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Dit nummer bevat de teksten van de uiteenzettingen ter gelegenheid van de vergadering van de Belgische Vereniging voor Stralingsbescherming en de Belgische Genootschap voor Nucleaire Geneeskunde in Brussel, op 8 mei 2004.

Nuclear Medicine and Radiation Protection

INHOUD **SOMMAIRE**

Annales de l'Association belge de Radioprotection, Vol.29, n°3, 2004

HEALTH EFFECTS FROM EXPOSURE TO IONIZING RADIATIONS

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There is a large body of literature concerning the effects of ionizing radiations. The radio-induced character of some cancers and leukemias is well established. The mechanisms of the lesions are partially understood, and in particular DNA mutations which may constitute the initiation step of a future cancer.
If the risk of exposure to ionizing radiations at large doses is well quantified, what is the risk at low doses and low dose rates ?

Risk evaluation : an international consensus

There is an international consensus regarding the risk of exposures to ionizing radiations. It is based on the scientific work of the United Nations Scientific Committee on the Effects of Ionizing Radiations (UNSCEAR) and on the interpretation by the International Commission of Radiological Protection (ICRP). The epidemiologic studies, and especially those of the survivors of Hirsohima and Nagasaki bombing, have permitted the evaluation of the risk of exposure to ionizing radiations. The risk is quantified at high dose and dose rate as proportional to the received dose in 3 domains :

- The teratogenic risk is evaluated at 50% per Sv of effective dose ;
- The excess risk of fatal cancer is evaluated at 5% per Sv of effective dose;
- The risk of hereditary disease is evaluated at 0,5% per Sv of effective dose

The extension of the linear dose-effect relationship to the domain of low doses without any treshold has been retained for the practical management of the radiologic risk.

Aside from the international consensus, there are 2 opposed views which are expressed in a manichean and endless debate : on the one hand, the risk is considered as lower or non existing, and on the other hand, the risk is considered as underestimated.

The overestimated risk

One may think from a few observations that the real risk resulting from exposures to ionizing radiations is lower than the risk indicated by the linear no treshold hypothesis

- The epidemiologic studies which have been used to quantify the risk do not demonstrate significant effects below doses in the range of 100 mSv. The evaluation of the risk for lower doses results from the application of the precautionary principle, with the extrapolation to low doses and low doses rates of the observations made for high doses and high doses rates;
- The epidemiologic studies concerning exposures to natural radiations in the countries with elevated background are negative.
- Globally, the epidemiologic studies of nuclear workers exposed to low doses do not demonstrate any significant increase in cancer (to be confirmed in the final paper from IARC).
- A mechanism of adaptive response to ionizing radiations (essentially to γ radiations) appears in some experimental situations, as if low doses have had a "mythridatisation" effect vis à vis future exposures.
- The general model of cancerisation has 3 main successive phases, i.e., induction, promotion and progression, which are not in favor of a model of linear risk.

The underestimated risk

Other studies are in favor of an underestimation of the risk by the linear no treshold model.

- In the bystander effect, irradiated cells signal their distress to their un-irradiated neighbours, by direct contact or through molecules secreted in the medium. The neighbour cells express genotoxic lesions. Furthermore, such DNA lesions may be observed in cells after the exclusive irradiation of the cytoplasm with α particles.
- Genomic instability is a phenomenon in which some amplification of DNA lesions appears in the progeny of irradiated cells. When a cell

survives after irradiation, mutations corresponding to lesions which were repaired are supposed in theory to be stable in future cell divisions. This is not the case after irradiation and new mutations are observed in the progeny. Mechanisms of genomic instability are not well understood, but it appears that telomeres have some responsiblity when not properly protecting chromosome ends.

At this stage, bystander effect, genomic instability or adaptive response indicate the quite high complexity of cellular mechanisms. So far, there are no critical reasons to re-evaluate the risk of exposure to ionizing radiations. New researches will be necessary to bring more comprehension and the results, whatever they are, will have to be accepted.

For example, the new method developped by Rothkamm (PNAS, 2003) can demonstrate and quantify DNA double strand breaks with a sensitivity 100 times greater than previous methods. It takes into account the observation of the phosphorylation of histone H2AX at the very site of DNA DSBs as evidenced by fluorescent antibodies. The number of DSBs in primitive human fibroblasts exposed to low doses of X rays increases linearly with the dose ranging from 1mGy à 100Gy. For one acute irradiation of 1mGy, 3% of cells shows DSBs which are not repaired for 3 days.

What happen with other DNA lesions, and especially these mutations which may constitute the first step of cancerogenesis ?

Cancerogenesis

Cancerogenesis studies demonstrate the involvement of 2 categories of genes: oncogenes and tumor suppressor genes.

Oncogenes are implicated in cellular signalisation. The anarchic proliferation of cancer cells may result from the activation or permanent modification of proto-oncogenes by mutation or by structural rearrangement. They are targeted alterations such as the mutation of one codon or the recombination of 2 genes. They produce the alteration of one allele of one gene with a dominant expression at the cellular level.

Tumor suppresor genes control the main metabolic and proliferative pathways. The molecular alteration is not targeted because there are many ways to inactivate a gene. The loss of a gene function may yield to the loss

of cellular adhesion and the loss of the control of proliferation. The alteration of one allele has usually no consequence ; mutation is recessive at the cellular level and the loss of the gene function appears only when the 2 alleles are impaired.

If the capacity of initiation of a cancer by one oncogene is greater than that of a tumor suppressor gene because the oncogene expression is dominant, the activation of one oncogene by a specific translocation is far less probable than the loss by deletion of a tumor suppressor gene.

Observations also indicate that cancer is a disease of cellular aging.

Cancer risk is 300 times greater at 80 yo than at 10 yo ;

95% of cancers in the elderly are carcinomas ;

Aging is characterized by the accumulation of mutations; a dozen of mutations are necessary for creating a cancer and since the number of combinations is quite high, it is likely that each cancer is unique ;

Environmental factors are implicated in cancer development, the main ones being tobacco, poor quality food, infections and alcohol, all of which contributing to cellular aging.

Cancerogenesis and ionizing radiations

The following hypotheses are currently formulated regarding cancerogenesis and ionizing radiations (Dutrillaux, 2000).

Radio-induced cancers are the same as those of the elderly ;

They are initiated by the loss of a tumor suppressor gene because the majority of radio-induced lesions is expressed recessively due to the statistical dispersion of lesions ;

Cancers with a dominant alteration of one oncogene are observed at all ages ;

There is no specific signature of radio-induced cancerogenesis.

These hypotheses are compatible with the observations and the epidemiologic data on radio-induced cancers.

Radiologic and genotoxic risks

The risk of cancer after exposure to ionizing radiations is significant at high doses and very low at low doses, unless one considers their genotoxic character and the DNA mutations as the potential initial step of cancer induction.

Ionizing radiations are part of a large family of genotoxic compounds : oxygen species of cellular metabolism, chemical products, e.g., derivatives of oil and gas, heavy metals, UV ,... which effects may combine together with other environmental effects ; furthermore, they may eventually potentialize and end up with premature cellular aging as a first step towards cancerogenesis.

Although we do not know yet how to quantify the risk of exposure to low doses of genotoxics, and among these to ionizing radiations, we cannot ignore it ; indeed, the battle against genotoxic exposure is one part of the battle for preventing cancer. Would not it be stupid to accept, knowingly and willingly, to be exposed to a genotoxic, whatever it would be, just because cells have developed repair mechanisms of their DNA ?

Thus, it seems justified to prevent useless exposures to ionizing radiations, and to optimize all justified exposures.

The simple application of the radiation protection principles drives us to the willingness to reduce and minimize exposures which can be easily controlled, i.e., radon and medical exposures which are the 2 main sources of exposure of the population.

Finally, much attention should be paid to the protection against all genotoxics of the youth and especially young children. Indeed, the protection of their genetic capital will contribute to delay the probability of an eventual cancer and to minimize germinal mutations which are difficult to demonstrate today.

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Legal and Regulatory Framework for Radiological Protection in Belgium

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Abstract
In Belgium, radiological protection is within the competence of the federal regulator. Federal laws and regulations dealing with radiological protection are based on European directives and international recommendations. The Federal Agency for Nuclear Control (FANC) has been set up by law to implement and enforce those regulations. This paper gives an overview of the general principles with respect to the organisation of radiological protection and their application and enforcement in nuclear medicine.

Introduction

The general regulations on radiological protection have been laid down by royal decree of July 20, 2001[1]. They are based on the law of April 15, 1994 on the protection of people and the environment against the hazards of ionising radiation and on the Federal Agency for Nuclear Control[2] and implement a number of European Directives, in particular those on the basic safety standards for radiological protection[3] and on the protection of patients[4]. The Federal Agency for Nuclear Control (FANC) has been set up by law to implement and enforce those regulations. It is a public agency headed by a board of directors and a general manager. The organisational chart is given in the annex. On the first of September 2001 the FANC has taken over the duties of the specialised offices of the federal ministries of Public Health and Social Affairs on one hand and Employment and Labour on the other hand.

The basic principles of radiological protection (justification of practices, optimisation of protection and individual dose limits) are implemented and enforced through a system of authorisations (licensed facilities, qualified persons, certified devices) and controls.

