Stakeholder Involvement in Medical Practices

Report of the Working Group

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I. Introduction

In diagnostic radiology radiation is used to form an image of a plane or volume, or in nuclear medicine to visualize the function of an organ, and the radiation dose to the patient is just an unwanted side effect. In radiation therapy radiation as such is used to control cancer growth for cure or palliation. We have seen a tremendous technological development both in diagnostic and therapeutic applications of radiation. This growth and development is mainly of great benefit to the patients as individuals and to the society as a whole, but it also causes a strong increase of medical radiation exposure of the population which is of concern for radiation protection reasons. Only a close collaboration between all the stakeholders will allow this dose increase to be understood and kept under control.

The working group has reviewed a large variety of examples of stakeholder involvements which have already been performed in the member states (see Annex A) and in addition had look on possible stakeholder involvements for the future, where a leading role of the national radiation protection authority is needed. The authorities should take the lead to bring stakeholders together to solve today’s challenge in a concerted manner. These challenges appear where different professional groups work together on new technologies and/or new processes. Examples can be found in radiation therapy (image guided radiotherapy, dealing with accidents), in nuclear medicine (PET/SPECT-CT), in radiology (going digital, patient dose optimization), screening, the complex of problems through self referral and many others.

The participating experts from Member states have discussed the role of the authority in the involvement of stakeholders, tried to identify relevant parties and give some recommendations and examples of stakeholder involvement.

II. Definition and identification of stakeholders in medical practices

A stakeholder is someone who is (or should be) entitled to have an interest in radiation protection in medicine. To give a better overview, stakeholders are split into three groups

Justification, Optimization and General.
| Justification                                      | • Medical doctors, medical societies and associations  
|                                                 | • Patients, patient organizations                    
|                                                 | • Legislator                                         |
| Optimization                                    | • Medical doctors, medical physicists, radiographers, other medical staff  
|                                                 | • Manufacturers and suppliers, staff undertaking installation and maintenance  
|                                                 | • Hospital directors                                |
| General                                         | • Patients and their relatives                       
|                                                 | • Patient ombudsman                                 
|                                                 | • members of the public                             
|                                                 | • Insurance                                         
|                                                 | • Legislator and authorities                        |

In the group \textit{Justification} the stakeholders are involved in the process before a prescription has been issued by the medical doctor. Subsequently in the group \textit{Optimization}, the stakeholders are carrying out the procedure.

### III. The overall goals of stakeholders involvement

The national authority in radiation protection should take the lead in bringing the different stakeholders together (stakeholder platform), analyzing the different interests and needs (stakeholder analysis) and motivate them to participate actively in optimizing medical radiation exposure (stakeholder participation).

The goals, which should be achieved by this process, are summarized in the following table:

| Justification                                      | • Specialized Medical doctors in charge of radiotherapy, radiology, nuclear medicine, etc are aware of the principle of justification (ICRP Publication 103 ….)  
|                                                 | • Specialists and generalists use the guidelines “good practices” (Guide du bon usage, Orientierungshilfe, EU referral criteria RP 118…)  
|                                                 | • Medical doctors and dentists (generalist) are aware of the justification of radiological examination  
|                                                 | • Patients are informed of the risks and the benefits of radiology |
| Optimization                                    | For the application of the principle of optimization, medical doctors in charge of radiotherapy, radiology and nuclear medicine, physicists and radiographers are in charge of :  
|                                                 | • State-of-the-art technical equipment, quality assurance and maintenance |
IV. The role of the national radiation protection authority

There is no doubt that important benefits can result from interactions between stakeholders and regulatory authorities.

These interactions can vary significantly from situation to situation. Their importance, intensity, purpose and expected outcome depend on well-known factors (benefits, detriments, risks – real as well as perceived). Associated circumstances (e.g. sense of urgency, potential crisis situation) also affect the interactions, as well as socio-economical factors (e.g. need for improved business conditions). In addition, the expertise and resources available to the authorities, as well as the potential need for improved regulatory framework, play a role on the interactions with the stakeholders.

The purposes and expected outcomes of the involvement can be any of these: information exchange, development of tools (books, guidelines, training), advice and expertise, recommendations, legal texts and instruments, direct or indirect involvement in decision making as well as in activities related to authorization and control, emergency prevention, preparedness, and response.

The WG agrees with the recommendations concerning stakeholder involvement formulated during the 10th European ALARA Network Workshop:

“Regulatory bodies have an important role to play in facilitating stakeholder involvement, and are encouraged to establish mechanisms for communicating with relevant parties and encouraging their participation. This may for example include seminars, consultation exercises, public meetings, internet forums, etc.”

- Stakeholders should be consulted as widely as possible, whenever acceptable (there may be security related restrictions for some types of interactions) and manageable.
Authorities should try to be clear on the purpose of the involvement and on the output expected from the interaction (transparency).

- Authorities should try whenever possible to build structural mechanisms for consultation with stakeholders.

One could find several kinds of roles for Radiation protecting authority when working with stakeholders and getting their involvement to reach appropriate level of the safety. Roles could be for example:

1. Forerunner

Radiation protection authority shall initiate, co-ordinate and monitor safety related research and development. The results of the research will support its regulatory functions and also stakeholders in using justified and optimized methods and equipment and to perform optimized work procedures.

The Radiation protecting authority could promote research projects where stakeholders are partners to achieve common goal. The authority could give ideas for topics to be investigated and initiate and motivate research projects which will be performed by research groups, universities and research institutions as well. Also small scale studies together with educational institutes and students are valuable.

Especially in medical sector the opinion leaders are in universities, central hospitals, and educational institutes and in specialized research institutes. Co-operation with these stakeholders will give good base for further work in radiation protection and will give credibility for radiation protection authority in further actions.

Specialists of the Radiation protecting authority should participate in international congresses to get understanding of the newest applications of ionizing radiation.

One has to investigate the needs of education and training together with the users of radiation in discussions and meetings with different kind of specialists and organizations. Surveys together with educational organizations of the needs are valuable as well. Based on this information Radiation protecting authority could propose further education for radiation users in universities and training institutions.

2. Rule maker

According to IAEA GR-S-1 “In order to fulfil its statutory obligations, the Regulatory authority shall define policies, safety principles and associated criteria as a basis for regulatory actions”. To get commitment from stakeholders for the regulation it is useful to prepare basic regulations using consultation with stakeholders. Sometimes pre-stage in preparing regulation is to perform preliminary study or research project to get better understanding of the status quo. Here you could involve some key stakeholders in the work. The results of the projects could serve as basic information for the base of the regulation.
Many times it is practical to invite experts from professional activities to join in to the working groups to prepare special regulatory documents. Furthermore it is important to ask comments from all involved stakeholders on the drafts of the documents and take these opinions account in final version if appropriate on the view of radiation protection.

