Superior
Health Council

THE USE OF CT OUTSIDE MEDICAL IMAGING DEPARTMENTS IN GENERAL AND IN PARTICULAR IN THE OPERATING THEATRE

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Federal Public Service Health, Food Chain Safety and Environment

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9297

The use of CT outside medical imaging departments in general and in particular in the operating theatre

In this scientific advisory report on public health policy, the Superior Health Council of Belgium provides a legislation assessment about the conditions governing the use of CT outside medical imaging departments.

It would like to provide to ionizing radiations risk managers, specific recommendations for medical physicist and practitioners.

This version was validated by the Board on
9 November 2016[1]

1 INTRODUCTION AND ISSUE

The Superior Health Council of Belgium (SHC) was asked to provide an advice to the Federal Agency for Nuclear Control (FANC). This request concerns the examination by the SHC of the requirements to use CT scanners outside medical imaging departments and more specifically in the operating theatre, having in mind justification and optimisation as mentioned in the Royal Decree of 20/07/2001.
These CT scanners can be considered as a bridge between diagnostic CT and classical C-arm and O-arm. A few of them have been recently installed in Belgium to allow a direct evaluation of the correct placement of surgical material, with the main objective of getting images of better quality with a lower dose.
The FANC asks advice on the following points:
Question 1: is the use of CT scanners outside medical imaging departments authorized for diagnostic imaging, and what should be the relationship with medical imaging departments and the responsibility of radiologists
Question 2: what are the requirements for the users of these equipment's outside the medical imaging department
Question 3: regarding quality control and quality assurance: does the intraoperative CT (i-CT) have to fulfil the requirements of FACN decree of 18/02/2014 on CT and/or are specific criteria necessary
Question 4: scope,
To which extent should the CT scanners outside MID be included in the register of heavy equipment?

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

In the future, more applications will be found outside the MID. How should the use of these systems be authorized?

2 RECOMMENDATIONS

- A clarification of the legal framework regarding the register for heavy medical devices is required concerning CT :
    - no clear and unambiguous definition of a CT scanner exists
    - different categories of CT should be created based on their specific use: diagnostic CT on the one hand and CT used for specific applications such as i-CT on the other hand.
- In the authorization delivered by the FANC a distinction should also be made between these two categories: i-CT should appear in a specific category, in analogy to PET or SPECT CT systems.
- The use of CT outside the MID should be restricted to specific non- radiological' diagnostic applications to the benefit of the patient.
- Any use of CT outside the MID shall only be authorized if all the requirements of the RD of 20/07/2001 regarding building, staff…are strictly fulfilled.
- All specific applications using CT shall be justified and done according to the ALARA principle.
- Taking in consideration the particular sensitivity to radiation of children, pediatric applications shall be strictly justified case by case and great effort should be performed to limit the use of radiation.
- All users, medical practitioners and auxiliaries shall receive a dedicated training in radiation protection for the use of the CT, including a specific training delivered by the manufacturer. The FANC should insist / check that this training is provided before the device is used.
- Written medical procedures for the intervention shall exist as well as CT written procedures for the auxiliaries, approved by a medical physicist.
- Regarding acceptance and quality control, an addendum to the FANC decree of 18/02/2014 in accordance with the suggestions of point 4.3 should be encouraged.
- A comparative (dose-image quality) study between the different modalities (i-CT, O-arm, 3D C-arm) used in the OR in Belgium, financially supported by the Authorities, must be encouraged.
- A clarification of the authorization and use of 3D mobile system, other than I-CT, should be done.

