lines
  - Physics basics

In the event of a procedure modification or precursory events
- Targeted training on the designated system(s).
APPENDIX 7. Results of the questionnaire addressed to HERCA

In 2014 a questionnaire was sent to the representatives of the competent authorities in radiation protection and nuclear safety of several European countries that are members of the association HERCA.\(^\text{11}\)

The aim was to gather information on any national regulations or recommendations concerning the implementation of new techniques and practices in radiotherapy.

The following 11 countries responded: Germany, Belgium, Spain, Estonia, Greece, Hungary, Luxembourg, Norway, Netherlands, Sweden and Switzerland.

The United Kingdom and Finland provided answers to certain questions.

1. Quality control of linear accelerators

   a. Protocol used by the radiotherapy centres to ensure the quality control of accelerators

The protocols used are:

- **national recommendations** in 5 countries. These recommendations are often based on international recommendations. Among these 5 countries, 3 of them (Netherlands, Greece, Switzerland) only have national recommendations for "conventional" linear accelerators.

- **international recommendations** in 5 countries. These recommendations are often based on AAPM or NCS\(^\text{12}\) protocols (for Belgium).

- **recommendations issue by the manufacturers** in 7 countries. This situation primarily concerns equipment such as Cyberknife or Tomotherapy systems.

The national protocols, when they exist, are developed by specific commissions (the NCS in the Netherlands, the KVIST\(^\text{13}\) in Norway, the DIN-NAR in Germany), by the Society of Medical Physics (Switzerland) or the nuclear safety authority (Greece).

The countries that do not have national recommendations for accelerators other than conventional accelerators use international recommendations or the recommendations issued by the manufacturers.

**Links to the national protocols:**


Switzerland: [www.sgsmp.ch](http://www.sgsmp.ch)

Germany: DIN website [http://www.nar.din.de/cmdjsessionid=KGU7AZEE0C1X2DJO7XZ5MTLB.1?=&languageid=en&workflowname=InitCommittee&search_committee=nar](http://www.nar.din.de/cmdjsessionid=KGU7AZEE0C1X2DJO7XZ5MTLB.1?=&languageid=en&workflowname=InitCommittee&search_committee=nar)


Norway: [http://www.nrpa.no/dav/aa5d7337eb.pdf](http://www.nrpa.no/dav/aa5d7337eb.pdf)


\(^\text{11}\) [http://www.herca.org/](http://www.herca.org/)

\(^\text{12}\) NCS: Netherland Commission on radiations dosimetry.

\(^\text{13}\) KVIST: Norwegian abbreviation for "quality assurance in radiotherapy"
b. Existence of national protocols for complex equipment or techniques

The majority of the respondent countries do not have national quality control protocols for the equipment or techniques such as IMRT, VMAT, Cyberknife or Tomotherapy. No country at present has a national protocol for:

- Cyberknife (under preparation in Switzerland);
- helical tomotherapy (under preparation in Switzerland and the Netherlands).

National protocols exist for both IMRT and VMAT in 2 countries and for IMRT alone in 2 other countries (Switzerland and the Netherlands), and are under preparation in the Netherlands for VMAT.

c. Is the use of recommendations mandatory?

The use of these recommendations is made mandatory by the regulations in 5 countries and considered good practice in 5 others. In Germany the regulations differ according to the state in question. In Belgium, medical physicists are obliged by the regulations to perform periodic quality controls, but the conditions are not specified.

2. Dosimetric audit

The dosimetric audit is mandatory in 7 countries. In Switzerland, where this audit is mandatory, it involves a dosimetric intercomparison organised by the society of medical physics, with the content changing each year. In the United Kingdom these audits involve intercomparisons, and are not specified in the regulations. In Belgium, it is planned that this audit, which at present is based on voluntary participation through Beld'Art programmes, will become mandatory.

These audits are generally held once every 2 or 3 years, but the frequency can vary according to the techniques involved.

3. External clinical audit (by peers)

Five countries have an organisational set up for the performance of clinical audits. In Norway, external clinical audits were held for a certain time and have now been replaced by internal audits. In Switzerland these audits are planned to start in 2015 (www.clinicalaudit.ch).

Various institutions are in charge of organising the audits:

- the Ministry of Health in several countries,
- the College of Radiotherapy in Belgium,
- The Radiation Protection Authority in Norway at the time when external audits were performed.