3. Advisor

Radiation protection authority shall provide guidance to the operator on developing and presenting safety assessments or any other required safety related information. This is according to the IAEA GR-S-1. It is important to make surveys which kind of guidance is needed by license holders and specialists in the field. This is also to get better mutual understanding of the common goals in radiation protection and to prepare proper guidance. When preparing such guidance and information it is useful to prepare guidance together with the specialists working in actual practices.

4. Communicator

Radiation protecting authority shall introduce the regulation and guides for all radiation users (organizations, experts) and involved parties. All radiation users should have information on new regulations and guides soonest possible. Good practice is to mail this information based on the registers of the stakeholders if any. Good service for stakeholders is to provide all kind of general information on radiation protection for stakeholders on the www-pages of the authority.

Effective method is to organize regular discussions and meetings on current topics with different specialists and organizations.

How to communicate risk is a particular challenge, it should be prepared with other stakeholders like medical doctor organizations, hospital directors, patient organizations, press bodies. Communicate the risk in advance (booklet), communicate the risk after an incident/accident (info unit important)

5. Supervisor

Radiation protecting authority should have high reputation in his work. To reach this goal authority should have competent experts in all applications of radiation practices with good understanding on radiation protection. He should inform from all his activities transparently to get well known status among users of radiation. When recognized status is reached the supervisory work will be effective and stakeholders will be cooperative to reach optimal radiation protection.

6. Connection to other Health authorities

Radiation protection authority should have a strong connection to health authorities; they are a very important stakeholder. Health authorities obviously have responsibilities for all aspects of health care provision; while the radiation protection authorities have selected duties. There a many different national approaches. In some countries the health authorities are giving expertise of radiobiology, where in others the competence is within
the radiation protection authority. In some countries the responsibility for staff protection and patient protection may be in different authorities.

Where is the justification question set in the national legislation; In the RP legislation, or in a more generic legislation? For example, are other health authorities involved in the justification question? Example breast screening program, the justification question in Finland is judged in a medical – ethical trial.

Examples of areas where other health authorities are involved in addition to the radiation protection authority:

- Justification
- Patient safety
- How patient data is stored, frequency of examinations and treatments, dose data, and other information needed for surveys
- Financing
- Following up of epidemiological data
- International standards

A detailed description of the cooperation between the different authorities is given in Appendix B

7. Network creator

Information transfer between stakeholders is important part of learning process in radiation protection. Users of radiation can learn good practices from each other and also learn from the mistakes of other stakeholders. Radiation protecting authority could activate this information transfer by creating discussion forums for example in regular meetings with target groups. Discussion forums on web pages might be useful as well. Data banks of incidents and accidents could be created to be available through network.

8. Trainer

Radiation protecting authority could act as trainer of trainers in special topics. In this meaning one could educate and train some opinion leaders of stakeholders who can distribute the information on radiation effects, radiation protection and regulation and guides among other specialists.

9. Role to verify and improve radiation protection

Radiation protecting authority should verify time to time the present situation for example by making surveys with stakeholder groups on special topics related to radiation protection. The results of the verification are useful material to create fruitful discussion with stakeholders in the meetings to improve the process of radiation protection.

V. Priorities which justify stakeholders involvement
The progressively but steadily increasing exposure associated with medical applications should be specifically addressed. The lack of awareness of the general public and some medical professions in relation to medical exposures needs to be addressed. Consultations with all stakeholders (medical devices manufacturers, medical staff, hospital managers, structures involved in the organization of national health systems, patients) should be organized in order to address this complex problem and try to find appropriate solutions.

Concerning medical devices, consultations with manufacturers and suppliers should be developed to address the radiation protection issue directly at the source. Additionally, a discussion (on a national or international level), allowing better understanding and more transparency concerning the EC specifications for medical devices, should be initiated with the responsible EC structure.

Consultations concerning the notification of medical events and conditions for reporting those events to the medical community and the public should be developed (medical staff, hospital managers, structures involved in the organization of national health systems, patients).

Other priorities have also been identified by WG:

- Establish platform for discussion and analysis open to stakeholders
- Make the information available for all stakeholders
- Initiate research projects related to radiation protection and organize discussion on the results of research with stakeholders
- Internet based training and education tools (in English …)
- Involve proper stakeholders in preparing guides
- Identify most important stakeholders and focus them
- Financing of this platform itself

VI. Examples of good practices

Examples of good practices are highlighted from some of the participating countries in Annex A to the report.

Annex A

1. Finland Implementation of Clinical Audit in Finland
2. France Notification of events in radiotherapy and information of public in France
3. Switzerland Introduction of Diagnostic Reference Levels in Switzerland
4. Spain Permanent Forum concerning Radiological Protection in the Medical Field Spain
5. Norway A national program on Quality Assurance in Radiotherapy (KVIST) initiated as part of the national cancer plan

Annex B Belgium Cooperation between health authorities and radiation control authorities
Annex A1

Implementation of Clinical Audit in Finland

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A1.1. Legislative basis

The basic requirement for the implementation of clinical audit has been set by a Radiation Law (1142/1998). The detailed requirements are given in the Degree on the medical use of radiation (423/2000).

When the implementation of Council Directive 97/43/EURATOM was prepared, the Ministry of Social Affairs and Health nominated together with STUK drafting committee for the Degree on the medical use of radiation. There were members from most important stakeholders in medical use of radiation. This committee prepared also a small booklet with essential parts of the background of the articles in the Degree.

According to the Degree, clinical audits shall be arranged to supplement in an appropriate way the self-evaluation of the practices. The goal shall be set that all radiological practices would be audited for all essential parts at the minimum every five years. The Degree also specifies the following ten points which shall, among other things, be considered in clinical audits:

1. Definition of authority and responsibilities
2. Recommendation for referring a patient to medical radiological procedures
3. Practices and the information flow in justification process
4. Instructions and practices for delivery of medical exposure
5. Diagnostic and treatment equipment
6. Doses to patients and the outcome of diagnosis or treatment
7. Quality, storage and flow of information
8. Training of staff
9. Quality assurance procedures
10. Self-evaluation of practices

According to the Degree, clinical audits shall be carried out by competent and experienced auditors, who are independent of the organisation to be audited.