Facilities

Facilities where practices involving ionising radiation take place belong to different classes according to the hazards involved: class 1 includes nuclear fuel cycle facilities; class 2 includes facilities where humans are exposed to radiation for medical diagnosis or therapy (hospitals); class 3 includes facilities where rather small quantities of radioactive substances are kept and used (in vitro laboratories). Class 1 facilities are licensed by royal decree. Class 2 and class 3 facilities are now licensed by the FANC and no longer the provincial authorities. The licenses are granted following an application that gives information on who (the operator) does what (practice and installations), where (location) and how (provisions for radiological protection, including the health physics control and the medical surveillance of the workers). As a general rule, the licenses issued by the FANC are valid for a period of 15 years. Changes of activities are subject to notification and are followed by a revised license in case of a major change with impact on safety.

Health physics control is to be organised by the head of the facility and is to be directed by a recognised expert. The health physics control department is under supervision of a recognised body. In case there is no in-house expert, health physics control is to be performed by a recognised expert belonging to a recognised body.

Health physics control comprises amongst others:

- supervision of the compliance with radiological protection regulations and provisions for workers, the general public and the environment;
- determination of controlled and supervised areas;
- commissioning of new installations;
- approval of clearance procedures;
- determination of doses to workers (in consultation with the recognised physician who is in charge of the medical surveillance);
- approval of procedures for transport of radioactive sources.

Unless the license sets facility specific limits for gaseous and liquid releases, the generic limits specified in the general regulations apply. Clearance is an option for the management of solid waste: generic clearance levels are set in the general regulations, but facility specific levels may be set by the FANC. Those specific

levels shall not be higher than the exemption levels in the general regulations. In case of short-lived nuclides, storage for decay is required. It must be noted that the Belgian Agency for radioactive waste management (NIRAS/ONDRAF) need to be involved in the removal of such waste.

Practitioners and Helpers, Medical physics experts

Medical doctors who want to use radioactive substances for diagnosis or treatment of patient must be individually authorised by the FANC, following the advice of a medical council. The authorisation is granted only if the practitioner has a basic education in radiological protection (120 hours of theoretical education and 80 hours of practical training). As a general rule, the validity of the authorisation is limited to a period of 10 years and is restricted to a limited number of facilities. Any change of the terms of the authorisation is subject to notification and an amended authorisation. An extension of the period of validity is granted only following the demonstration of continuing education in radiological protection.

Helpers of the practitioners must also have a basic education in radiological protection: 50 hours of theoretical education (60 hours in the case of nuclear medicine) and 10 hours of practical training. They are not individually authorised by the FANC. On request, the FANC may certify that the training courses comply with the regulatory provisions.

It must also be noted that the general regulations require the operator of a facility to organise education and training of his personnel on a regular basis.

Practitioners have the obligation to seek advice of a recognised medical radiation physicist with the aim to optimise the protection of the patients. In general, a university degree in medical radiation physics is required (600 hours) and for the domain of nuclear medicine, an additional one year on-site training. The physicists are recognised by the FANC, following the advice of the medical council. As a general rule, the first recognition is valid for three years and any consecutive extension for six years. Extensions are granted only following a report of activities and upon demonstration of continuing education in radiological protection. Amongst the duties of the expert in medical radiation physics are: the commissioning of new devices, the annual verification of the devices and report to the health physics department (and to the FANC in case problems were found).

Medical devices

The European Directive 93/42/EEC deals with medical devices in general[5], and has been implemented by the royal decree of March 18, 1999[6]. European Directive 98/79/EC specifically deals with 'in vitro' medical devices[7] and has been implemented by the royal decree of November 14, 2001[8].
Medical devices have to be certified by the manufacturer, according to European standards. As mentioned above, the expert in medical radiation physics must be involved in the commissioning of new devices and has to verify annually whether the devices are still acceptable. In case of malfunctioning of a device the expert has to notify the authorities. Procedures are in place for the follow-up of the so-called vigilance reports.

Enforcement

Radiological protection is enforced through a system of notifications, licenses and authorisations and through a system of controls and inspections.

An overview of the licenses and authorisations that are most relevant to nuclear medicine has been given above. Other activities, which have interfaces with nuclear medicine, such as import and transport of radioactive materials, production and distribution of radiopharmaceuticals are also subject to license. Other general provisions, such as those dealing with emergency planning, must also be complied with.

Controls and inspections are built in at different levels. The prime responsibility for safety is with the operator of the facility. The first level of control is in-house, by the experts in health physics, the experts in medical radiation physics and the physicians in charge of medical surveillance of the workers. At the second level we have the recognised bodies. At the third level there is the FANC supervising the recognised bodies and inspecting facilities.

REFERENCES

[1] Koninklijk Besluit van 20 juli 2001 houdende algemeen reglement op de bescherming van de bevolking, van de werknemers en van het leefmilieu tegen het gevaar van de ioniserende stralingen, gewijzigd bij koninklijk besluit van 12 maart 2002.

[2] Wet van 15 april 1994 betreffende de bescherming van de bevolking en van het leefmilieu tegen de uit ioniserende stralingen voortspruitende gevaren en betreffende het Federaal Agentschap voor Nucleaire Controle, voor het laatst gewijzigd door de wet van 22 december 2003.

[3] Council Directive 96/29/Euratom of 13 May 1966 laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation,
Official Journal of 29 June 1996.

[4] Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom,
Official Journal of 9 July 1997.

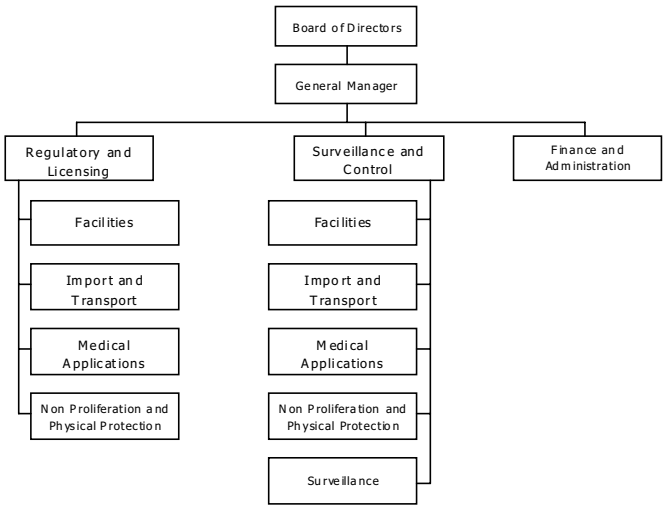
[5] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices,
Official Journal of 12 July 1993.

[6] Koninklijk Besluit van 18 maart 1999 betreffende de medische hulpmiddelen.

[7] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices,
Official Journal of 7 December 1998.

[8] Koninklijk Besluit van 14 november betreffende medische hulpmiddelen voor in-vitro diagnostiek.

Annex: Organisational chart of the Federal Agency for Nuclear Control



Samanvatting
In België behoort de stralingsbescherming tot de bevoegdheid van de federale regelgevende overheid. Federale wetten en reglementen die handelen over stralingsbescherming zijn gebaseerd op Europese Richtlijnen en internationale aanbevelingen. Het Federaal Agentschap voor Nucleaire Controle (FANC) werd bij wet opgericht om deze reglementen te implementeren en te doen naleven. Dit artikel geeft een overzicht van de algemene principes met betrekking tot de organisatie van de stralingsbescherming en hun toepassing en uitvoering binnen de nucleaire geneeskunde.

Résumé
En Belgique, la radioprotection est de la compétence du régulateur fédéral. Les lois et réglementations fédérales traitant de la radioprotection sont basées sur des Directives européennes et des recommandations internationales. L'Agence Fédérale de Contrôle Nucléaire (AFCN) a été créée par loi pour implémenter et faire respecter ces réglementations. Le présent article donne un aperçu des principes généraux relatifs à l'organisation de la radioprotection et leur application et exécution en médecine nucléaire.

PRACTICAL IMPLICATIONS OF THE BELGIAN REGULATION.

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Abstract

The Belgian regulations have been developed along three main axes: Facility, Users, Medical Devices.
The implementation of the European Directives to our regulatory environment is leading to obligations for each one of these. As said previously, these are subject to control. Nevertheless, it is important to remind that the control must not be the driving element in this matter. The responsibility belongs to the practitioner for most of the constraints and obligations and it is his duty to have the radiation protection risks under control as it is for every user of ionizing radiations.

The presentation analyses typical risks which must be under control in the three groups; it insists on the role of each one of the actors and responsible persons:

- Facilities: the usual examination room requirements are exposed as well as some hot lab procedures “not to be forgotten”; therapy rooms will be brought to the table of discussion while reminding the existing recommendations.
- Qualified users: the regulation has now been extended to other levels than practitioner; the lecture will bring other users into light.
- Authorized medical devices: reminding about general features while buying and using devices will be exposed.

Finally, some concepts of quality assurance will be presented in order to set the position of each one of the upper mentioned requirements in the general scope of Quality management programs; the relative position of QC and QA will be explained and set in perspective while presenting the effort done on the European level.

Belgian regulations that are applicable to the Nuclear Medicine Departments can be classified along three different axes: facilities, qualified users and authorized material.
It is not the objective of this presentation to be exhaustive but well to let the readers understand what the content of the law is and where to find out more details.