The frequency of performance in the majority of cases is one external audit every 5 or 6 years.

The audit teams usually comprise one radiation oncologist, one medical physicist and one radiographer.
These audits are financed by:
- the audited hospitals in 4 countries,
- the Ministry of Health or the radiation protection authority in 3 countries. In Switzerland the Federal Office of Public Health will finance the pilot audits once they are set up.

The audits generally last between 1 and 3 days.

4. Licensing of new techniques in radiotherapy

In Sweden, the radiotherapy licenses specifically mention the introduction of new techniques and/or practices with a description of the technique being sent to the SSM (the Swedish radiation protection oversight authority) no later than one month before its clinical use.

In Belgium, the practices that could lead to exposure to ionising radiation must, prior to the first license or large-scale adoption, be justified by their advantages, after taking into consideration all the advantages and drawbacks, including in the area of health. In such cases, a justification study must be completed and appended to the license application file. [http://www.fanc.fgov.be/fr/page/processus-d-autorisation-et-reception-etablissements-medicaux/1429.aspx#P_6625](http://www.fanc.fgov.be/fr/page/processus-d-autorisation-et-reception-etablissements-medicaux/1429.aspx#P_6625)

In Greece, before new equipment is used, a list of all the personnel that will use the equipment must be sent to the radiation protection authority. A "feasibility" licence is delivered by the Ministry of Health before new equipment and techniques are implemented. This licence plays an important role in the justification process: it takes into account criteria of geographical distribution, population, the skills and existing infrastructure of the hospital / institution, personnel, etc., to avoid propagating the unjustified and uncontrolled utilisation of equipment emitting ionising radiation.

In Norway, the Health Department is responsible for the generic evaluation (level-2 justification) of a medical device at national level. The Norwegian Radiation Protection Authority (NRPA) was recently given responsibility for evaluating the generic justification of new radiotherapy techniques.

5. Personnel numbers in medical physics

Several countries have criteria concerning personnel numbers in medical physics.

Germany has recommendations in terms of personnel numbers (radiation oncologists, physicists and "MTRA" (= radiographer)) which include particular provisions for particular techniques (number of medical physics experts (MPE) and radiation oncologists = number of accelerators +1, + 1 if two particular techniques are used (IMRT, intraoperative, stereotaxy, etc.)). [http://www.bmu.de/files/pdfs/allgemein/application/pdf/rl_strlschv_strlschmed_en.pdf](http://www.bmu.de/files/pdfs/allgemein/application/pdf/rl_strlschv_strlschmed_en.pdf)

In Belgium, in each radiotherapy department, the presence of at least one medical physics expert (MPE) is required on a full-time basis. Above 750 new patients per year, an additional full-time MPE must be provided for. And depending on the level of application of specific and more specialised techniques, an additional MPE must be recruited.
The United Kingdom has criteria for human resources in radiotherapy published by the Institute of Physics and Engineering in Medicine (IPEM) in 2009. Norway also uses these recommendations. These recommendations take into account the complexity of the techniques proposed by a radiotherapy department (IMRT, stereotactic radiotherapy, TBI, etc.). This report also mentions that additional resources are necessary for the development of new techniques. [http://www.ipem.ac.uk/Portals/0/Documents/Recommendations%20for%20Prov%20of%20Phys%20Serv%20to%20RT.pdf](http://www.ipem.ac.uk/Portals/0/Documents/Recommendations%20for%20Prov%20of%20Phys%20Serv%20to%20RT.pdf)

Finland has sizing criteria for its teams (radiation oncologists, physicists and radiographers). In terms of "Medical Physics Experts" (MPE), Finland requires that establishments have at least one medical physicist for 400 patients per year and recommends 1 to 2 additional physicists when specialised treatment techniques are used (such as IMRT or stereotactic radiotherapy) or when brachytherapy or radionuclide therapy are practised. [http://www.finlex.fi/data/normit/22197-ST2-1e.pdf](http://www.finlex.fi/data/normit/22197-ST2-1e.pdf)

Switzerland and Greece require that the establishments have at least one medical physicist per linear accelerator.

In the Netherlands, minimum requirements in terms of personnel (radiation oncologists, physicists, radiographers) have also been established. Radiotherapy treatments have been divided into several categories of increasing complexity (the number of categories is currently being revised). Required personnel numbers are determined by the number of treatments in each category.