A1.2. Practical implementation

A1.2.1 Auditing organisation and auditors

After introduction of the Council Directive 97/43/EURATOM, the Regulatory authority STUK recruited medical doctor, radiologist, to educate and train other physicians in health care to understand the meaning of the new regulations. His role was also to create interest in clinical audits in health care system.
The legislation does not assign any specific organisation to carry out clinical audits. Since the Degree was issued, representatives of professional societies, authorities and other key organizations discussed the implementation of the requirements for clinical audit in Finland. This discussion was promoted and activated by STUK. STUK participated as observer in starting phase in the meetings where the drafts for the audit criteria’s were formulated. Discussion resulted in 2001 in the establishment of a special company, Qualisan Oy, to develop and provide the necessary clinical audit services. Qualisan is a joint-stock company established and supported by the major professional societies such as the Finnish Society of Radiologists and the Society of Radiographers in Finland. Qualisan developed detailed criteria for the first round of audits (2000-2005), based on the ten points of interest specified in the Degree. In good time before the creation of the company STUK withdraw completely from the meetings and let the process go further without further involvement.

The company has organized a number of training courses for auditors, inviting volunteers from among the major professional groups (radiologists, oncologists, medical physicists, radiographers) to participate. The purpose has been to train sufficient number of auditors for each health care district in Finland. Altogether about 150 auditors have been trained to undertake clinical audits through Qualisan, on request of the radiological units. The auditors are paid for their services while the audits are charged from the audited organizations.

A1.2.2 National Steering Committee

STUK proposed in year 2003 to the Ministry of Social Affairs and Health to nominate a national advisory committee for clinical audits. This was to create independent party to take care of the quality of the clinical audits and also to prepare chances for other companies to arrive on the markets. Proposal included that the members should be representative persons from main stakeholder groups in medical use of radiation. From March 2004, a national advisory group, or a Steering Committee, for the development and follow-up of the clinical audits was established by the Ministry of Social Affairs and Health. This is a multi-disciplinary group of clinical experts, independent of Qualisan or any other auditing organizations. Its tasks include, among other things, evaluation of the suitability and coverage of the criteria used in clinical audits for different sub-areas (diagnostic radiology, nuclear medicine and radiotherapy), evaluation of the importance of other quality audits in medical practice (such as audits for accreditation), making proposals and promoting the use of special practice-specific criteria in clinical audits, and collecting summaries and review of the results, including analysis of the impact of audits on radiation protection of the patient. The Committee has been established for a three years’ term and has now extension for second period.

One of the first actions of the Steering Committee was to prepare guidelines on the detailed requirements of competence, experience and independence of the auditors. For example, the auditors are required to have practical clinical experience in the field to be audited, the lead auditors must have at least one week specific training on the audit techniques, and the composition of the audit team must generally include a physician (e.g., radiologist, oncologist, or nuclear medicine expert), a physicist and a radiation technologist.

Information on the Committee and its publications are available from the Committee website “www.clinicalaudit.net”.

A1.2.3 Radiation and Nuclear Safety Authority

The role of the Radiation and Nuclear safety Authority (STUK) is to control the implementation of clinical audits through regular inspections of radiation practices. Further, STUK has a representative in the national Steering Committee (a secretary of the Committee) and provides the secretarial services to the Committee. STUK and the auditing organisation Qualisan have convened joint meetings to compare the audit and regulatory activities in order to avoid unnecessary overlap between audits and regulatory inspections.

A1.3. International symposium on Clinical Audit

In May 2003, an international symposium was convened in Tampere to discuss the meaning of Clinical Audit and to exchange views and experiences in the practical implementation of this concept. The symposium was organized by the Ministry of Social Affairs and Health of Finland, Radiation and Nuclear Safety Authority (STUK) and the Finnish auditing organization, Qualisan Oy, in collaboration with some Finnish professional societies and with support of the EC. The symposium, with about 170 participants from 21 European countries, revealed that the understanding of the concept as well as its practical implementation varies highly from country to country, and further guidance from the EC was called for.

A1.4. Present status of Clinical Audits

For several years Qualisan was the only organization providing Clinical Audit services in Finland. By the year 2006 Qualisan has audited for the first time all of the 450 health care units including university hospitals, central and local hospitals, health centres and private clinics. During the year 2007 there was also another company created to provide clinical audits. Second five years round of clinical audits has started.

A1.5. Review of the outcome of clinical audits

In autumn 2004, the Steering Committee conducted a review of the outcome of clinical audits carried out by the end of September 2004. The review was based on the audit reports given to the audited organizations. It included clinical audits of 94 diagnostic radiology and 10 nuclear medicine units which is about 25% of all units (by that time no radiotherapy unit had been audited).

The conclusions from the review indicate that clinical audits had been well started and the health care units comply on the average rather well with the criteria of good practice deduced from the legislative requirements. There were no serious violations as for the radiation safety of the patient. Most of the recommendations given by the auditors were easily to be implemented, while the implementation of some of them might require more time and extra resources. Major findings (in 30 to 40% of the audits) concerned the lacking services by the Medical Physics expert, shortcomings of the examination guidance, insufficient evaluation of the results of examinations, and insufficient recording of radiation protection training. Other frequent and important recommendations concerned for example the referral practice, shortcomings in the Quality Control program and lack of training programme for radiation protection.
The first audit round was more or less a review of the current situation, while it became evident that the later rounds should include more profound evaluation of selected practices. The results also indicated the need to improve the guidance given to the auditors in order to achieve more consistent application of the criteria in the evaluation and completing the audit reports. An important supplementary benefit of clinical audits was noted to be that their implementation has speeded up the development of appropriate quality systems in health care units. The review was published in its final form in October 2005 and is available through the Committee website (in Finnish).

A1.6. Future activities

The specific topics of the second round have been selected based on the outcome of the first audit round and the recommendations are now given by the National Steering Committee. Many requests of the second audit have already been received from the health care units.

The National Steering committee has consulted several other clinical experts (besides those sitting in the Committee) and have given the recommendation on priorities and the selection of criteria for the second audit run. Some points with a high priority have been identified (e.g. self-evaluation practices, paediatric radiology and computed tomography). Further, the current audit criteria are planned to be supplemented by more practice-specific criteria, selected for each audit round by separate considerations of the actual needs.

Parallel to this development, collection and preparation of guidance for good practices has been initiated, with the support of the STUK and the National Steering Committee. As an example, a guide on the good practice in paediatric radiology was prepared by an expert panel of paediatric radiologists, coordinated and published by STUK.

A1.7. Conclusions

The organization and criteria for practical procedures of clinical audits in Finland have been developed, providing the radiological units with easy access to implementing clinical audits. The objectives and criteria of Clinical audits seem to be in close consistency with the general principles highlighted by the consensus statements of the international symposium in Tampere 2003. The review of the outcome of clinical audits indicates many practical benefits of the audits, such as improvements in the referral practice, quality assurance programmes, distribution of responsibilities, and communication between different professionals. The development of appropriate documented Quality Management Systems, caused by the implementation of Clinical Audits, is a significant supplementary benefit of the audits. The plans for the second audit round have identified some important specific objects of audit and the need to include more profound evaluation for selected practices. The role of the National Steering Committee, in collaboration with the Radiation and Nuclear Safety authority STUK, has proved to be important for coordination, review and development of the national efforts as well as maintaining good quality and consistent methods of the clinical audits.