This brief presentation is explaining each of the above mentioned axes and add a fourth dimension to the review of the regulation: quality.

Facilities:

1) Most of the constraints applicable to the nuclear medicine departments are due to the fact that they are belonging to the class II (except for the ones departments handling in-vitro only).
   As such, the creation, transfer, changes in the activity need to be mentioned to the regulatory authority: FANC. The changes will be analyzed and might lead to a new authorization.

2) The head of the facility is bearing responsibilities and must:
   - organize health physics control
   - have health physics control checked once a year
   - organize medical surveillance including workers dose evaluation
   - organize information and education for the potentially exposed workers (art. 25)
   - organize continuous education for the helping persons (art 53.2)

Each of these lines has an impact on the obligations of the head of the facility; for instance, the health physics control roles are described as “organize and survey the security and work conditions except for medical control”. This implies:
- delineation and signalization of the controlled area
- protection against radiation risks (including new proposals)
- dose evaluation
- new project of installation
- new installation validation
- contamination, waste, accident, loss, internal transport procedure, ...
- waste and reject inventory.

The head of the facility must organize occupational health surveillance, i.e., he must evaluate doses to the worker together with the health physics control responsible. He must, as well, follow up the occupationally exposed workers. This health surveillance must be done by an authorized Medical Doctor.

3) Belonging to the Class II means as well that Nuclear Medicine Departments have a “controlled area” and a “supervised area”.
   - Controlled Area = "area where 3/10 of the annual dose limits for occupationally exposed workers could be exceeded”, i.e.,
     - Drink, eat, smoke, ... are forbidden
     - Signs at the entrance
     - Isotopes must be kept in specially designed rooms
     - Inventory of the sources must exist
     - Area can be closed
     - Dose at the surface of the area may not exceed 0.02 mSv/w.
   - Supervised area = area where exposure to the ionizing radiation might exceed any of the dose limits for the members of the public.

4) How do we need to consider the “hot room” (laboratory for doses preparation)? Obviously, it is a controlled area and as such, must answer to the criteria mentioned here up. On top of this, one should forecast:
   - isotopes registration and activity bookkeeping
   - measures of the activities must be executed with material under Quality Control
   - procedures to prepare all products
   - all product preparation procedures must be under Quality Control as well
   - radio isotopes and radio pharmaceutical must be registered.

5) If the department has some procedures including injections of radioisotopes as radio therapy agents, one should not forget to think about the “metabolic room” or patient isolation room. Recommendations on this subject have been made available from the “Conseil Supérieur d’Hygiène - Jury Médical de la Commission Spéciale”. One should note that:
   - walls and floor should be easily cleanable
   - patients urines and excreta must be collected
   - protection against radiation screen should be available
   - single use material must be available (e.g. gloves, ...)
   - physical control must be done by an expert accredited for Cl II
   - collected waste must be stored
   - monitoring(dose level) of the workers is required
   - intervention and emergency procedures must exist

- visits to patient must be organized
- dose measured in neighboring rooms may not exceed 0.5 mSv/y.

As an example developed in the above mentioned recommendations, one could take the injection of I-131 to patient; in this particular case, it is recommended to isolate the patient as long as the dose at 1 meter distance is > 20 µGy/h or 10 µGy/h if small children are present. The same recommendations are advising to keep patients hospitalized when the injected activity is > 400 MBq.

6) As it is often the case that the department is not concentrated at the same place, one should not forget that the transport of ionizing sources inside the facility is to be executed under validated procedure. This procedure is under health physics control responsibility. It must include the reception of goods and must take risks into account.
   When we look at transport of radio active sources outside the facility, this must be executed by an authorized company / person. One should not forget that the transport of "waste" falls into this category.

7) There are some constraints as for waste management as well; one could briefly summarize these as follows:
   - if the department is a waste producer, it must be registered at "ONDRAF"
   - liquid and solid waste must be kept in specially designed rooms(fire protection, locked, ...)
   - collecting procedures must be approved by health physics control
   - precise bookkeeping of the waste must be kept
   - if T1/2 of the isotope is > 6M. ➔ one should refer to the allowance level
   - if T1/2 of the isotope is < 6M. ➔ one should, in addition, hold the waste for 10 X T1/2

There are different ways to handle the wastes produced by patients(urines and excreta); one could store or freeze and store these.

Qualified users:

The second axis followed by this presentation is simply reminding some basics. Once again it is not the intent to be exhaustive but to remind some guidelines along the lines of the "occupationally exposed workers", the radio-physicist and his roles and, finally, the practitioner.

1) Occupationally exposed workers.

The well known rules for the exposure are reminded:

- max dose on 12 consecutive months: 20 mSv
- nobody younger than 18 Years old should be professionally exposed
- student must be considered as occupationally exposed workers if older than 18 years and as public person if younger than 16 years
- student between 16 and 18 y. old should not be exposed to more than 6 mSv on 12 consecutive months

2) As a reminder, one should recall that person from the general public may not be exposed to more than 1 mSv on 12 consecutive months.

3) Radio physicist;

He is certified in Nuclear Medicine; among others, his roles are:

- dosimetry of the machines or material used
- patient dosimetry
- technical specification of the material to be bought
- selection, acceptance, calibration of dose measurement material
- QC procedure preparation
- material QC procedure preparation
- patient dose optimization with the medical staff

4) The practitioner.

He is the person who may hold and use radio isotopes ; his authorization is depending on isotopes and type of practice. It is, as well, depending on the facilities which is the place where he is allowed to keep sources.

Authorized Material:

Just in order to draw the basic lines of this axis, one should recall that all the material bought after 14/06/98 must be CE marked. All material bought before that date must be authorized.

The QC applied to the material must happen after installation, major repairs and for some part of the QC on a routinely basis(day, week, month ...: to be included in the physicist report). One could find practical recommendation about frequency of QC in some international publications(e.g. IAEA NM courses, ...).

Quality:

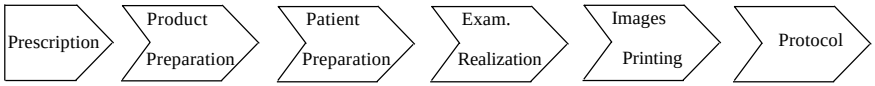
The whole regulation set is including aspects of Quality, Quality Control and Quality Assurance; it was considered useful to remind the definitions of these words and to have a look at their meaning in this environment.

Quality is defined as the “ability for a set of intrinsic characteristics to satisfy requests”.

Quality Control is “the set of operations intended to maintain or improve quality; it includes definition, evaluation, performance measuring and controlling of equipment”.

Quality Assurance is “the planned systematic actions necessary to provide adequate confidence that a system, process, structure will perform satisfactorily”.

The process to which these concepts are to be applied has been called the image chain. It can be summarized by the following scheme:



One could easily agree that the goals of the image chain must be defined, although the words used can vary, along the axis of:

- clinically useful examination,
- dose to the patients, the workers and the populations ALARA,
- no mistakes in the process chain.

Having in mind that radioprotection rules includes Quality Assurance system in place, one must admit that managing a Nuclear Medicine Department process where a quality system is in place is more than applying regulations. With the Quality dimension added to the rules, regulation becomes a dynamic subject, a must for the department and for the Specialty of Nuclear Medicine in General.

Samenvatting
“ Praktische implicaties van de Belgische reglementering”.

De Belgische reglementering werd uitgewerkt rond drie belangrijke pijlers: inrichtingen, gebruikers en medische toestellen.
De implementering van de Europese richtlijnen in ons regelgevingsgebied leidt tot verplichtingen voor elk van deze pijlers. Zoals reeds eerder vermeld, zijn deze verplichtingen onderworpen aan een controle door de bevoegde overheid. Het is evenwel niet deze controle die de stuwende kracht achter de stralingsbescherming dient te zijn. De verantwoordelijkheid hieromtrent ligt vaak bij de practicus en het is dus zijn plicht om - zoals alle gebruikers van ioniserende stralingen - de risico’s i.v.m. de stralingsbescherming te controleren.

De voorstelling analyseert de typische risico’s die in elk van de drie groepen gecontroleerd moeten worden; de nadruk wordt gelegd op de rol van elk van de actoren en de verantwoordelijke personen:

- Inrichtingen: uiteenzetting van de verplichtingen voor de gewone onderzoekszalen evenals van enkele nuttige herhalingen m.b.t. de ‘warme kamers/ laboratoria’; de bestaande aanbevelingen voor de therapiekamers worden herhaald.
- Erkende gebruikers: de belangrijkste categorieën en de regels die dienaangaande van toepassing zijn, worden herhaald.
- Vergunde medische toestellen: de algemene toepassingsvoorschriften hieromtrent worden herhaald.

Ten slotte zullen enkele concepten inzake kwaliteitsborging (QA) voorgesteld worden om deze te midden van bovenvermelde regels en van de kwaliteitsbeheersingsprogramma’s in het algemeen te positioneren; de desbetreffende posities van de QC en de QA zullen eveneens toegelicht worden en de inspanningen inzake de accreditatie op Europees vlak (kwaliteitszorg inbegrepen) zullen ook worden uiteengezet.

Résumé

« Les implications pratiques de la réglementation belge ».