In Spain, the Spanish Royal Decree 1566/1988 (quality control criteria in radiotherapy) establishes the requirement for a "Radiation physics unit" in each radiotherapy department. The person in charge of this unit must be a medical physics expert (MPE). The human and material resources must be in conformity with the "recommendations of the competent and recognised national or international learned societies, bodies or institutions".

In May 2014, the Nuclear Safety Council (CSN), the Society for Medical Physics (SEFM) and the Society for Radiation Protection (SEPR) published a guide containing detailed information on the recommended numbers and qualification of the personnel, taking into account the type of equipment, the number of components in the department, the number of patients and other activities (training, teaching, administrative tasks, etc.).

APPENDIX 8. References

1. Scientific publications, guides and technical reports

   - Recommendations and guides in Europe


   [STUK-2011] Safety in radiotherapy- Guide ST 2.1

   - International recommendations and guides

   IAEA

   General information on radiotherapy:

   https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/2_Radiotherapy/Standards.htm

   General information on radiotherapy safety and quality:

   https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/2_Radiotherapy/RadSafetyExtBeamRadiotherapy.htm

   "Radiation Oncology Physics A Handbook for Teachers and Students":

   https://rpop.iaea.org/RPOP/RPoP/Content/InformationFor/HealthProfessionals/2_Radiotherapy/RadSafetyExtBeamRadiotherapy.htm

"Transition from 2-D Radiotherapy to 3-D Conformal and Intensity Modulated Radiotherapy". IAEA-TECDOC-1588

"Lessons learned from accidental exposures in radiotherapy". Safety Reports series N°17

"Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement"

"Planning National Radiotherapy Services: a practical tool" IAEA Human Health Series N°14

"Standards Applications and QA in Medical Radiation Dosimetry (IDOS)" Vol 1 & 2

"Applying Radiation Safety Standards in Radiotherapy" Safety Reports Series N°38

"Radiation Protection in the Design of Radiotherapy Facilities" Safety Reports Series N°47

ASTRO

[ASTRO-2012] Safety Is No Accident, ASTRO 2012
https://www.astro.org/uploadedFiles/Main_Site/Clinical_Practice/Patient_Safety/Blue_Book/SafetyisnoAccident.pdf

ICRP


ICRU

[ICRU 83] Prescribing, Recording, and Reporting Intensity-Modulated Photon-Beam Therapy (IMRT)(ICRU Report 83)
MISCELLANEOUS

Quality and Safety in Radiotherapy, William R. Hendee, Series Editor. Edited by Todd Pawlicki, Peter B. Dunscombe, Arno J. Mundt, Pierre Scalliet. 2011


- Recommendations and guides in France

ASN

HAS

INCA

Guide to the daily practice of in vivo dosimetry in external-beam radiotherapy drawn up under the aegis of the INCA (National Cancer Institute), with the collaboration of the SFP (French Society for Medical Physics) and ASN (French Nuclear Safety Authority). October 2008.

SFP

[SFP and SBPH Report No.20] Quality Control of Multi-Leaf Collimators. – 2003


[SFPM Report No.27] Recommendations for putting into service and using a radiotherapy treatment planning system (TPS) – December 2010


[SFPM Report No.29] Image-Guided Radiotherapy, Quality Control of X-ray equipment - 2013.

Tools

[SPA] Self-assessment tool for evaluating the quality of treatment of patients in oncological radiotherapy developed by the AAPM (Safety Profile Assessment - SPA), of which several questions concern innovation.
http://spa.aapm.org/

2. Regulatory references and opinions

[DIR 2013/59] COUNCIL DIRECTIVE 2013/59/EURATOM of 5th December 2013 setting out the basic safety standards for protecting health against the dangers arising from exposure to ionising radiation and abrogating Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

[Order of 03.03.2003] Order of 3rd March 2003 setting the list of medical devices subject to the obligation for maintenance and quality control mentioned in Articles L. 5212-1 and D. 665-5-3 of the Public Health Code.


The working group submitted the report establishing recommendations concerning the conditions of implementation of "new techniques and practices" in radiotherapy to the Chairman of the GPMED on 9th December 2014.

The report and the opinion of the GPMED can be consulted on the ASN website

www.asn.fr