Keywords and MeSH *descriptor terms*[2]

MeSH terms*	Keywords	Sleutelwoorden	Mots clés	Schlüsselwörter
Radiation protection	Radiation protection	stralingsbescherming	Radioprotection	Strahlenschutz
	Computed tomography	computertomografie	Tomodensitométrie	Computertomographie
	Mobile CT scanner	mobiel CT-scanner	Mobile CT scanner	mobil CT-Scanner
Neurosurgery	Neurosurgery	Neurochirurgie	neurochirurgie	Neurosurgery
Neuronavigation	Neuronavigation	neuronavigatie	Neuronavigation	Neuronavigation
	Intraoperative CT	intraoperatieve CT	CT peropératoire	Die intraoperative CT
Radiographic Image Enhancement	O-arm	O-arm	O-arm	O-arm
Radiation Dosage	Image guided spinal radiosurgery	Beeldgeleide spinale radiosurgery	radiochirurgie spinale guidée par l'image	Bildgestützte spinalen Radiochirurgie
	Surgical Imaging	Surgical Imaging	Imagerie chirurgicale	Surgical Imaging
	Image Quality	Beeldkwaliteit	Qualité d'image	Bildqualität
	Dose to patient and staff	Dosis tot patiënt en personeel	Dose au patient et au personnel	Dosis zu Patient und Personal

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed http://www.ncbi.nlm.nih.gov/mesh.

[2] The Council wishes to clarify that the MeSH terms and keywords are used for referencing purposes as well as to provide an easy definition of the scope of the advisory report. For more information, see the section entitled "methodology".

3 METHODOLOGY

After analysing the request, the Board and, when appropriate, the Chair of the area physical agents and the chair of the working group identified the necessary fields of expertise. An *ad hoc* working group was then set up which included experts in medical imaging, neurosurgery, radiation protection and medical physics. The experts of this working group provided a general and an *ad hoc* declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

This advisory report is based on a review of the scientific literature published in both scientific journals and reports from national and international organisations competent in this field (peer-reviewed), as well as on the opinion of the experts.

Once the advisory report was endorsed by the working group, it was ultimately validated by the Board.

4 ELABORATION AND ARGUMENTATION

List of abbreviations used

ALARA: As Low As Reasonably Achievable
ARBIS/RGPRI : Réglement general pour la protection des rayonnements ionisants/ Algemene regels voor de bescherming van ioniserende straling (royal decree of 20/07/2001); Royal Decree of 20 July 2001 laying down the General Regulation for the protection of the public, workers and the environment against the hazards of ionizing radiation, as amended
BHPA: Belgian Hospital Physicists Association
CBCT: cone beam CT
CT: computed tomography
ANC: Federal Agency for Nuclear Control
i-CT: intraoperative CT
IQ: image quality
MID: Medical Imaging department
NIHDI - National Institute for Health and Disability Insurance
OT: operation theatre
OR: operating room
QC: quality control
PACS: picture archiving and communication system
PET-CT: hybrid imaging device consisting of a positron emission tomography scanner (PET) with a CT scanner.
RP: radiation protection
SPECT-CT: hybrid imaging device consisting of a single photon emission computed tomography scanner (PET) with a CT scanner.
TIM: technologist in medical imaging

Definitions

CT: the definition of CT is unclear in the Belgian legislation. As mentioned in the register of the heavy medical devices, CT is simply “axial transverse tomography” instead of “axial transverse computed tomography “

i-CT: (portable) axial transverse computed tomography used for intraoperative purposes, with typical 360˚ tube rotation times below 1 sec.

CBCT: cone beam computed tomography with typical 360˚ - or partial - tube rotation times greater than 2 sec (RP 162), used for several applications such as dental or image-guided radiotherapy; they are not the subject of this advice.

O-arm: 3D-C arm with a flat panel detector, intraoperative-CBCT with navigation, trademark of Medtronic, introduced in 2005, with typical 360˚ tube rotation times greater than 20 sec

C-arm: only capable of 2D imaging, static and dynamic (fluoroscopy)

3D-C arm: modification of C-arm system by adding a rotational motor, increasing the isocentric precision and adding CBCT algorithms, 3D-imaging is available since 2001 in OR with these systems. Typical partial (*e.g.* 200°) tube rotation times are greater than 4 sec.

4.1 The Use of CT scanners outside medical imaging departments

Only axial transverse computed tomography devices (CT and i-CT, mobile or not) are concerned here, not CBCT with the exception of elements of comparison with O-arm found in many OT (+/-300 systems worldwide) for a similar use as the i-CT and 3D-C arm (several hundred systems around the world).
Taking into consideration the number of these 3D CBCT mobile systems and the associated dose to the patient and the staff, a clarification in the authorization of their use is needed.