Implementation of Clinical Audits in Finland has included a lot of stakeholder involvement and has lead to successful improvement of clinical procedures and radiation safety in Finnish health care system.
Annex A2

Involving stakeholders in the development of the ASN-SFRO rating scale of radiation protection events that affect patients undergoing a radiotherapy medical procedure.

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A2.1 Introduction

Since 2005, ASN has received a large number of event reports in the field of radiotherapy, some of which have not impacted on health to date, but others have led to serious complications for patients and even, in some cases, to death. There are various reasons for these events: patient identification error at the point of admission, communication breakdowns between operators, inadequate training and internal inspections, poor practice with regard to data transfer and even poor medical practice. In many cases, the events occur as a result of failures at an organizational and human level; however, in some cases problems linked to the materials used have been detected but these have not had any particular effects on the patients exposed.

A2.2 Reporting incidents to ASN

On the basis of systems set up in the field of Basic Nuclear Installation safety, ASN has decided to implement an event reporting system, in particular for the medical field, some of which are likely to lead to serious events. Early reporting of these events in the radiotherapy department and the analysis of their causes by the physician responsible for the activity, in conjunction with his team, is chiefly aimed at improving the safety of treatments through corrective actions. Mandatory reporting of events to ASN may lead to an immediate inspection and then, if necessary, dissemination of the information to other professionals in order to improve safety in all of the departments concerned.

The reporting criteria are set out in the guide ASN/DEU/03 which has been available at www.asn.fr since July 2007.

A2.3 The ASN-SFRO severity scale

The ASN-SFRO (French society of radiation oncology) severity scale that was published in July 2007 is also available on www.asn.fr and is designed to provide the public with information in clear and accessible language on radiation protection for patients undergoing a radiotherapy medical procedure.

Since the INES scale, published by the International Atomic Agency, does not, to date, cover events relating to the radiation protection of patients, ASN, in conjunction with SFRO has developed a scale that is compatible with the existing INES scale as well as the rating tables already used by practitioners (CTCAE1).

The ASN-SFRO experimental scale was tested over a 12-month period. Following assessment and consultation with stakeholders, amendments were made in July 2008 to both the reporting criteria and the ASN/SFRO scale.

On this new experimental scale, the events are rated on an 8-level severity scale: the upper levels (4 to 7) correspond to events rated as accidents, the lower levels (1 to 3) to events rated as incidents and level 0 is used to rate events with no consequences. The severity of the effects is assessed with reference to the international clinical classification (CTCAE [0]) already used by practitioners.

From 16% of the French centres (30 out of 180) 126 events were reported to ASN between July 2007 and the end of June 2008: most of the events (94%) were rated between level 0 and level 1:
- 4 events: level 2 (moderate effects)
- 62 events: level (no anticipated consequences)
- 57 events: level 0

**A2.4 Involvement of stakeholders**

1. The event reporting criteria that are set out in the ASN/DEU/03 guide have been developed by ASN following a process of written consultation with professionals. With regard to the reporting criteria of events that affect radiation protection of patients undergoing a medical radiotherapy procedure (box above), the contribution by professionals has been quite poor.

On the other hand, ASN evaluated the criteria in June 2008 by bringing together radiotherapists and radio physicians. The findings showed confusion between “event reporting” and “rating on the ASN/SFRO scale”. A large number of centers had thought that events rated at level 0 did not need to be reported to ASN (between July 2007 and June 2008, only 18% of the radiotherapy centers out of a total of 180 centers had effectively implemented the reporting system).

The close involvement of professionals enabled a consensus to be reached on amendments to the new ASN reporting criterion which will be communicated to radiotherapy centers in September 2008.

2. The development of the ASN/SFRO scale has been a joint initiative between the ASN and radiotherapists. A working group set up a project which was based both on the experience gained by ASN in the rating of events concerning nuclear safety and radiation protection, with the implementation of the INES international scale, and on the experiences of radiotherapists in the rating of side-effects of cancer treatments using the CTCAE scale (Common Terminology Criteria for Adverse Events – Cancer Therapy Evaluation Program, http://ctep.cancer.gov).

Final discussions on this project focused on the communication modalities for the reporting of events. Finally, the professionals agreed (as an experiment) to ASN’s communication strategy based on the publication of an incident notification on www.asn.fr for any event of a level higher or equal to 1 (for each incident notification the name of the establishment appears).
The experimental approach (report + rating + informing the public) was then presented to the press by ASN and SFRO. Many press articles were then published on this subject.

The scale was evaluated in June 2008 in close cooperation with radiotherapists and radio physicians. Amendments were made in order to clarify the event rating criteria for levels 0 and 1. The ASN communication strategy was also discussed and the professionals mentioned that the under reporting of events was chiefly due to the systematic publication of incident warnings on the ASN website, regardless of the level of severity.

In the end, ASN agreed to allow anonymous reporting for level 1 events and, each quarter, to publish a summary of events reported without reference to the establishments concerned. The publication of incident warnings on www.asn.fr with the name of the establishment concerned would be continued for level 2 events and for any event that affects a patient cohort.

The amendments to the experimental scale (report + rating + informing the public) were presented to the press by ASN alone. During the press conference, ASN indicated that from July 2008 inspection reports produced in the radiotherapy centers would be published on www.asn.fr.

The communiqués that were subsequently issued gave details on how the system had evolved, and did not contain any particular criticisms.

It was not possible, however, to achieve overall consensus with the professionals owing to their disagreement over the publication of ASN inspection reports and the lack of anonymity for level 2 events. The new scale was published in July 2008 (see table).

3. Patient associations were not involved in the development of this initiative (report + rating + informing the public). However, after contacts established in June 2008 by ASN with the League against Cancer, the decision was taken to create an information pack to be made available to all public information centers in hospitals in order to respond to the large number of questions posed by patients following the accidents that occurred in Epinal and Toulouse in France.

A2.5 Conclusion

The preparation and development of the ASN-SFRO scale for the rating of radiation protection events affecting patients undergoing a radiotherapy medical procedure is an example of the importance of involving stakeholders, without whom it would have been difficult for the ASN, as the authority responsible for inspecting nuclear safety and radiation protection, to put in place the tools needed for reporting events and informing the public.

This initiative marks an innovative step forward given its dependence on the involvement of the media in the process of disseminating information to the general public on the tools developed in conjunction with the professionals.