La réglementation belge a été développée suivant trios axes principaux: les établissements, l'utilisateur et le matériel médical.
La mise en place des directives européennes dans notre environnement réglementaire amène des contraintes pour chacun de ces axes. Comme cela a été dit précédemment, ces contraintes sont sujettes à contrôles de la part de l'autorité compétente. Ce n'est pas cependant ce contrôle qui doit être l'élément moteur de la radioprotection. La responsabilité dans cette matière appartient souvent aux praticiens et il est de son devoir de contrôler les risques en matière de radioprotection comme le ferait tout utilisateur de rayonnement ionisant.

La présentation analyse les risques typiques devant être contrôlés dans chacun des groupes ; elle insiste sur le rôle de chacun des acteurs et des personnes responsables:

- Etablissements : les obligations de la salle d'examen usuelles sont exposées de même que les rappels utiles pour les « chambres chaudes / laboratoires » ; les recommandations existantes sur les chambres de thérapie sont rappelées.
- Utilisateurs : les principales catégories et les règles qui s'y appliquent sont rappelées.
- Le matériel médical : les règles générales d'application sont rappelées à ce sujet.

Enfin, quelques concepts d'assurance qualité seront présentés de façon à les positionner parmi les règles et dans les programmes de gestion de la Qualité en général ; les positions relatives de QC et QA seront également rappelées ; la présentation se terminera par la revue des efforts d'accréditation (comprenant la qualité) au niveau européen.

GUIDELINES FOR THE REFERENCE ADMINISTERED ACTIVITIES (RESULTS FROM THE BGNG RP WORKGROUP)

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Abstract

The task group 'Radiation protection' of the Belgian Association of Nuclear Medicine was created in 2001.Members are experts in different subject matters such as medicine, radiation physics, physical control. The objective is to analyse the problems encountered- and questions raised, in the day-to-day practice. The stress is put on the achievement of high-level radiation protection for the patients as well as for the nuclear workers. Information sheets with practical hints and more basic background information are available on the web.

The already treated subjects are presented:

1. 'Belgian Guidelines for the Reference Administered Activities.
   Guidelines for the doses to be administered for various examinations were elaborated. The aim was to reach a harmonisation as in the neighbouring states. The starting point has been a study made in 19 Belgian institutions of different size and main activity. Results have been confronted with the national guidelines in force in the neighbouring countries. The proposal was then submitted to a variety of professional and involved groups and eventually finalised.
   A second list is for the prescribing practitioner to include the main indication, the effective dose, etc.
   The third list provides absorbed and effective doses per organ and per treatment and is intended for the nuclear physician.
2. Practical hints for the waste management.
3. Information leaves for the practitioner related to pregnant and breastfeeding patients.
4. Work in progress :
   - Leaflets about the "information of patients and families and dosimetry in therapeutic applications".
   - Leaflet on general information of the patients
   - Preparation of a text : "Awareness of colleagues about dosimetry after injection for a NM procedure. How "dangerous" are the NM patients?".

The workgroup 'radiological protection' of the Belgian Society for Nuclear Medicine started its activities at the end of 2001 and consists of professionals in different areas : physicians, medical physicists and health physicists. The goal is to study in detail all kind of questions and problems related to the day to day practise. The practical implementation of a qualitative radiological protection for the nuclear worker aswell as for the patient is the main concern. Leaflets and tables with practical approaches and background information are presented at the website (www.belnuc.be) and at scientific meetings.

This text presents the work from the workgroup and the presentation of the work in progress :

A. "Guidelines for the Reference Administered Activities"

The Medical Exposure Directive (Ref. 2) requires the Member states of the European Union to establish reference levels for diagnostic examinations. Due to the implementation of these recommendations in the Belgian national legislation and the need to harmonise within Belgium, guidelines for reference administered activities of different examinations were made. The work is based on a multicentre study in Belgium (Ref. 1). The results were compared in an international context (Ref. 3) and a proposal was submitted for approval to local groups of physicians and the Health Council. The first list contains the approved version of the guidelines for reference administered activities and is presented below.

The second part is a list for the referring physicians on which the name of the examination, the tracer, the main indications and the effective dose for the reference administered activity are indicated.

The third part is intended for the nuclear physician. For each examination the reference activity, the effective dose (Ref. 4) and the absorbed dose for the three most exposed organs are listed.

The three lists can be downloaded from the website : www.belnuc.be

Belgian Society for Nuclear Medicine Guidelines for the Reference Administered Activities				
Important instructions for use:				
This table shows the typical reference administered activities for diagnostic nuclear medicine procedures.				
Reference activity	Guidelines for a typical adult (male, 70kg). Variations from these guidelines should always be justified on the basis of specific techniques (e.g. SPECT vs planar) or patients' needs.			
Maximum	These values should normally not be exceeded			
Minimum	Minimum activities are for children and based on 10 % of the adult dose or on EANM Paediatric task group guidelines, whichever is higher.			
System	***Tracer***	***Reference activities MBq (~mCi)***	***Maximum MBq (~mCi)***	***Minimum MBq (~mCi)***
Osteo-articular				
Bone	Tc-99m-HDP/MDP	740 (20)	925 (25)	70 (2)
Perfusion	Tc-99m-Albumin	220 (6)	370 (10)	55 (1.5)
Endocrinology				
Thyroid	Tc-99m-Pertechnetate	110 (3)	200 (5.5)	20 (0.5)
	I-123	40 (1)	50 (1.3)	5 (0.13)
	Thyroid Cancer (I-131)	110 (3)	370 (10)	20 (0.5)
Parathyroid	Thallium (Tl-201)	70 (2)	110 (3)	16 (0.4)
	Tc-99m-agent	740 (20)	900 (24)	95 (2.5)
Adrenals	I-123-MIBG	185 (5)	260 (7)	30 (0.8)
	I-131-MIBG	40 (1)	80 (2)	20 (0.5)
Tumor detection				
Breast	Tc-99m-agent	740 (20)	900 (24)	NA
Gallium	67-Ga-Citrate	220 (6)	370 (10)	30 (0.8)
Octreotide	In-111-Octreotide	220 (6)	220 (6)	30 (0.8)
FDG	F-18-FDG	260 (7)	370 (10)	70 (2)
Lung				
Lung Perfusion	Tc-99m-MAA	110 (3)	220 (6)	20 (0.5)

Brain				
Perfusion	Tc-99m-agent	740 (20)	1110 (30)	140 (3.7)
Cisterno	In-111-DTPA	20 (0.5)	40 (1)	3 (0.1)
Uro-genital				
Renal				
DMSA	Tc-99m-DMSA	150 (4)	185 (5)	11 (0.3)
DTPA	Tc-99m-DTPA	185 (5)	250 (6.8)	40 (1)
MAG3	Tc-99m-MAG3	70 (2)	200 (5.5)	15 (0.4)
VUR	Tc-99m-DTPA	7 (0.2)	40 (1)	3 (0.1)
Gastro-Enterology				
Gastric Emptying / reflux	Tc-99m-colloid	40 (1)	55 (1.5)	15 (0.4)
Bleeding	Red Cells/Tc-99m-Alb	740 (20)	925 (25)	125 (3.5)
Meckel	Pertechnetate	185 (5)	260 (7)	40 (1)
Liver	Tc-99m-colloid	185 (5)	260 (7)	40 (1)
Galbladder	Tc-99m-iminodiacetate	70 (2)	185 (5)	25 (0.7)
Salivary Glands	Pertechnetate	110 (3)	200 (5.5)	20 (0.5)
Heart				
Perfusion	Thallium (Tl-201)*	150 (4)	150 (4)	15 (0.4)
	Tc-99m-agent (1 day)**	S 300 (8) / R 900 (24)	S 300 (8) / R 900 (24)	125 (3.5)
	Tc-99m-agent (2 days)**	S 900 (24) / R 900 (24)	S 900 (24) / R 900 (24)	125 (3.5)
Ventricular function	Tc-99m-agent	740 (20)	925 (25)	125 (3.5)
Infection /inflammation				
Immunoglobulins	Tc-99m-HIG	370 (10)	555 (15)	55 (1.5)
White Blood Cells	White Cells/HMPAO	550 (15)	740 (20)	80 (2)
White Blood Cells	In-111-oxinate	20 (0.5)	40 (1)	9 (0.3)
Nanocolloid	Tc-99m-nanocolloid	370 (10)	740 (20)	60 (1.5)

*: including reinjection **: S and R denote stress and rest respectively

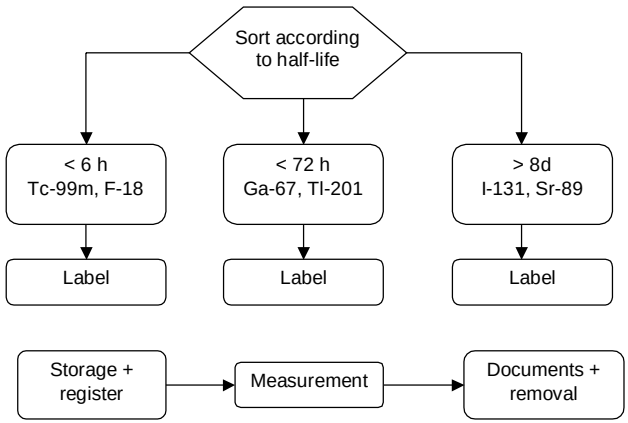
For obese patients dosages can be adapted.

For children the EANM task group table must be followed.