Classical CT scanners have been used outside the MID for imaging in radiotherapy and then in the OT since several years, on rails or on wheels for neurosurgery and orthopaedic surgery; hundreds of these units have been installed worldwide. Some installations can deserve 2 rooms. (Hosoda et al, 2011)

AIRO Brainlab i-CT (32 slices) with extra-large bore has around 50 systems installed since 2014, 4 are in Belgium.
Samsung-Neurologica offers 2 models: Ceretom dedicated to head CT, 8 slice CT with a small bore and Bodytom portable full body CT 32-slice, presented as multi-departmental imaging solution

The FANC asks advice on the following points:

4.1.1 Only for imaging use

Is the intraoperative use of a CT in place of standard imaging devices justified before, during and after the intervention?

Yes, this use is justified as portable i-CT provides useful real time information during neurosurgery (position of implants, stimulation electrodes…) and should be considered more as an extension of neuronavigation than as a standard imaging device. It can have a positive impact on the intervention time and the security of the patient. In case of doubt, without this i-CT, it might be necessary to repeat imaging outside the operating theatre and return for a new surgery. Imaging at any time without repositioning the patient is possible.
At the end of the surgical procedure, positioning verification can be done directly in the operating theatre in the actual position of the patient, avoiding his (her) transfer in the imaging department and reinstallation on another CT table. The technical feasibility and usefulness of portable i-CT in image-guided surgical resection of high-grade gliomas was verified by G.M.V.Barbagallo and his group (Barbagallo et al, 2015). The role of i-CT in the early identification of complications during neurosurgery was also highlighted by Hosoda (Hosoda et al, 2011) and its impact in the surgical strategies of different neurosurgical procedures was analyzed by Carlson (Carlson et al, 2012).

Their use seems justified in place of standard imaging devices because:
The images acquired with the i-CT used for verification can be integrated and used by the neuronavigation system. This is not the case for all the other standard imaging systems.
Nevertheless, the image quality must be at least as good as the one from standard systems and deliver less doses to the personnel and if possible to the patient. This has to be verified by a qualified expert in medical physics in radiology, considering the total dose delivered to the patient, including the post operative CT when necessary.
With i-CT, the surgeons, nurses and radiographers operate the CT as in an imaging department, at the console protected by a lead glass and in an appropriate shielding room approved by a radiation protection expert. Safety measures, approved by the radiation protection expert, must be taken so that they do not have to be near the patient. The dose to the staff in this situation is therefore lower than the dose received with standard fluoroscopy systems.

This was shown by Tabaree et al,2013 in a cadaveric study for the placement of pedicle screws comparing O-arm system with navigation to a conventional fluoroscopy system (C arm). On the other hand, doses to the cadavers were higher, but in the C-arm group, a postoperative CT scan was needed and this decreases the difference in total dose between the two groups. Zhang and his group (2009) have evaluated in their dosimetric study comparing O-arm and 64 slice CT, that the O-arm patient dose was approximately half of the CT. In a study conducted by V.Weir in 2015, a similar comparison was made between the AIRO i-CT and a 64 slice CT and concluded that under identical technique conditions, radiation dose (mGy/mAs) from the AIRO is higher than that from the 64 slice CT.
Regarding patient doses, very few studies can be found in the international literature comparing i-CT with standard fluoro imaging techniques. In one of them on an anthropomorphic male phantom, Norah A.Foster (2016) determined organ doses from point measurements with Mosfet dosimeters placed in 11 locations and calculated effective dose to the phantom. This resulted in less dose given to the patients by the fluoroscopic systems than by the three CT (two i-CT and one O-arm). It is worth mentioning that there is a significant difference between flat panel scanners (CBCT) and conventional CT in term of dose distribution and effective doses, which makes the comparison difficult.
In Belgium, no comparative study about doses delivered by the different modalities is presently available, this should be further investigated.