The involvement of patient associations with regard to the modalities of providing information to the general public forms part of ASN’s ongoing work.
**Table:** ASN-SFRO scale for the rating of radiation protection events affecting patients undergoing a radiotherapy procedure

<table>
<thead>
<tr>
<th>Event (unforeseen, unexpected)</th>
<th>Cause</th>
<th>Consequences (CTCAE v3.0 grade)</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td>Dose (or irradiated volume) far higher than normal leading to fatal complications or sequelae</td>
<td>Death</td>
<td><strong>5 to 7</strong>&lt;sup&gt;(1)&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Serious</strong> life-threatening event, disabling complication or sequelae</td>
<td>Dose or irradiated volume far higher than tolerable doses or volumes</td>
<td>Acute or late serious effect, either unexpected or unforeseeable, grade 4</td>
<td>4&lt;sup&gt;(2)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Event leading to a <strong>severe</strong> impairment of one or more organs or functions</td>
<td>Dose or irradiated volume higher than tolerable doses or volumes</td>
<td>Acute or late severe effect, either unexpected or unforeseeable, grade 3</td>
<td>3&lt;sup&gt;(2)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Event leading to or liable to lead to a <strong>moderate</strong> impairment of an organ or function</td>
<td>Dose higher than recommended doses, or irradiation of a volume liable to lead to unexpected but moderate complications</td>
<td>Acute or late moderate, unexpected or unforeseeable effect, grade 2, minimal or no disablement</td>
<td>2&lt;sup&gt;(2)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Event with dosimetric consequences but <strong>no expected clinical consequences</strong></td>
<td>Dose or volume error (for example, non-compensable target error or dose during a sequence)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Event <strong>without consequence</strong> for the patient</td>
<td>Error of beam (compensable on all of the treatment) Error of identification of a patient treated for the same pathology (compensable on all of the treatment).</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>(1)</sup> In the event of death of several patients:
- the minimum level 5 is raised to 6 if the number of patients is higher than 1 but no more than 10
- the minimum level 5 is raised to 7 if the number of patients is higher than 10

<sup>(2)</sup> If the number of patients is higher than 1, a + sign is added to the chosen level (for example: 3 becomes 3+).
Annex A3

Introduction of Diagnostic Reference Levels in Switzerland

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A3.1 Introduction

The Swiss Federal Office of Public Health, as the national regulatory body for the use of ionizing radiation in medicine, has launched the project OSUR (Optimizing the radiation protection in Radiology) in 2001 to introduce Diagnostic Reference Levels (DRL) in Switzerland.

At the international level, the establishment of diagnostic reference levels for X-ray examinations had been recommended. Diagnostic reference levels can be used as guidelines by the operators in terms of delivering the radiation dose to the patient and as an important tool to optimize the dose management. The results of the first study OSUR have shown that a significant optimization potential exists. The project aims to use this optimization potential and to lower the patient exposure.

The project has the following objectives:

- The concept of diagnostic reference levels is thoroughly understood by the medical staff.
- A comprehensive management of the patient dose is applied.
- The education and training courses are established.
- The concept of diagnostic reference values is included in the Radiation Protection Ordinance.
- Regular surveys of the Federal Office lead to an optimization of patient dose and a realistic determination of the diagnostic reference levels.

In order to achieve these objectives the concept of the diagnostic reference values needs a legal base. The awareness of physicians for the radiation risk by diagnostic exposures and the motivation to participate in national optimization processes is also a very important factor. Further goals which have been set by the Federal Office are to create a national patients dose database, to collect regularly the relevant dose values in national surveys, to determine the national diagnostic reference values and to create a training and education concept.

The stakeholders in this process are various and were defined by the Federal Office: radiologists, nuclear medicine staff, general practitioners, medical physicists, radiographers, companies of radiological equipment, patient organizations etc. A task group has been created where all stakeholder groups were represented with at least one person.

A3.2 Stakeholder Analysis
The project to develop the concept of diagnostic reference levels has various stakeholders, who have differing views on the project and also different demands in the project. One of the great challenges of the project is, therefore, to develop a common understanding of the system of diagnostic reference values in cooperation with the various stakeholders. In a stakeholder analysis the participants recognize, on one side, their role and their contribution in the implementation of the diagnostic reference values and, on the other side, the role and contribution of other stakeholders.

A specialized company has been mandated to lead this system analysis and to find a common understanding of the introduction of diagnostic reference levels. In two workshops the participants were very much engaged in the discussions of using diagnostic reference levels in their field of activity and in the findings of an optimal introduction. They stressed on one side, that the introduction of DRL is positive, but on the other hand that they would like to be closely involved in the process. The stakeholders appreciated very much that they could address their concerns and make suggestions in the two workshops.

The Federal Office has now established annual meetings (the so-called OSUR group) with all the participants of the workshops and other interested partners.

A3.3 Implementation of Diagnostic Reference Levels

In a first attempt international recommendations and values from scientific publications were used to determine the 1st order diagnostic reference levels. By surveying the present situation of the radiological practice in the different modalities in Switzerland more appropriate reference levels could be defined. This process is still ongoing.

Since 2008 the concept of the diagnostic reference levels has been introduced in the Swiss legislation. The clinics have to check their practice with respect to the published diagnostic reference levels and must provide the Federal Office of Public Health with the appropriate data.

A3.3.1 Computed tomography

In a national survey of the CT-practice the used protocols of 20 commonly used indications for standard patients are reviewed. The received distribution has been discussed within the OSUR group and national reference levels were defined. A large number of the CT-sites will be revisited in 2008 and 2009 and a change of the practice will lead to a modification of the reference levels.

A3.3.2 Interventional Radiology and Cardiology

In a national survey more than 50% of the clinics applied interventional procedures were asked to participate. Together with recommendations from the literature reference levels have been defined for 12 diagnostic procedures and for 15 therapeutic procedures. For an optimal dose management in fluoroscopy reference levels for the following quantities are given: dose-area product, duration of the fluoroscopy and the number of images. During this year the personnel of the clinics is being trained in the concept of the diagnostic reference levels. A
review of the situation in the coming year will show how the concept can be implemented in this difficult field.

A3.3.3 Radiography

In a first attempt the reference levels proposed by the European Union were adopted. They relate to the entrance surface dose of the patient or the dose-area product for a single image. Due to the fact that the installations in radiography are seldom equipped with a dose-area meter, the entrance surface dose is used as the relevant dose quantity. In all X-ray institutes the situation should periodically be reviewed with respect to the diagnostic reference levels. For this purpose, it is recommended for each setting to estimate the surface-dose of a standard patient by a measurement or a calculation. A survey of three major examinations (lung, pelvis and lumbar spine) is currently running to improve the setting of the diagnostic reference values.