These guidelines have been approved by the workgroup Nuclear Medicine of the Health Council (CSH/HGR)

B. Waste treatment in the nuclear medicine department

The work concerning the treatment of radioactive waste in the nuclear medicine department is divided in 2 parts.
The first is a flowchart where the way to sort, store and evacuate the waste is schematically explained. A short version is shown below :



The second part gives hints for a practical approach : How to collect and to store the radioactive waste, how to keep a waste register, what to do with hospitalised patients (and what if they are incontinent), ...

The leaflets can be downloaded from the website : www.belnuc.be

C. Information concerning pregnant and breastfeeding patients

As a result of the survey of the nuclear physicians attitude towards pregnant or breastfeeding patient (Ref. 5) guidelines about how to deal with this problem were elaborated. They consist of a theoretical basis followed by a question - answer.

A summary of the leaflets is presented.

Preliminaries

- The justification and optimisation principles must be kept in mind. More than in any other patient, the indication of the procedure should be weighed and the benefit to the mother should largely outweigh the potential inconvenience (e.g. for the diagnosis of PE). Alternative diagnostic procedure(s), especially with non-ionising techniques should be discussed (remember the complete abandon of placental scintigraphy since the availability of ultrasound!). In addition, every effort should be made to reduce the administered activity, hence the absorbed dose to the embryo. This may lead to procedures longer than the usual duration.
- It must be kept in mind that every patient of childbearing age should be carefully interviewed before any nuclear medicine procedure. Care should be taken with patients under oral contraception or intrauterine devices, by explicitly asking for the date of the last period. If any doubt persists, a pregnancy test is strongly recommended before administration of a diagnostic dose and mandatory before a therapeutic dose.
- It is a legal obligation to clearly identify any controlled and protected zone, to post appropriate caution marks and to warn attending patients about a potential pregnancy and about the importance of informing the physician prior to any procedure.

Radiobiological basis

- Two weeks after conception: major risk of embryo resorption, followed by carcinogenesis
- 2-8 weeks: risk of congenital malformation followed by carcinogenesis
- 8-15 (25) weeks: risk of mental retardation, followed by carcinogenesis
- 25 weeks: risk of carcinogenesis

Followed by 4 questions

- What to do if you have a query for a nuclear medicine procedure on a pregnant woman?
- What to do if a nuclear medicine procedure was performed on a pregnant woman?

- Breastfeeding, what to do?
- Is it necessary to advise limiting close contacts between parents and their children if one of them had a nuclear medicine test?

The leaflets can be downloaded from the website : www.belnuc.be

D. Work in progress.

At this moment the radioprotection workgroup is preparing leaflets or information brochures on 3 subjects:

- General information of the patients (adults and children)
- Information for patients and families on dosimetry in therapeutic applications
- Awareness of colleagues (non nuclear medicine physicians) about dosimetry after injection for a NM procedure. How “dangerous” are the NM patients?

References :

1 De Geest, E;
A multicenter study of the administered activity in nuclear medicine departments in Belgium. Oral presentation, EANM, Vienna, Austria, 2002

2 European Commission.
Council Directive 97/43/EURATOM. Official J.European Communities; 1997.

3 European Commission.
Radiation Protection 109. Guidance on diagnostic reference levels (DRLs) for medical exposures; 1999

4 International Commission on Radiological Protection.
Radiation Dose to Patients from Radiopharmaceuticals. Addendum 2 to ICRP Publication 53. ICRP publication 80, Ann. ICRP 28 (3); 1998

5 Sand, A.;
Scintigraphic examinations during pregnancy : a survey of Belgian nuclear medicine physician's attitudes. Poster, EANM, Vienna, Austria, 2002

Samenvatting

Richtlijnen voor de toegediende activiteit in de nucleaire geneeskunde (Resultaten van de werkgroep van het Belgisch genootschap voor Nucleaire geneeskunde)

De werkgroep “stralingsbescherming” van het Belgische Genootschap voor Nucleaire Geneeskunde werd eind 2001 opgericht. De werkgroep bestaat uit deskundigen op verschillende vlakken : artsen, stralingsfysici en deskundigen fysische controle, en heeft als doel problemen of vragen uit de dagdagelijkse praktijk meer in detail te bestuderen. Het accent ligt op de praktische invulling van een kwaliteitsvolle stralingsbescherming voor zowel de patiënt als voor de nucleaire werkers. Infoblaadjes met praktische tips of meer achtergrond informatie worden verspreid via de website.

De reeds behandelde onderwerpen zullen worden voorgesteld :

1. “Belgian Guidelines for the Reference Administered Activities”
   Richtlijnen voor de toe te dienen activiteiten voor verschillende onderzoeken werden opgesteld. Het doel bestaat erin om tot een harmonisatie te komen zoals in de ons omringende buurlanden.
   Er werd vertrokken van een anonieme studie in België in 19 diensten nucleaire geneeskunde van verschillende omvang en met verschillende zwaartepunten. De resultaten werden vergeleken met nationale richtlijnen van de ons omringende buurlanden. Het voorstel uit de werkgroep werd vervolgens voorgelegd aan de ‘Lok-groepen’ en andere vakgroepen (bv. Hoge Gezondheidsraad) en gefinaliseerd.
   In een 2’de luik wordt een aanvulling van deze lijst voorgesteld voor de voorschrijvende arts. Hierin zullen de voornaamste indicatie, effectieve dosis, ... worden opgenomen.
   In een 3’de luik wordt de effectieve dosis en de geabsorbeerde dosis per orgaan per onderzoek besproken.
2. Praktische tips voor afvalbeheer
3. Infoblaadjes voor de arts in verband met zwangere of borstvoedinggevende patiënten
4. Te verwachten :
   - Informatie voor de patiënten en hun familie over dosimetrie in therapeutische behandelingen
   - Algemene informatie voor de patiënt
   - Dosimetrie van patiënten van nucleaire geneeskunde. Hoe gevaarlijk zijn ze?

Résumé

Directive pour les doses à administrer en médecine nucléaire (Résultats du groupe de travail de la Société Belge de Médecine Nucléaire)

L'association belge de médecine nucléaire a constitué un groupe de travail en 2001. Il compte des experts dans divers domaines: des médecins, des physiciens des radiations, des physiciens agrées, chargés du contrôle, etc. Il a pour objectif de procéder à une analyse fouillée des problèmes rencontrés dans la pratique de la routine journalière. L'accent est posé sur l'obtention d'une protection contre les radiations de qualité élevée pour les patients comme pour les travailleurs nucléaires. Le groupe rédige des feuilles d'information, disponibles sur le web, qui contiennent des indications pratiques et des informations ayant un caractère plus fondamental. Les sujets déjà traités sont présentés:

1. 'Belgian guidelines for Reference Administered Activities'
   Ces directives concerne les doses à administrer pour différents traitements. Le but a été de réaliser une harmonisation semblable à celle existant déjà dans les pays voisins. Le point de départ a été une étude anonyme réalisée dans 19 institutions d'importance et d'activité différentes. Les résultats obtenus ont été comparés aux directives nationales en vigueur dans ces pays. La proposition a été soumise ensuite à différents groupes intéressés ou directement impliqués avant la rédaction finale.
   Dans une prochaine étape, à destination des médecins prescripteurs, la liste a été complétée en y incluant les indications et les doses effectives, etc.
   Le troisième volet donne les doses absorbées et les doses effectives, par organe et par traitement.
2. Conseils pratiques pour la gestion des déchets
3. Feuilles d'information pour le médecin concernant les femmes enceintes ou allaitantes.
4. En prévision pour le futur :
   - Information pour les patients et leur famille sur la dosimétrie dans les traitements thérapeutiques.
   - Information générale pour le patient.
   - Dosimétrie des patients de médecine nucléaire. Quel est leur degré de gravité ?

EXTREMITY DOSES DURING MANIPULATION OF RADIOPHARMACEUTICALS

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Abstract

The increasing number of medical procedures requires proper attention of extremity doses of radiopharmacy staff members in nuclear medicine. In the academic hospital of the University of Brussels (AZ-VUB), hand doses have been monitored for several years by means of wristdosemeters and ringdosemeters (TLDs). Both types are convenient to wear but do not necessarily represent the location on the hand where the highest skin dose is received. The number of manipulations, the amount of handled activity and the results of the routine monitoring emphasise the need of more detailed dosimetry for radiopharmacy workers. Mapping the dose distribution of the hand, in function of the manipulation, can give a notion about the location and the order of magnitude of the highest skin dose.

In this study, two radiopharmacists were monitored during more then 300 manipulations at 18 different locations on each hand. The results are expressed in dose per unit of handled activity during a specific manipulation. They show a good reproducibility for the individual radiopharmacist. Typical values of Hp(0.07) range from 50 to 600 µSv/GBq of handled activity and usually indicate the fingertips as the highest dose location. Particular personal habits in handling the radiopharmaceuticals determine the location and the order of magnitude of the highest skin dose, especially when manipulating radiopharmaceuticals with high exposure rates, such as ^{18}FDG.

The calculation of the ratio “highest dose / ringdosemeter dose” and the evaluation of the total workload, made it possible to estimate the yearly received highest skin dose. This exercise shows that the annual dose limit of 500mSv can be exceeded without further optimisation but also indicates where specific radiation protection measures are appropriate.