If yes, do mandatory requirements exist following the ARBIS and must they be followed?

All the requirements, without exception, regarding the protection against ionizing radiation in the building, for the personnel and public…are strictly applicable. Regarding the building, these requirements might be “very stringent”, if the CT is really mobile and can be used in different operation rooms: each of them must be shielded and equipped with adequate personal protection to be in agreement with the principles of limitation of doses. This is the reason why, for the moment in Belgium, some i-CTs are not really mobile and are used in only one dedicated room. The i-CT must of course have a CE conformity certificate and comply to all requirements to be included in the authorization of the hospital delivered by the FANC.

Moreover, an access to a PACS or another archiving system is necessary. Reporting of technical dose descriptors shall be organized as on any other CT.

4.1.2 For diagnosic purposes

Is the use of CT for radiological diagnostic purposes outside the medical imaging department authorized?

Different use of CT, mobile or not, outside the imaging department must be considered:

Portable i-CT used in the operation theatre, as described in 4.1 should not be authorized for medical diagnostics as their image quality is not sufficient for diagnostic purposes. Their use must be limited to verification.

Diagnostic CT has to be performed in the MID under the responsibility of the radiologist and carried out by technologists in radiology (TIM). In most hospitals in Belgium the emergency department is near the MID and diagnostic CT required by the “emergency specialist” can be done in the MID and the diagnoses discussed with the radiologist. Nevertheless, in some hospitals a dedicated CT for emergency can be found. In this case, it must have the same quality as those used in the MID and can be authorized for diagnostic purposes under the responsibility of a radiologist.
A comparable situation is the use of fixed CTs in trucks, for example during building modifications or following catastrophes. In this case the truck is an extension of the MID.

In Belgium for the moment, diagnostic CT is not used elsewhere and mobile CT is only found in the operating theatre. This might change in the future as it will be shown in question 4 below.

The use of PET-CT and SPECT-CT are not considered here, being clearly defined in the legislation.

If yes, which conditions must be fulfilled following the ARBIS?

For the particular situation of CT in the emergency department or in the truck, all the requirements, without exception, regarding the protection against ionizing radiation in the building, for the personnel and public…are strictly applicable. The requirements for the users are the same as in MID and a protocol written by a radiologist must be linked to the examination. This requirements are applicable to any application in the future.

4.1.3 Relation with the medical imaging department

Must a CT scanner be always under the responsibility of the medical imaging department?

According to art 53.1. of ARBIS , the use of a radiological installation is limited to medical doctors having received a proper training in radiation protection and having received a personal license delivered by the FACN.
If the CT is used for medical diagnostics, art 53.3.1 is applicable, the authorization is only delivered to radiologists.
Therefore if the CT is used for diagnostic purposes, it has to be under the responsibility of a radiologist, being or not in the MID.
If its use is limited to other specific applications, it can be used under the responsibility of a licensed medical doctor mentioned in art 53.1, such as a neurosurgeon with specific training in radiation protection.
Nevertheless, the working group recommends that any CT be used in close collaboration with the medical imaging department. The installation, the implementation of scan protocols of mobile CTs should be done under the responsibility of the medical imaging department, in close collaboration with the medical physicists. All users should comply to the regulation of the FANC regarding the use of equipment generating ionizing radiation.

Do the images acquired for diagnostic always have to be interpreted by a radiologist?

Yes, as for any images acquired for medical diagnostic purpose, this is already the case, for example, with PET-CT for the CT images used for diagnostics.
All requests for examinations on a mobile CT should be done according to the requirements of article 17 of the coding legislation (Medische Beeldvorming - Radiologie), resulting in a formal report by a radiologist.

4.2 The user of CT scanner outside the medical imaging department (MID)

For the use of a CT-scan, the Royal Decree of 20 July 2001 regarding the General Regulations concerning the protection of the population, the workers, and the environment against the danger of ionizing radiation (ARBIS) is applicable.