A3.3.4 Nuclear medicine

In the case of nuclear diagnostics the reference levels were determined by a comprehensive survey which has been carried out in Switzerland in 2004. Basis of the diagnostic reference value is the median value from the distribution of the monitored activity. Experience from practice, which were discussed in a task force of specialists (a subgroup of OSUR) served to fix the diagnostic reference levels. In addition, the neighboring countries Germany and Austria were consulted. Within the framework of quality assurance nuclear medicine clinics have to compare regularly the applied activities with the diagnostic reference level (applied activity ≤ DRL) and if necessary optimize their procedure.

A3.4 Conclusion

The involvements of the stakeholders in an early stage of the implementation of new regulations and optimization procedures have lead to a wide acceptance of the concept. It is important that a platform has been created where all participants are invited to bring in their own understanding of the situation and that problems can be openly discussed. Once the interest has been produced in the different groups of stakeholders, they started to take their own initiative and handle more proactive in their field to optimize their dose management.
Annex A4

Radiological Protection Forum in Spain

Marina Sánchez Sánchez, Nuclear Safety Council (CSN), SPAIN

A4.1 Introduction

The law by which the Nuclear Safety Council was set up establishes, in connection with its functions and responsibilities, that the Council is solely competent as regards the radiological protection of the workers, the public and the environment.

The Nuclear Safety Council (CSN), as well as being the authority in regulatory matters, must apply an appropriate safety culture allowing a proper relationship to be established between the Regulatory Body and the professional radiological protection workers within a framework of open dialogue.

In this context, in 2001 the CSN established a permanent Forum concerning Radiological Protection in the Medical field, to favor communications between the regulators and stakeholders.

A4.2 The radiological protection forum in the medical field

A4.2.1 Members and Goals

This Forum is made up of three components: The Nuclear Safety Council, The Radiological Protection Association and the Medical Physics Association.

The Spanish Association of Radiological Protection and the Spanish Association of Medical Physics are both scientific associations that bring together professional workers with common professional interests. At the same time, these associations create a framework for dialogue, communication, information and participation between their members and the public, companies and the private and public institutions whose activities are related to radiological protection in the medical field. Both associations include a large number of stakeholders working in the radiological protection field, in the design of radioactive facilities in medical areas.

This framework enables discussion of objectives and regulatory requirements and optimization of the available resources, ensuring that the necessary attention is paid to radiological protection issues at the medical radioactive facilities.

The Nuclear Safety Council maintains direct relationships with the owners of the radioactive facilities, and furthermore the intervention of the Forum influences the operational conditions at these facilities.

The Associations are responsible for their members’ participation in the Forum’s activities and for keeping them informed on the issues it deals with and the results obtained.

The Forum Committee meets four times a year on the premises of the CSN and The Nuclear Safety Council helps the members of the Committee with the expenses involved.

The main aim of the Forum CSN/Associations is to identify topics of common interest in order to encourage dialogue and improve both the safety culture and radiological protection at medical radioactive facilities.
A4.2.2 Structure

The Forum is structured as follows:

- A permanent Forum Committee: made up of six members of the CSN headed by The Radiological Protection Technical Director and four members of each of the scientific associations (the president and three representatives)
- Ad-hoc Working Groups: Their composition depends on the issue they deal with. The length of time during which the group is active depends on the job it carries out.

A4.2.3 Forum activity

The activities that the Forum carries out are the following:

a) Setting up of working groups dealing with issues of common interest in the radiological protection field applied to medical radioactive facilities. These working groups may perform different activities in the short, medium or long term in accordance with the preliminary program.

The topics the working groups deal with are mainly the following:
- Practical Application of regulations and regulatory conditions.
- Analysis of new standards, requirements and recommendations.
- Identification of needs for new standards to be applied in companies that provides services to these facilities, such as laboratories, technical assistance services and radioactive material and equipment sellers.

b) Coordination of issues of common interest.

c) Exchange of information concerning activities or programs related to radiological protection at medical radioactive facilities.

A4.2.4 Working matters

Up to now, the Forum has defined fourteen topics, and 10 working groups have been set up to discuss the following issues:

1. Radiological protection of pregnant workers
2. Radiological protection of children in medical procedures
3. Preparation of a general Radiological Protection Manual in accordance with the Directive 96/29/EURATOM, used by the radiological protection Services and Units
4. Effluent discharge criteria
5. Management of solid radioactive wastes
6. Area dosimetry
7. Licensing of new facilities and modification of operating facilities
8. Metabolic therapy
9. Metrology in brachy therapy
10. Internal dosimetry
The conclusions of the first four working groups have been included in different reports, working groups number 5 and 6 expect to present its conclusions soon, whereas the work of the others has not yet concluded.

A4.3 Conclusion

The Spanish experience with stakeholder involvement in the medical field has been developed since 2001 through a Permanent Forum, integrated by members of the regulatory body (CSN) and two Scientific Associations, the Radiological Protection Association and the Medical Physics Association. Issues of current interest have been selected and working groups designed to discuss them. The experience may be described as being very positive, favoring communication and the exchange of information between the parties. Furthermore, the technical quality and the great interest of the documents that the Forum has produced - specific guidelines, procedures or recommendations depending on the characteristics of each issue - have proven to be very useful to ensure better working at the facilities and to encourage the safety culture.
Annex A5

A national program on Quality Assurance in Radiotherapy (KVIST) initiated as part of the national cancer plan in Norway

The Norwegian Radiation Protection Authority (NRPA), Østerås, Oslo, Norway

A5.1 Introduction

The Norwegian Radiation Protection Authority (NRPA) is the national regulatory body for all use of ionizing and non-ionizing radiation in Norway. The health enterprises need specific approvals to perform radiation therapy, nuclear medicine and advanced radiology (fluoroscopy examinations, angio/intervention, mammography, CT, MR), all according to NRPA’s role as a role “rule maker”; the most obvious role for an authority. On the other hand NRPA has advanced its role as “network creator”, “adviser” and “communicator” beyond what may be customary by inviting the stakeholders to the inside of the organization:

A5.2 KVIST organization and aim

As a part of the national cancer strategy, the Norwegian Radiation Protection Authority (NRPA) was engaged from the Ministry of Health to develop a national quality assurance program in radiotherapy in the late nineties. A multidisciplinary group (oncologists, medical physicists, RT technologist) has been allocated to the task since then; all experienced professionals in shared positions between a RT department in a hospital and the NRPA. This group, named the “KVIST group”, coordinates a national reference group which again proposes task groups with a range of mandates, all with consideration to multicenter representation and in close collaboration with the medical societies The costs for the KVIST initiative are shared between the NRPA and the radiotherapy enterprises in Norway: NRPA covers the meeting arena and travel costs for the delegates, the radiation therapy centers cover the staff hours of duty, in the understanding this represents a mutual effort to help them improve their internal quality systems. The aim is to stimulate collaboration by focusing on clinical, technical and administrative problems that can be solved through a national plan. An important objective is to establish a positive attitude towards quality assurance and better communication between centers and the various stakeholders involved in radiotherapy.