1. Introduction

Besides some therapeutic procedures, a nuclear medicine department can be generally characterised by various diagnostic examinations involving intravenous administration of radiopharmaceuticals. These pharmaceuticals are usually labelled with ^{99m}Tc and among the more common are also ^{18}F, ^{201}Tl, ^{123}I, ^{51}Cr and ^{67}Ga. Current trends in clinical nuclear medicine include an emphasis on radioimmunodiagnosis, single photon emission tomography (SPECT) and positron emission tomography (PET) which mainly involves the use of ^{18}F-labelled fluorodeoxyglucose (^{18}FDG).

The distribution of the principal radiopharmaceuticals which contribute to extremity doses in AZ-VUB are 85% ^{99m}Tc, 10% ^{18}F and 5% other labelled pharmaceuticals (^{123}I, ^{201}Tl, ^{51}Cr,...).

Before imaging the patient with SPECT or PET, the radiopharmaceutical causes radiation exposure during a number of manipulations. Generally one can consider three basic manipulations (FIG. 1):

- During kit preparation multidose kit vials of different radiopharmaceuticals are prepared. The preparation of ^{18}FDG occurs generally by fully automated modules in heavy shielded 'hot cells' and is not considered as a significant source of exposure to the extremities. This is however not the case during ^{99m}Tc-labelling where the manipulation starts with the elution of the ^{99m}o-^{99m}Tc generator into an elution vial and ends up with the injection of a typical activity into a multidose kit vial.
- These kit vials have to be dispensed into syringes after which the individual patient activity is checked in the dose (activity) calibrator and the syringe is transferred with a shielded transport box to the administration room.
- The third manipulation is the administration to the patient. The insertion of a butterfly cannula into a vein, prior to the radiopharmaceutical administration, is prevalent in many hospitals in terms of dose reduction [5] to the staff members performing this task.

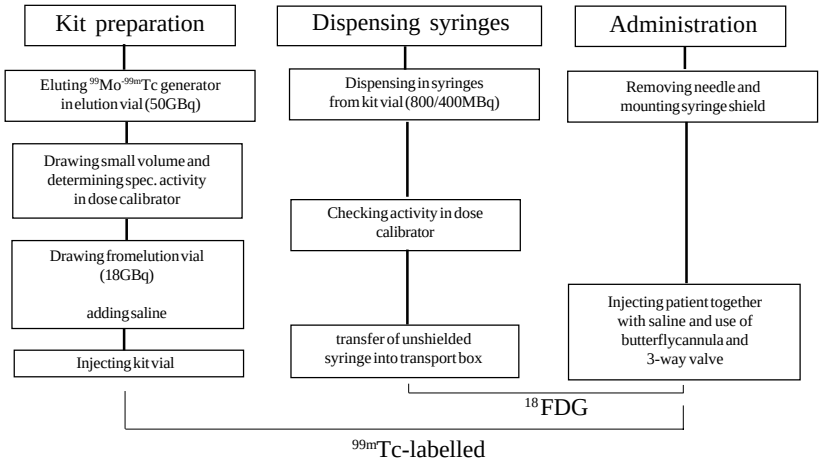

FIG. 1. Three basic manipulations of radiopharmaceuticals in nuclear medicine

The internal organisation of these three basic tasks can differ from department to department. Radiopharmacy staff can carry out kit preparation and dispensing, while nursing staff is responsible for administration (AZ-VUB). In other hospitals radiopharmacy staff prepares the kits after which nursing staff dispenses the syringes and administers the activity. In some hospitals, nursing staff members walk through the entire procedure.

2. Extremity dose assessments

The radiation dose to the hands of staff members in nuclear medicine is mainly received during the above-described manipulations.

Extremity dose assessments are usually carried out using thermoluminescent dosemeters (TLDs) because of their convenient size. For accurate measurement of $H_P(0.07)$ the dosemeter must be physically thin to avoid significant attenuation of the radiation. The dosemeter also needs to be robust because it may be placed on the hands carrying out manual work.

The position on the hand at which a dosemeter is worn and the choice of hand on which it is placed both have a large influence on the value of the assessed dose, especially when working with localised sources. Since the skin dose limit is applied to the dose averaged over any area of $1cm^2$ **[1,2]**, it is necessary to identify, as accurately as possible, the location of the highest dose. Extremity dose monitoring in a nuclear medicine department can be carried out by TLD-tapes or

finger stalls which enables to measure doses at the tip of the finger. However, these dosemeters are often inconvenient during manipulations, which can result in longer exposure time. Ringdosemeters are usually worn at the base of the middle finger and are quite convenient during manipulations but give an underestimation of the highest dose. A wristdosemeter does not hamper most manipulations but results in a significant underestimation of the dose due to the distance between the wrist and the possible highest dose location. Ideally a dosemeter should be used to monitor the part of the extremity receiving the highest dose. If this is impractical, it may be necessary to monitor a different part in which case a factor may be employed to ensure dose limits are not being exceeded.

This study emphasises the distribution of the extremity doses during kit preparation and dispensing (FIG. 1.) since only two radiopharmacy staff members carry out these manipulations in AZ-VUB and substantial extremity doses were recorded during routine monitoring.

3. Materials and methods

The use of cotton gloves, prior to protective latex gloves, enables to attach PVC capsules at 18 locations (FIG. 2.) on the palm of each hand. These capsules have an attenuation thickness of 20mg/cm^2 and can easily hold TLD100H chips (LiF:Mg,Cu,P:3.2 x 3.2 x 0.5mm).

The TLDs were calibrated on a rod phantom and exposed to N150 X-rays according to ISO 4037 [3]. The exposure measurements for this calibration were conducted with a 30cm^3 cylindrical ionisation chamber (Model PM-30 Capintec) connected to an electrometer (Model 192, Capintec). Doses were calculated with consideration of the accompanying conversionfactors $h_{pK}(0.07;N)$ for air kerma K_a, to equivalent dose $H_p(0.07)$. The TLDs were processed with a Harshaw-Bicron 5500 TLD reader in an atmosphere of inert nitrogen and annealed in a PTW-TLDO oven.

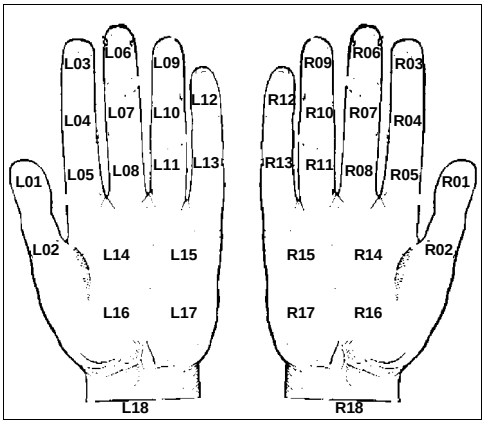

FIG. 2. Location of 18 TLD100H chips on the palm of each hand. TLDs R08 and R18 correspond respectively with the position of routine ringdosemeter and wristdosemeter.

The time in which a single radiopharmaceutical kit or syringe is prepared (FIG. 1.) can vary. For this reason, the extremity dose measurements were carried out during a procedure, which covers the preparation of a number of kits or the dispensing of a number of syringes. The radiopharmacists logged the total handled activity during a procedure so that the results can be expressed as 'specific skin dose':SHp(0.07) (µSv/handled GBq) at a certain location (FIG 2.) on the hand. A set of 4 background TLDs was placed in the radiopharmacy during each procedure in addition to the 36 TLDs on the cotton gloves. The total batch of 40 TLDs was read out after each procedure and the average background value of the 4 TLDs was deducted before calculating the specific skin dose. The total number of procedures per radiopharmacist, the average number of manipulations and the average handled activity per procedure is shown in TABLE 1.

TABLE 1. Overview of the total number of extremity dose measurements

Type of procedure	Number of monitored procedures per radiopharmacist	Average number of monitored kits/syringes per procedure	Average handled activity per procedure
Kit preparation of ^{99m}Tc-labelled radiopharmaceuticals	10	3	45 GBq
Dispensing syringes ^{99m}Tc-labelled radiopharmaceuticals	30	5	4 GBq
Dispensing syringes ^{18}FDG	10	5	3 GBq

4. Results

4.1. Specific skin dose during manipulations

The specific skin dose SHp(0.07) (µSv/handled GBq) at a dose location during a procedure of several manipulation was calculated using following formula:

$$SHp(0.07)_{m,i,j} = \frac{Hp(0.07)_{m,i,j} - \overline{BHp(0.07)_{m,i}}}{A_m} \qquad (1)$$

Where: $Hp(0.07)_{m,i,j}$: Skin dose at location j for radiopharmacist i, during a procedure of several manipulations m (µSv)

$BHp(0.07)_{m,i}$: Background value of skin dose for radiopharmacist i during a procedure of several manipulations m (µSv)

A_m: Total handled activity during a procedure of several manipulations m (GBq)

The results give generally a good reproducibility for the individual radiopharmacist, despite the general bad reproducibility during manipulations of localised sources. Particular personal habits in handling the radiopharmaceuticals determine the location and the order of magnitude of the highest skin dose. FIG. 3. shows the average SHp(0.07) in function of the handled activity at the 36 different locations during kit preparation. Both radiopharmacists are right-handed and the highest specific skin dose can be found at the tip of the middle finger. However, the dose distribution of the left hand is not similar. The injection of the activity in the kit vial is carried out with a shielded syringe, which radiopharmacist B often supports with the left hand and in this way results in a dose distribution comparable to the distribution of the right hand.