In chapter VI “uses of ionizing radiation in human and veterinary medicine”:

Article 50 stipulates that every institution has to have a valid permit for the use of such a device, as it applies to

any radiological installation for medical purposes in human and veterinary medicine (art 50.2.1)

specifically to the exposure of patients as part of their own medical diagnosis or treatment (art.50.2.2)

Articles 51.3 and 53 further stipulate that “any medical exposure as specified in article 50.2.2. shall be performed under the medical responsibility of a practitioner licensed in accordance with the provisions of articles 53, 54.3 and 54.5.c”. These practitioners must have a legal degree in medicine, surgery and obstetrics, or an academic degree in medicine or a degree in veterinary medicine. The licenses specified in the paragraphs above shall be only granted to individuals who have acquired expertise in radiological protection and who have received an appropriate training course on the relevant techniques and methods in human or veterinary medicine, in medical, veterinary or dental radiology, in radiotherapy or in nuclear medicine for human beings or animals depending on the case.
The training for human applications shall pay particular attention to the medical exposure of children, to medical exposures as part of a health screening program and to medical exposures involving high doses to the patient, such as interventional radiology, computed tomography and radiotherapy.”
A license may be restricted:

a) In time;
b) to certain ionizing radiation sources and radiological installations;
c) to certain types of ionizing radiation applications.

Article 51.3 also mentions that “without prejudice to the legal and regulatory provisions concerning the art of healing and the provisions of article 51.7**,** the practical aspects of the procedure, or part of the procedure, may be delegated by the practitioner specified in the preceding paragraph to one or more individuals entitled to act in this respect in a recognized field of specialization”.
Article 53.2 specifies that these auxiliaries are nurses, paramedics and equivalent individuals etc. that may only work on the instructions and under the supervision and responsibility of the individual licensed in accordance with article 53.1, as long as they all have followed “an appropriate training for their professional activity”. The requirements for this training are specified in article 53.2. and shall cover the techniques used and pay particular attention to medical exposures involving high doses to the patient such as interventional radiology, computed tomography and radiotherapy.

That means that patients can be scanned by an auxiliary, but only under the responsibility of the practitioner and that both medical practitioners and auxiliaries need specific training. However mobile CT is not specifically addressed during the training of medical doctors or auxiliaries.

The working group of the SHC:

considers that the biggest difference between mobile and stationary CT devices is not the technology but the changing circumstances where the device is used.

advices that, given also that mobile CT scanners are not common yet, specific on the job training must be provided to all licensed professionals who work with each individual mobile CT device. The training should consist of more than the training provided by the mobile CT company and should include specifically: daily check-up, quality assurance and radiation protection protocols.

also advices that the FANC insists / checks that this training is provided before the device is used.

4.3 Quality control and quality assurance of CT scanners used in the operation theatre (OT) (i-CT)

As suggested by the FANC this part has been discussed during a dedicated meeting of the working group radiology (CT) of the BHPA.

4.3.1 Should we apply the same criteria to CT scanners in the OT as to the scanners for diagnostic purposes in the department of radiology?

First of all, the Royal Decree, ARBIS, is applicable everywhere, along with the European Directive of December 2013 (EU 2013).
We agree that the basic document for QA and QC of CT scanners in the OT is the text that is actually applied for CT scanners in use in the medical imaging department (MID) for diagnostic purposes (RD 2014)

The working group wants to stress the following aspects in particular:

(1) The introduction of a mobile CT scanner in the OT requires justification similar to the introduction of other new x-ray systems. Justification compares all important aspects of the new situation to the earlier situation without the new system. Justification can be task specific. In this particular case, justification includes patient dose, performance of the system and safety of the complete CT guided procedure. Often the new modality will replace other procedures: a CT in the OT may replace a CT scan to prepare the procedure, fluoroscopy during the procedure and a CT scan after the surgery. The complete dose picture has to be considered. Next, patient safety in general, due to shortened procedures, less complications and possibly an improved quality of life when avoiding transport, are important issues.
(2) Following ARBIS, a medical physics acceptance test and subsequent clearance of the system is an obligation prior to the clinical use of the system (RD 2001)
(3) This medical physics acceptance test will use, whenever possible, all current tests described in the FANC decree, with particular attention to dose verification and imaging performance. In addition to this, also the radiation protection of the workers, the accuracy of biopsy systems, navigation systems etc…have to be verified by experts.
(4) Patient doses should be compared to the doses from alternative earlier procedures, using other devices as 3D-C arm or O-arm
    a. Comparison of effective doses is an accepted way. It has to be verified first whether the same conversion factors can be used from (indicated) CTDIvol to effective dose.
    b. Dose indicators in general have to be correct. It is well understood today that the concept of CTDI has limitations for wider beams. A candidate verification procedure is the method proposed by the IAEA (IAEA 2011)
    c. As specified in RP 162, dose reduction techniques such as tube current modulation have to be present on any new CT equipment. Using it or not has to be decided depending on the surgical situations (presence of metallic equipment etc.)

4.3.2 Specify other criteria if needed.

(1) If the limiting values from the conventional CT scanners are not fulfilled, the medical physicist has to use personal judgement to set up a proper acceptance test and to adjust the limiting values that apply to classical CT scanners towards the specific situation of CT in OT. The DRL calculated per CT scan of an i-CT scanner should not be above the DRL of standard CT scanners of the same anatomical regions. The criteria of CT scanners that have to be applied in Belgium (RD 2014) are the best basis for a dedicated protocol for the CT scanner in the OT. As the systems are usually more simple, some tests might not be applicable. If one or more tests are not performed on CT in OT, the medical physicist has to justify this decision.
(2) Specific performance, dosimetry or safety issues may not be covered by the actual protocol (RD 2014). The following items should also be tested or at least verified:
    a. Stability of the system after different runs of the CT scanner, as an example via the checking of the increments between successive slices.

b. Reproducibility of positioning accuracy of the system with regard to the patient.
c. Verification of x-ray filtration. Some CT scanners may have a very limited filtration. This has consequences for the ratio of the peripheral dose to the central dose measurements. If this ratio is very different from standard CT scanners, new conversion factors will have to be developed to go from CTDI to effective dose.
d. Overbeaming.
e. The quality of the displayed images and ambient light in the surgery rooms.
f. Attenuation and bending of the table.

(3) Some systems come with a constancy check protocol. Daily quality control measurements are today not imposed by specific rules or protocols, it should be general practice. Current QC of the i-CT should be included in a frequent QC program until it is proven that this system is sufficiently stable.

Testing these i-CT can be very time consuming. After proper training to the use of the equipment, enough time must be devoted to acceptance testing and afterwards to periodic quality control.

The working group recommends to make an addendum for application specific CT to the FANC decree of 18/02/2014 regarding the minimum acceptability criteria for CT scanners.

4.4 Applications

4.4.1 Heavy medical devices register and relationship between the different official bodies (federal and regional)

In which way do the CT's (application specific or not) fall under the register of heavy medical devices?

The Belgian legal framework regarding mobile CT-scans is unclear. The Act of 10 July 2008 regarding hospitals and care-institutions stipulates in article 51 that heavy medical devices are devices or equipment for research or treatment that are expensive either because of their price, or because of the functioning by highly qualified personnel. According to article 52 of the same Act, the King can make up the list of devices that can be qualified as heavy medical devices. Such a list is provided by the Royal Decree of 25 April 2014 regarding the list of heavy medical devices in the sense of article 52 of the coordinated act of 10 July 2008 regarding hospitals and care-institutions. This list mentions in article 1, 1° the CT-scan as a heavy medical device. It does not further specify which type of CT-scan. Therefore, the sole conclusion is that every type of CT-scan, including a mobile CT-scan, is qualified as a heavy medical device, as long as no legislation stipulates otherwise.
Medical imaging devices like O-arms and C-arms are not mentioned in this list of heavy medical devices, neither are CBCT used in radiotherapy or dental CBCT.

How should the different bodies involved deal with this?

Different bodies are involved:

The register of heavy medical devices depends of the Public Health Federal Service but the limitation of the number of some of these devices (IRM, PET) is regulated by the federated entities, as they are now in charge of them. So far, no limitation exists on the number of CT but this might change in the near future.