A5.3 KVIST ongoing work

The KVIST initiative has been a driving force in improving the quality of radiation treatment of cancer patients on a national basis, and has caused a range of harmonized national recommendations. This is achieved through a wide range of activities covering e.g.

- A system of annual reporting and documentation of radiotherapy activities in Norway provides useful statistics both for the hospitals in evolving their own quality systems and for information to the health authorities.
- An extranet solution serving the KVIST reference group, the working groups, the RT departments, the medical society and the health authorities, is under construction, http://kvist.nrpa.no . All draft information is password protected, while general information will be open for the public.
– A national system for reporting treatment errors is implemented as a part of the hospital quality systems, and condensed statistics sent annually to KVIST.
– The IAEA dosimetric protocol (TRS 398) has been implemented in the hospitals. In close collaboration with NRPA’s secondary standard dosimetry laboratory (SSDL), dosimetry revisions were performed in 2004 and will be provided again in 2008.
– KVIST provides two phantoms for quality control of the non-dosimetric information exchange between different data systems in the radiotherapy chain.
– A post-qualifying educational system for medical physicists with calculus exercises is provided. This is particularly useful in Norway since we do not have formal system for authorization of medical physicists.
– A mutual understanding of the target volume definitions, implementing recommendations from the International Commission on Radiation Units and Measurements (ICRU).
– A common radiotherapy prescription form is in course preparation with necessary parameters for radiotherapy, also to be used as a tool to register intended treatment.
– A system for clinical audits have been developed and tested on the treatment of bone metastases in 2002–2004. In 2008 we will further develop this method for treatment of breast cancer.
– As a national reference standard for clinical audits, radiotherapy guidelines are needed. Per 2008 a template is published, and draft guidelines are provided for gastro intestinal cancer and lung cancer, furthermore, work have been initiated to provide guidelines for prostate cancer and lymphomas.

A5.4 Meeting places and work-shops for the radiotherapy community
KVIST has also established the Norwegian Radiotherapy Meeting, an annual meeting where oncologists, RT technologists and physicists meet to discuss radiotherapy related issues. Workshops dedicated specific cancer diagnoses are also arranged as part of these meetings. Planning of the meeting include choice of diagnosis, finding and inviting attractive lecturers, and most important preparing clinical cases for centre home work before the workshop. The clinical cases consist of two or three anonymized patient histories and CT-image sets for treatment planning. The first workshop focused entirely on delineation of target volumes and organs at risk. Later meetings have also included treatment planning with field set-up and dose distribution. Data from all centers have been compiled by the KVIST group. So far plans for rectal, lung, prostate and breast cancer have been examined.

Two or three centers are asked to prepare a presentation of the cases on how they define treatment volumes, organs at risk, (presented by an oncologist) and their way of making a typical treatment plan (presented by a physicist or technologist). Members of the KVIST group present compile data, typically contours and dose distributions from all centers on selected CT-slices, both to show where there is a consensus and what the differences are. A well prepared expert panel appointed by the KVIST group and national diagnosis working parties consisting of oncologists, physicist and technologist lead the sessions, pose questions both to presenters and the audience to enhance fruitful discussions.

Information about the KVIST initiative and ongoing work is found on www.nrpa.no (search KVIST), e.g. NRPA Bulletin 8:2008 Quality Assurance in Radiotherapy – eight years outcome
Annex B

Cooperation between health authorities and radiation control authorities

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Foreword

We thank the FPS in charge of Public Health, in particular Christiaan Decoster, for the review of this article.

B1 Introduction

In the field of medical applications, it is possible for a country to give the responsibility, at least partially, of radiation control to the health authorities. But it is also frequent that national authorities decide to use separate regulatory bodies for the organization of health care provision and protection on one hand and for radiation control on the other. This last is the situation prevailing in Belgium.

The existence of two separate bodies pursuing different regulatory objectives in a particular domain of activity can be a definite advantage but also a source of confusion. Radiation control authorities should have a strong connection with health authorities. The overlap between their respective fields of responsibility is wide and the benefits of an effective cooperation should not be underestimated.

After a brief description of the Belgian situation, which provides an example of allocation of responsibilities between radiation control and health authorities, we will present important issues related to the existence of two or more regulatory bodies. We will then give examples of initiatives adopted in Belgium by the authorities in order to improve cooperation and their effectiveness.

B2 Belgian context: the actors and their roles

The Belgian radiation control authority, the Federal Agency for Nuclear Control (the FANC, the Agency), was created by law (law of April 15, 1994). This law confers to the Agency the responsibility for protecting the population (including patients), workers and the environment against the risks resulting from the use of ionizing radiation. The Agency itself is the result of a fusion of different bodies, originating from different ministerial departments, and grouped together in order to treat nuclear and radiological matters in a more effective manner. One of these bodies was the Service for the Protection against Ionizing Radiation (Service de Protection contre les Radiations Ionisantes, SPRI) directly transferred from the Department of Public Health. Another important body was the Service for Technical Safety of Nuclear Installations (Service de Sécurité Technique des Installations Nucléaires, SSTIN) from the Department of Labour. Other important bodies came from the Departments of Justice, of Economy and of Foreign Affairs. The Agency, operational since September 2001, through a
Royal Decree (of July 20, 2001), benefits from a certain degree of autonomy in its actions and decisions, but reports to the Minister in charge of Homeland Affairs/Security and the legislative Chambers.

A simplistic statement on the responsibilities of the Agency could be: the Agency has responsibility for authorization and control of the use of sources, for authorization and control of users of sources, for communication to the public about the radiological risk, as well as for emergency preparedness and response (mainly an advisory role based on a full assessment of the situation) and for monitoring of the environment.

Practically, the scope of activities in which the Agency is involved is a lot wider and includes: developing legal instruments related to radiation protection, safety and security; providing incentives to research initiatives; determining specific education and training requirements for different types of users; providing education and training; providing its expertise to various official bodies; direct involvement in diverse projects; etc.

In the case of medical application, the FANC, beyond its already described responsibilities, is by law responsible for a correct implementation of the principles of justification and optimization.

Other actors are involved with the regulation and management of medical applications. They belong to different health authorities. In Belgium, the tasks and responsibilities involved for the management of public health are divided between the federal and regional/community levels.