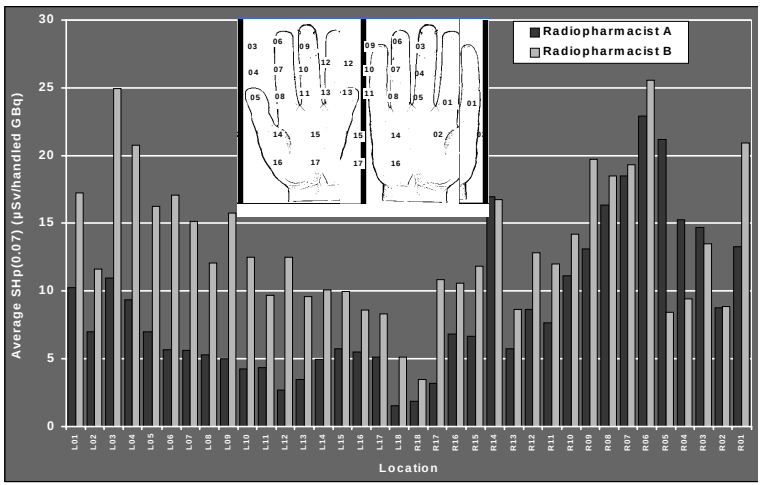

FIG. 3. SHp(0.07) at 36 locations on the hand during kit preparation of ^{99m}Tc-labelled radiopharmaceuticals

During dispensing of radiopharmaceuticals, a syringe shield will not allow a good view of the liquid in the syringe. The use of the shield is impractical and hampers when an accurate volume and corresponding activity has to be drawn. Moreover, after measurement of the syringe in the activity calibrator, adjustment of the volume and removal of air bubbles from the syringe can lengthen the procedure. The specific skin dose during the dispensing of ^{99m}Tc-labelled radiopharmaceuticals (FIG. 4.) is much higher then during kit preparation, especially for radiopharmacist B, who carries out more adjustments to the drawn volume. The high results on the non-dominant left hand are caused by the removal of air bubbles from the syringe.

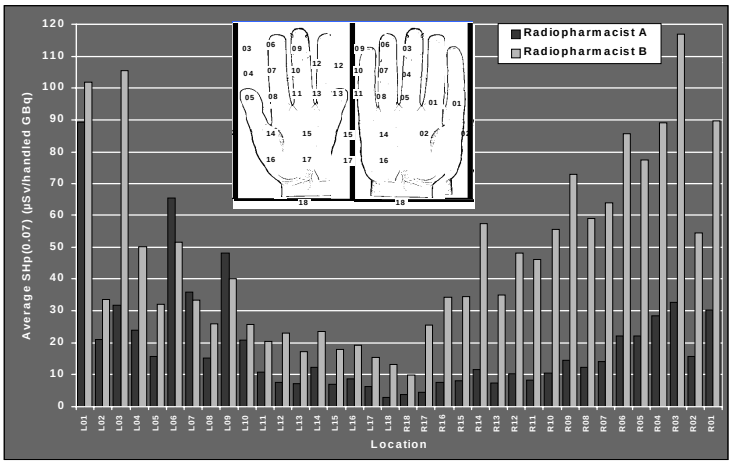

FIG. 4. SHp(0.07) at 36 locations on the hand during dispensing of ^{99m}Tc-labelled radiopharmaceuticals

18FDG causes much higher (7x) exposure rates than ^{99m}Tc-labelled radiopharmaceuticals. However nursing staff members use a 3-way valve during administration, which allows the presence of air bubbles in the syringe after dispensing. The dose distribution of the hands (FIG. 5.) shows a substantial difference between both radiopharmacists.

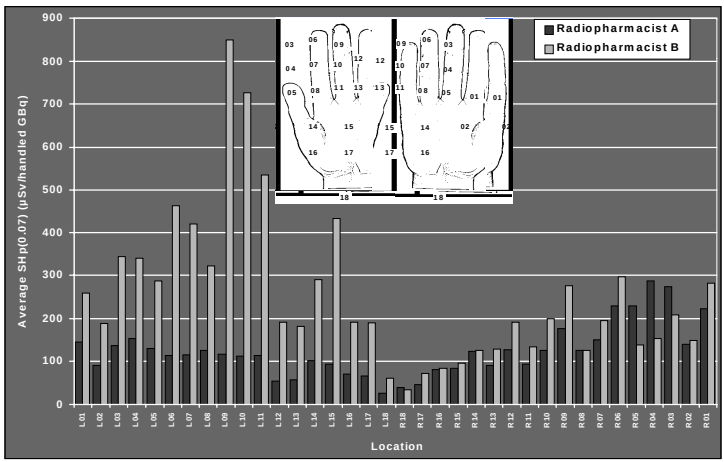

FIG. 5. SHp(0.07) at 36 locations on the hand during dispensing of ^{18}FDG

Radiopharmacist A draws the ^{18}FDG-syringes without the use of a syringe shield. After activity measurement and possible volume (activity) adjustment, the syringe is mounted in a tungsten shield, ready for use by the nursing staff. Radiopharmacist B uses a tungsten shield during dispensing, which is due to the weight, supported by the left hand. Activity measurement requires the removal of this shield during which it is also supported by the left hand. This results in much longer exposure time, especially for the left hand.

4.2. Ratio highest dose / ringdosemeter dose

Routine extremity dose assessments cannot be carried out at 36 locations. The use of a ringdosemeter is convenient during routine operation. The results of this study indicate however the location and the order of magnitude of the highest skin dose, which is manipulation related. In the future, the values of the routine measurements (location R08) can be multiplied by a factor to obtain the value of the highest dose. TABLE 2. shows for each manipulation the critical location and accompanying ratio in relation to the ringdosemeter location.

TABLE 2. Critical locations and accompanying ratios in relation to the ringdosemeter location

Radiopharmacist	Manipulation	Highest dose location	Ratio highest dose / ringdosemeter dose
A	Kit preparation ^{99m}Tc	R06: Tip middle finger	1.4
	Dispensing ^{99m}Tc	L01: Tip thumb	7.0
	Dispensing ^{18}FDG	R04: Middle part index finger	2.3
B	Kit preparation ^{99m}Tc	R06: Tip middle finger	1.4
	Dispensing ^{99m}Tc	R03: Tip index finger	2.0
	Dispensing ^{18}FDG	L09: Tip ring finger	6.7

Applying the average or the highest ratio as the future factor for routine monitoring would be incorrect since the contribution of the different manipulations to the monthly skin dose is not equal.

TABLE 3. shows the average monthly workload of the nuclear medicine department AZ-VUB in terms of prepared ^{99m}Tc-labelled kits and dispensed syringes with either ^{99m}Tc-labelled radiopharmaceuticals or ^{18}FDG.

TABLE 3. Monthly workload of the nuclear medicine department and contribution of both radiopharmacist to the handled activity

Type of manipulation m		Preparation ^{99m}Tc-labelled kits	Dispensing Syringes ^{99m}Tc-labelled	Dispensing Syringes ^{18}FDG
Average monthly workload WL_m (GBq)		1000	600	60
Fraction of monthly handled activity $F_{m,I}$	Radiopharmacist A	75%	75%	20%
	Radiopharmacist B	25%	25%	80%

The monthly skin dose at 36 positions of the hand can be predicted by using following formula:

$$MHp(0.07)_{i,j} = \sum_{m=1}^{3} (\overline{SHp(0.07)_{m,i,j}} \times WL_m \times F_{m,i}) \qquad (2)$$

Where:

$MHp(0.07)_{i,j}$: Average monthly skin dose for radiopharmacist i at location j (mSv/month)

$SpHp(0.07)_{m,i,j}$: Specific skin dose for radiopharmacist i at location j during a procedure of several manipulations m (µSv/ handled GBq)

WL_m: Average monthly workload for type of manipulation m

$F_{m,i}$: Fraction of monthly handled activity by radiopharmacist i during manipulation m (%)

The results of the calculation (2) are shown in FIG. 6. and FIG. 7. for respectively radiopharmacists A and B and confirm the accuracy of the SHp(0.07) values at location R08 since the average routine results of the ringdosemeter (year 2002) can be compared to the values calculated with formula (2).