CT in the emergency departments are included in the register, and may receive an identification number if there is an authorized medical imaging department in the hospital and if the medical examinations done are interpreted by a licensed radiologist.

Their use is diagnostic. This is also true today for the i-CT if a protocol is realized by a radiologist even if the purpose of this CT is not medical diagnostic.
The SHC recommends that specific identification numbers be delivered to CT, fixed or mobile, used for specific, non medical diagnostic, applications outside the MID.

The NIHDI (National Institute for Health and Disability Insurance) will reimburse solely the examinations done on a registered medical device and if the number of examinations are counted. For PET-CT, a specific code is used, a similar rule should be applied to permit the billing outside medical diagnostic for the specific applications of these CT. Nevertheless for neurosurgery, a code exists for neuronavigation and it already includes image fusion with diagnostic images?

The FANC delivers to the hospitals a permit to exploit medical devices using ionizing radiation. The working group recommends that application specific CTs, as i-CT, be mentioned apart of diagnostic CT, like it is already done for hybrid machines like PET-CT or SPECT CT.

A strong concertation between those different official bodies is needed.

4.4.2 In the coming years, other applications will be developed, in which way shall the use of these CTs outside the MID be authorized?

Mobile CT can also be used:

- for neurosurgery in intensive care for unstable patients, the risk of brain deteriorations might be significantly reduced when the patient is not moved. For airway stenting and lung volume determination, pediatric patients in intensive care can also benefit from the use of mobile CT

- C-arm CBCT are already used in brachytherapy (Dieter Ritter and al) to verify at the end of the implantation the position of the ^{125}I seeds and be able to compare it with the CT realized one month after the implantation, an i-CT can be used the same way

- mobile CBCT dedicated to extremities are also used both in human and veterinary medicine

- mobile stroke treatment unit using Ceretom are already available in the US to speed intra-arterial revascularization therapy (Cerejo, R., et al., 2015)

- in mass fatality incidents, CT can also be used for forensic purposes, in most cases, the CT will be fixed in a truck

- in USA, mass screening is realized with CT in a truck and mobile CTs are intended to be used also in patient's room

Etc.

These new applications might be authorized if:

they are justified, and that no other less irradiating technique can give a similar result

the benefit to the patient justifies the use of a CT outside the MID

the examinations respect the conditions of quality and radiation protection. The requirements mentioned in the Royal Decree of 20 July 2001 regarding the General Regulations concerning the protection of the population, the workers, and the environment against the danger of ionizing radiation (ARBIS) is applicable without restriction

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6 COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: composition and mode of operation.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Marie-Thérése HOORNAERT**; the scientific secretary was Eric JADOUL.

BIELEN DIDIER	radiologist	UZ Leuven
BOSMANS Hilde	hospital physicist, medical Radiation Physics	UZ Leuven
BULS Nico	hospital physicist, medical Radiation Physics	UZ Brussel
CLAPUYT Philippe	radiologist	UCL
GOFFIN Tom	Lawyer	Ordomedic
GREFFE Jean-Louis	hospital physicist	CHU Charleroi
HOORNAERT Marie-Thérése	hospital physicist, medical Radiation Physics	CH Jolimont
MALCHAIR Françoise	hospital physicist, medical Radiation Physics	ULG
MONSIEURS Myriam	physical control, radiation protection	UGent
SMEETS Peter	radiologist	UZ Gent
TACK Denis	radiologist	CH EpiCURA

Les experts suivants ont été entendus mais n'ont pas participé à l'approbation de l'avis.

CHASKIS Cristo	neurosurgeon	CHU Charleroi
DELCORPS Xavier	physical control, radioprotection	Controlatom

The following administrations and/or ministerial cabinets were heard:

DEPAU Isabelle		FANC
FREMOUT An	Dép. Santé et environnement, protection de la santé	FANC

About the Superior Health Council (SHC)

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.hgr-css.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.

www.css-hgr.be

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