The Federal Public Service (FPS) in charge of Public Health has two main roles: ensure an appropriate provision of health care services and (para)medical manpower in the country, and ensure an adequate medical management of public health in case of emergencies. The FPS determines the rules applicable for licensing of the medical professions and controls if the manpower works with appropriate licenses. It takes initiatives in order to improve the quality of health care, etc... The FPS has an advisory and legislative role on public health policies. It sets the norms and standards for hospital services, like services using PET or CT Scanners. It plays a role in data collection (health care provision data) and analysis of epidemiological data. It is helped in its different tasks by different scientific bodies (councils, institutes, colleges and laboratories), some of them answering directly to the FPS. The Health Council (Conseil Supérieur de la Santé/Hoge GezondheidsRaad) addresses specific issues and gives advice and recommendations from a scientific perspective. The Expertise Centre (Kenniscentrum/Centre d’Expertise, KCE) assesses the benefit of new techniques from an Evidence Based Medicine (EBM) perspective. Colleges establish rules for good medical practices (GMP) and help determine policy in their respective fields (image quality, radiotherapy, …). There is a special body in charge of epidemiology (ISSP), special institutes (the Cancer Institute for example) and a series of national laboratories.

The financing of the health care system is partially under the responsibility of the FPS (for the financing of hospitals) and partially under the responsibility of another organ, the National Institute for Disease and Invalidity (Institut National d’Assurances Maladies-Invalidités, INAMI/RIZIV) (for the payment of doctors) with the FPS Social Affairs. These bodies take advice from different financial and scientific commissions, experts, as well as political bodies.

The regional/community public health ministries are in charge of prevention (vaccination, screening initiatives, preventive information campaigns, regulation concerning preventive
activities, ...), the application of the federal legislation for hospital services and finally inspection of the application of federal norms and standards in the hospitals.

B3 Issues

It is stated in the introduction that the existence of two separate bodies pursuing different regulatory objectives in a particular domain of activity - like here the FPS in charge of Public Health and the FANC, both involved in the protection of health and in the use of ionizing radiation in medical practices - can be a definite advantage but also a source of confusion. The need for collaboration depends mainly on the complexity and intricacy of the issues.

When collaboration between two bodies operating ‘on the same turf’ is kept minimal, potential advantages may result for each body:

- *They can gain time by addressing the situation directly without consultation of the other body.*
- *It simplifies their intervention because it is easier to address a situation from just one angle.*

When the issues are well defined and separated, the need for collaboration may be less pronounced. But this is usually not the case when we deal with regulation, in particular in the field of radiation protection and control and health provision.

A one-sided approach can become a source of confusion, because:

- *Each acting body may lack some crucial knowledge leading to faulty assumptions and less effective, inappropriate or even contra-productive initiatives.*
- *The initiatives taken by one body could go in another direction than those taken by the other body, hampering their counterpart’s initiatives, creating confusion for the stakeholders and reciprocal irritation for both bodies.*

This threat of conflict could convince each body to stay out of the field of competence of their counterpart, leaving a legislative void (where some issues remain unaddressed, neglected, causing additional problems along the road …)

The same void can also appear because each party assumes wrongly that a certain matter belongs to the domain of competence of the other party, and is treated by them.

On the contrary, when two bodies decide to initiate a dialogue, the potential benefits are:

- *A creation of synergies by pooling resources and expertise, with additional benefits like better conceived, integrated and effective policies.*
- *An economy of resources (by reducing the duplication of similar activities).*
- *A better distribution and sharing of roles, a more appropriate use of the available expertise.*
- *Improved results and increased credibility for both bodies.*

Even if what is written in the previous paragraphs looks and reads like a simplistic description of reality, it nevertheless describes the actual results of a poor or good cooperation.

The attribution of specific responsibilities to two independent authorities (the first focused on security and safety, the second on health service and care provision) can create very conflicting situations or generate improved results, depending on the quality of the cooperation.

Conditions for a good collaboration are: the ability to recognize its potential benefits, the willingness to abandon the potential benefits linked to a unilateral approach, the will to
understand and respect the perspective of the other party and the investment made in the process.

Radiation control authorities should have a strong connection with health authorities. The overlap between their respective fields of responsibilities is wide and the benefits of an effective cooperation should not be underestimated.

As an example, the intention (by a safety and security driven organization) to develop a safety culture in hospitals is by itself quite laudable. But it is no simple task. It should certainly not be carried out the way it would be possible with other types of activities. By definition, hospitals are structures open for all, which are driven by service provision. They are used to being supported in this attempt by health authorities. Pushing for or imposing measures could be deleterious to the quality of the service that hospitals have taken many years to develop. Dialogue is imperative on the way to proceed.

In the field of medical practices, justification and optimization are matters officially belonging to the tasks of the FANC. It must be recognized that you need a highly specialized personnel to address those issues. Stakeholders involvement is necessary. The generic justification depends on special Commissions in Public Health.

Specific initiatives for health assessment and protection can have more impact when they are designed and operated in cooperation. Their advertisement/promotion can have more weight if it is integrated in a common public health perspective.

For emergency preparedness and response, big improvements can be expected from a close collaboration between the health authorities and the control authorities. Assessing the risk, resources available, determining needs for improvement, priorities…

The way the health care system is organized and financed has a clear impact on the use of the applications. In order to improve the quality of health care provisions and to evolve toward better practices, incentives can possibly be designed through collaborative efforts by concerned parties.

B4 Initiatives adopted for an improved cooperation

Meetings have been organized between the Agency and the FPS Public Health in order to re-identify and re-assert our respective roles and fields of competence.

Activities that would probably benefit from collaborative efforts between the two organizations have been identified. A list has been made. A simplified version can be found hereunder:
It has been decided, as a first step, to establish a contact person in each institution to facilitate communication and transmission of information. A formal cooperation agreement, a text describing the agreed upon tasks and duties assigned on both parties by signature of this agreement, has been signed. The purpose is to clarify the expected tasks associated with and beneficial for our cooperation.

A radiological protection platform aiming to improve quality in the medical provision of care has already been created. Specific matters are discussed with ad hoc stakeholders.

The FANC has also initiated rounds of discussion with the radiotherapy community as well as with the radiology community, in order to improve quality. The FPS of Public Health is involved in those activities. Working groups have been created with stakeholders. An improved notification system for incidents in radiotherapy, as well as measures to improve quality in radiotherapy and radiology are being developed. Progresses are discussed in the radioprotection platform previously mentioned.

Discussions are ongoing between the FANC and the Public Health authorities in preparation of the next public information campaign designed for persons living in proximity to nuclear installations.

Another example of cooperation was in the management of a recent incidental release of limited amounts of radio nuclides from an industrial site. Information of the population and its screening were carried out after consultations and discussions the FANC and the FPS of Public Health.

**B5 Conclusion**

Cooperation is essential for topics that overlap between two governmental bodies. Potential benefits outweigh the inconveniences especially where public health is concerned. Belgium has reinvigorated the dialogue and cooperation between the bodies concerned with radiation protection. Sustained efforts will be necessary to achieve an effective and durable cooperation.