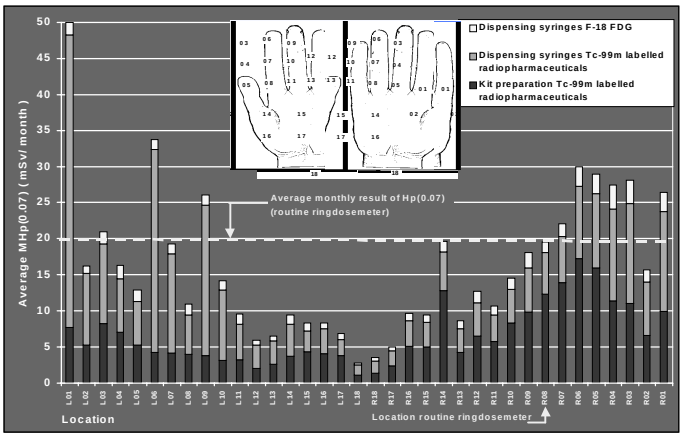

FIG. 6. Radiopharmacist A: Distribution of MHp(0.07) for 3 main manipulations

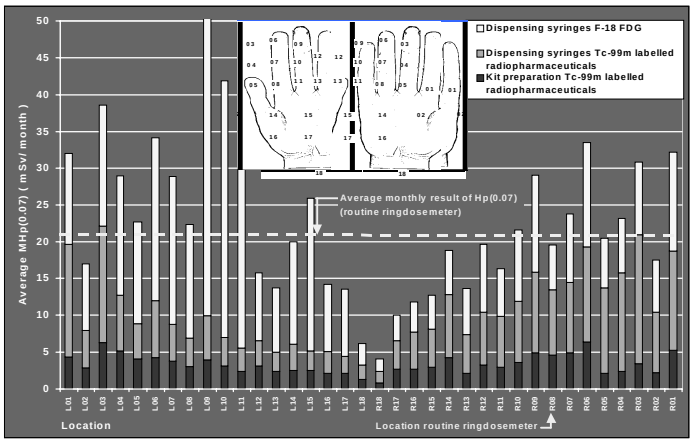

FIG. 7. Radiopharmacist B: Distribution of MHp(0.07) for 3 main manipulations

The results point out an overall ratio “highest dose/ringdosemeter dose” of “2.6” for both radiopharmacists. Without radiation protection measures, these staff members will easily exceed the yearly dose limit of 500mSv.
Former studies **[4, 5, 9, 10**] indicate the highest dose location on the dominant hand (fingertip index finger). Some of these studies also calculated the ratio between doses at the fingertip and doses at the base of middle finger during dispensing of ^{99m}Tc-labelled radiopharmaceuticals. References **[5]** and **[10]** found ratios ranging from 4 to 5 between the doses at these two locations. Dhanse et al. **[9]** state that trained staff members show ratios of only 2 when proper syringe shields are used.

5. Options of radiation protection measures

Many dose reduction tools are commercially available for elution vials, kit vials and syringes. Materials are usually lead, tungsten and high-density lead glass. The attenuation factors range from 4 to 200 depending on the design, material and the radionuclide for which the protective tool is used. These attenuation factors do not result in dose reduction by the same order of magnitude. Quality assurance and radiation protection of patients in a nuclear medicine department requires activity measurements in the dose calibrator, which involves the manipulation of unshielded syringes. Several authors **[5-8]** studied the value of syringe shields during dispensing of ^{99m}Tc-labelled radiopharmaceuticals and concluded that the extremity dose is only reduced by 30% for most types of syringe shields. Due to the poor effect of most syringe shields, departments should emphasise on performing radiopharmaceutical manipulations in the minimum time. In the meantime, quality assurance regarding the nuclear medicine patient should be preserved. The results of MHp(0.07) in FIG. 7 and 8 indicate that one needs to optimise radiation protection during all three manipulations. Bad habits like supporting the syringe with the left thumb and/or index finger during removal of air bubbles can possibly be avoided in the future. Other measures like drawing ^{18}FDG syringes without a tungsten shield are not obvious but indicate a significant difference according to FIG. 6. With the increasing number of PET-examinations automated dose dispensers for ^{18}FDG are now commercially available. These automated systems are very expensive and do not give the excepted dose reduction compared to the use of proper syringe shields **[8]**. The time the staff member needs to remove the filled syringe from the automated dose dispenser is in fact approximately the same when a shielded syringe is filled manually.

Other solutions for skin dose reduction like ‘Activofix’ **[11]** are innovating and based on an well thought-out concept. It is however not sure that this system will cover all different aspects of the three basic manipulations in the radiopharmacy department.

6. Conclusion

Extremity dosemeters should not hamper nuclear medicine staff members in order to perform the radiopharmaceutical manipulations in the minimum time. Ring-dosemeters can be worn at the base of the middle finger and are convenient during work. This study indicates the highest dose location on the hand, which is surprisingly for both radiopharmacists located on the non-dominant hand. The quantitative results emphasise the implementation of a multiplication factor to obtain the highest skin dose from routine monitoring with ringdosemeters. Avoiding bad habits during which high dose rates are received can reduce the present calculated factor of 2.6 to a value of “1.5”. Further radiation protection measures are however necessary since the skin dose would still reach the value of 400mSv/year. The distribution of monthly-received skin dose shows that these measures should cover all three described manipulations.

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WASTE MANAGEMENT FOR PATIENTS COMING FROM THE NUCLEAR MEDECINE DEPARTMENT

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A.Z.St. Jan A.V. BRUGES

We made extra specifications for the **collection and release** of radioactive waste produced by ward patients who were injected In the Nuclear Medecine Department of our hospital.

The **reasons** for starting this project were :

1. to pay less fines to the furnace company (I.V.B.O.)
2. to improve the general security in our hospital.
3. to realise a better communication between departments in our hospital (appointments for examinations, clinic, kinesitherapy, surgery, radiology, ...)
4. to inform the personal that some precautions must be taken.

How do we managed this ?

1. Each person working in the hospital must be able to recognise if a patient is a potential risk for irradiation or contamination.

RED BRACELET :
- injected isotope
- type of emitted radiation (γ, ß or γ/ß)
- date from which no precautions must be taken anymore

2. Each hospital worker has to know how to threat these patients.

In the concept of this study we made an important distinction by the half life of the concerned isotopes used in the Nuclear Medecine Department.

$T_f \leq 1$ day (^{99m}Tc, ^{123}I)
$T_f > 1$ day (^{131}I, ^{111}In, ^{67}Ga, ^{153}Sm)

^{89}Sr (T_f = 52,7 d - $E_ß$ = 1,463 Mev, $E_γ$ = 910 Kev for 0,009%) is replaced by ^{153}Sm (T_f = 1,95 d - $E_ß$ = 800 Kev, $E_γ$ = 103 Kev for 28%) in our hospital. For ^{153}Sm we admit the patient during the first 6 hours in a room of the radiotherapy department. This room has special collection accommodation for radioactive urine and faeces. Afterwards the patient join a Normal ward. (Both isotopes have the same behaviour on the patients).

For ^{131}I the patient is kept during the first week in one of the special rooms in the Radiotherapy Department. Afterwards (if possible) he is isolated during 2 weeks in a normal ward. This is done for patients who get less than 15 mCi and who are hospitalised for another pathology in the general clinic. Patients who get more than 15 mCi will remain in the radiotherapy ward until the activity decrease is big enough to release the patient with some restrictions.

For the data concerning the **date** written **on the bracelet** we used the next values:

^{99m}Tc : 48 hours
^{123}I : 3,0 days
^{111}In : 1,0 week
^{67}Ga : 1,5 weeks
^{131}I : 2,0 weeks (after a one week use of a radiotherapy chamber first)
^{153}Sm : 1,0 week (after a 6 hours use of a radiotherapy chamber first)

Precautions to be taken.

1. by the personal: - to prevent **contaminations** (gloves, use of semi plastified/absorbing fields, collection of urine, no pregnant women, waste collection,...)
   - to reduce **dose** (distance, shielding, time)
2. by the patient:
   - toilet flushing (twice)
   - reduce contact with children, babies and pregnant women
   - avoid public places
   - use disposable cutlery (for ^{131}I, ^{67}Ga, ^{111}In, ^{51}Cr)

- handwashing and abundant rinsing (own face cloth and towels)
- a document with directives is given in the N. M. Department

Reuse of bedpans:

Directives to reduce dose to members of the family:

1. Avoid personal contact with others (sex, long massages, public places, ...)
2. Avoid contact with pregnant women and babies.
3. Wash your hands with soap and abundant water after using the bathroom
4. Do not breastfeed your child before a period of x hours after the examination

isotope	T_f	Do this during the following period	Do not breastfeed before
^{99m}Tc	6,049 h	2 d	24 h
^{131}I	8,05 d	2 w	Avoid pregnancy during 6 months after the examination
^{111}In	2,81 d	7 d	4 w
^{67}Ga	3,24 d	10 d	4 w
^{123}I	13,3 h	3 d	2,5 d
^{153}Sm	1,95 d		

What do we call combustible waste ?

1. tubes, beads, pipettor tips, seringues in polypropylene
2. plastic drinking buckets, gloves (≠ P.V.C.)
3. paper, blankets, bed sheets, spewbags, plastic cups,..

What do we call non-combustible waste ?

1. glass (empty)
2. needles
3. all materials and containersin P.V.C.
4. Metal parts with a maximum thickness of 3 mm (no lead)

Biological contaminated waste must be handled as described for it (yellow waste bucket) but now being also radioactive.

Results:

1. In 2002 we generated 20 radioactive alarms in the furnace company
2. We started the project on January the 13th of 2003 and in the same year we were the cause of 4 alarms, from which 3 were generated in the first two months.
3. Talking about money we gained almost 4/5 of the price that we had to pay the year before.

Conclusions:

To achieve the results just mentioned with a small spending expenditure we just needed the following:

1. Buy a mobile bin for each ward. Each bin was closed above and covered with 0,75 mm of lead. The use of plastic bags to put the waste in.
2. A good organisation.
3. A good information to all concerned persons (nurses, technical department, medical department, logistic department,...). This information must be renewed several times.